

具条件可供本澳医疗机构使用及在澳门申请注册上市的新药  
(已获国家药监局、美国 FDA 或欧盟 EMA 批准上市的新药)

New drugs that meet the conditions for use by local healthcare institutions and for drug registration in Macao  
(New drugs approved by NMPA, USFDA and EMA)

| 项目 | 商品名称<br>Commercial Name | 主成分<br>Active<br>Ingredient(s)               | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                               | 药企<br>Pharmaceutical company                  |
|----|-------------------------|----------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| 1. | Abecma                  | idecabtagene<br>vicleucel                    | 注射剂<br>Injection  | 治疗复发性或难治性多发性骨髓瘤<br>To Treat relapsed/refractory multiple myeloma<br>(RRMM)                                                         | Celgene Corporation<br>(Bristol Myers Squibb) |
| 2. | Akeega                  | niraparib;<br>abiraterone acetate            | 片剂<br>Tablet      | 治疗成人 BRCA1/2 突变的转移性去势抗性前列腺癌<br>Treatment of metastatic castration-resistant<br>prostate cancer with BRCA1/2 mutations in<br>adults | Janssen Pharmaceuticals                       |
| 3. | Alhemo                  | concizumab                                   | 注射剂<br>Injection  | 用于 A 型及 B 型血友病人作为常规预防以避免出血<br>事件<br>For routine prophylaxis to prevent bleeding<br>episodes in hemophilia A and B                  | Novo Nordisk Inc.                             |
| 4. | Alyftrek                | Vanzacaftor;<br>tezacaftor;<br>deutivacaftor | 片剂<br>Tablet      | 治疗囊性纤维化<br>To treat cystic fibrosis                                                                                                | Vertex Pharmaceuticals<br>Incorporated        |
| 5. | Agamree                 | vamorolone                                   | 溶液剂<br>Solution   | 治疗裘馨氏肌肉失养症<br>To treat Duchenne muscular dystrophy                                                                                 | Santhera Pharmaceuticals                      |
| 6. | Amvuttra                | vutrisiran                                   | 注射剂<br>Injection  | 治疗遗传性淀粉样蛋白疾病所导致的多发性神经病<br>变<br>To treat polyneuropathy of hereditary<br>transthyretin-mediated amyloidosis                         | Alnylam Pharms Inc.                           |
| 7. | Andembry                | garadacimab                                  | 注射剂<br>Injection  | 预防遗传性血管性水肿发作<br>Prevention of recurrent attacks of hereditary<br>angioedema (HAE)                                                  | CSL Behring GmbH                              |
| 8. | Anktiva                 | nogapendekin alfa                            | 注射剂<br>Injection  | 治疗膀胱癌<br>To treat bladder cancer                                                                                                   | Altor BioScience, LLC                         |

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|-----|--------------------------|-----------------------------|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 9.  | Aqneursa                 | levacetylleucine            | 混悬剂<br>Suspension       | 治疗尼曼匹克疾病 C 型<br>To treat Niemann-Pick disease type C                                                                                      | IntraBio Inc.                |
| 10. | Attruby; Beyonttra       | acoramidis                  | 片剂<br>Tablet            | 治疗伴有心肌病的野生型或变异型转甲状腺素蛋白介导的淀粉样变性<br>To treat cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis                      | BridgeBio Pharma, Inc.       |
| 11. | Aucatzyl                 | obecabtagene autoleucel     | 注射剂<br>Injection        | 治疗复发性或难治性 B-细胞前体急性淋巴细胞白血病<br>Treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia                           | Autolus GmbH                 |
| 12. | Avmapki Fakzynja Co-Pack | avutometinib; defactinib    | 胶囊、片剂<br>Capsule、Tablet | 治疗既往接受过全身治疗的 KRAS 突变复发性低级别浆液性卵巢癌<br>To treat KRAS-mutated recurrent low-grade serous ovarian cancer after prior systemic therapy          | Verastem Oncology            |
| 13. | Awikli; 诺和期; 依柯胰岛素注射液    | insulin icodec              | 注射剂<br>Injection        | 治疗成人 2 型糖尿病<br>To treat type 2 diabetes mellitus                                                                                          | Novo Nordisk A/S             |
| 14. | Beqvez                   | fidanacogene elaparovec     | 注射剂<br>Injection        | 治疗 B 型血友病<br>Treatment of hemophilia B                                                                                                    | Pfizer Inc.                  |
| 15. | Bimzelx                  | bimekizumab                 | 注射剂<br>Injection        | 治疗适合全身治疗或光疗的成人中重度斑块型银屑病<br>To treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy | UCB, Inc.                    |
| 16. | Bizengri                 | zenocutuzumab               | 注射剂<br>Injection        | 治疗非小细胞肺癌及胰腺癌<br>To treat non-small cell lung cancer and pancreatic adenocarcinoma                                                         | Merus N.V.                   |

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|-----|-------------------------|----------------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| 17. | Blujepa                 | gepotidacin                      | 片剂<br>Tablet      | 治疗非复杂性尿路感染<br>To treat uncomplicated urinary tract infections                                                                                                                                                                  | GlaxoSmithKline                                      |
| 18. | Brenzavvy               | bexagliflozin                    | 片剂<br>Tablet      | 改善 2 型糖尿病成人患者的血糖控制<br>To improve glycemic control in adults with type 2 diabetes mellitus                                                                                                                                      | Theracos Inc.                                        |
| 19. | Breyanzi                | lisocabtagene maraleucel         | 注射剂<br>Injection  | 治疗复发性或难治性大 B 细胞淋巴瘤<br>Treatment of relapsed or refractory (r/r) large B-cell lymphoma (LBCL)                                                                                                                                   | Juno Therapeutics<br>(Bristol Myers Squibb)          |
| 20. | Brinsupri               | brensocatic                      | 片剂<br>Tablet      | 治疗非纤维囊肿型支气管扩张<br>To treat non-cystic fibrosis bronchiectasis                                                                                                                                                                   | Insmid Incorporated                                  |
| 21. | Briumvi                 | ublituximab                      | 注射剂<br>Injection  | 治疗成人复发性多发性硬化症<br>To treat relapsing forms of multiple sclerosis                                                                                                                                                                | TG Therapeutics, Inc.                                |
| 22. | Carvykti                | ciltacabtagene autoleucel        | 注射剂<br>Injection  | 治疗复发性或难治性多发性骨髓瘤<br>To Treat relapsed/refractory multiple myeloma (RRMM)                                                                                                                                                        | Legend Biotech Corporation;<br>Janssen Biotech, Inc. |
| 23. | Casgevy                 | exagamglogene autotemcel         | 注射剂<br>Injection  | 用于治疗β-地中海贫血及镰刀型红血球疾病<br>Treatment of beta thalassaemia and sickle cell disease                                                                                                                                                 | Vertex Pharmaceuticals<br>(Ireland) Limited          |
| 24. | Cobenfy                 | xanomeline;<br>trospium chloride | 胶囊<br>Capsule     | 治疗精神分裂症<br>To treat schizophrenia                                                                                                                                                                                              | Bristol-Myers Squibb<br>Company                      |
| 25. | Cosela                  | trilaciclib                      | 注射剂<br>Injection  | 在广泛期小细胞肺癌 (ES-SCLC) 的含铂/依托泊苷方案或含拓扑替康方案之前给药时，可降低成人患者化疗引起的骨髓抑制的发生率<br>To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or | G1 Therapeutics, Inc.                                |

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|-----|-------------------------|-----------------------------|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                         |                             |                                | topotecan containing regimen for extensive-stage small cell lung cancer (ES-SCLC)                                                                                                                                                                  |                              |
| 26. | Crenessity              | crinecerfont                | 胶囊、溶液剂<br>Capsule;<br>Solution | 治疗典型先天性肾上腺增生症<br>To treat classic congenital adrenal hyperplasia                                                                                                                                                                                   | Neurocrine Biosciences, Inc. |
| 27. | Datroway                | datopotamab<br>deruxtecan   | 注射剂<br>Injection               | 用于接受过内分泌治疗及化疗但无法切除或转移性<br>荷尔蒙受体阳性、HER2 阴性的乳腺癌<br>To treat unresectable or metastatic, HR-positive,<br>HER2-negative breast cancer who have received<br>prior endocrine-based therapy and<br>chemotherapy for unresectable or metastatic<br>disease | Daiichi Sankyo, Inc.         |
| 28. | Dawnzera <sup>#</sup>   | donidalorsen                | 注射剂<br>Injection               | 用于预防遗传性血管性水肿的发作<br>To prevent attacks of hereditary angioedema                                                                                                                                                                                     | Ionis Pharmaceuticals Inc.   |
| 29. | Daxxify                 | daxibotulinumtoxin<br>A     | 注射剂<br>Injection               | 治疗与皱眉肌和/或降眉肌活动相关的中度至重度眉<br>间皱纹<br>To treat moderate-to-severe glabellar lines<br>associated with corrugator and/or procerus<br>muscle activity                                                                                                     | Revance Therapeutics Inc.    |
| 30. | Daybue                  | trofinetide                 | 溶液剂<br>Solution                | 治疗雷特综合征<br>To treat Rett syndrome                                                                                                                                                                                                                  | Acadia Pharmaceuticals Inc.  |
| 31. | Defencath               | taurolidine<br>heparin      | 注射剂<br>Injection               | 用于降低通过中心静脉导管接受长期血液透析的肾<br>功能衰竭成年患者的导管相关血液感染的发生率<br>To reduce the incidence of catheter-related<br>bloodstream infections (CRBSI) in adults with<br>kidney failure receiving chronic hemodialysis<br>through a central venous catheter              | CorMedix Inc.                |

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| 32. | Duvyzat                 | givinostat                  | 混悬剂<br>Suspension | 治疗 6 岁及以上患者的杜氏肌营养不良症<br>To treat Duchenne muscular dystrophy in individuals aged 6 years and older                                                                                                                                                                                      | Italfarmaco S.A.;<br>ITF Therapeutics, LLC |
| 33. | Ebglyss                 | lebrikizumab                | 注射剂<br>Injection  | 治疗中度至重度异位性皮肤炎<br>To treat moderate-to-severe atopic dermatitis                                                                                                                                                                                                                          | Eli Lilly and Company                      |
| 34. | Ebvallo                 | tabelecleucel               | 注射剂<br>Injection  | 治疗既往至少接受过一种治疗的复发性或难治性 EBV 阳性的移植后淋巴增殖性疾病的两岁及以上儿童和成人患者<br>Treatment of adult and pediatric patients 2 years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy | Pierre Fabre Medicament                    |
| 35. | Ekterly                 | sebetralstat                | 片剂<br>Tablet      | 治疗遗传性血管性水肿急性发作<br>To treat acute attacks of hereditary angioedema                                                                                                                                                                                                                       | KalVista Pharmaceuticals, Inc.             |
| 36. | Elfabrio                | pegunigalsidase alfa        | 注射剂<br>Injection  | 作为酶替代疗法用于治疗法布里病的成人患者<br>Enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease                                                                                                                                                                        | Protalix BioTherapeutics Inc.              |
| 37. | Elrexio                 | elranatamab                 | 注射剂<br>Injection  | 治疗复发或难治性多发性骨髓瘤<br>To treat relapsed or refractory multiple myeloma                                                                                                                                                                                                                      | Pfizer Inc.                                |
| 38. | Elucirem                | gadopiclenol                | 注射剂<br>Injection  | 于 MRI 过程中用作检测中枢神经系统和身体的异常血管病变<br>To detect and visualize lesions, together with MRI, with abnormal vascularity in the central nervous system and the body                                                                                                                               | Guerbet                                    |

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|-----|------------------------------|-----------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 39. | Emrelis                      | telisotuzumab vedotin       | 注射剂<br>Injection  | 治疗先前接受过全身治疗且具高 c-Met 蛋白过表达的局部晚期或转移性的非小细胞肺癌<br>To treat locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression after prior systemic therapy                                                                                                    | AbbVie Inc.                  |
| 40. | Enflonsia                    | clesrovimab                 | 注射剂<br>Injection  | 预防新生儿及婴儿在呼吸道合胞病毒感染季节出生或进入第一个感染季节的婴儿的下呼吸道疾病<br>To prevent respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season                                                                                                     | Merck Sharp & Dohme LLC      |
| 41. | Enjaymo                      | sutimlimab                  | 注射剂<br>Injection  | 减少冷凝集素病溶血引起的输血需求<br>To decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease                                                                                                                                                                                           | Bioverativ Therapeutics Inc. |
| 42. | Enzeshu ;<br>恩泽舒 ; 注射用苏维西塔单抗 | suvemcitug (sevacizumab)    | 注射剂<br>Injection  | 联合紫杉醇、多柔比星脂质体或拓扑替康用于铂耐药后接受过不超过 1 种系统治疗的成人复发性卵巢癌、输卵管癌或原发性腹膜癌<br>Treating recurrent ovarian cancer, fallopian tube cancer, or primary peritoneal cancer in combination with paclitaxel, liposomal doxorubicin, or topotecan in adults who have received at least one systemic therapy after platinum resistance | 江苏先声生物制药有限公司                 |
| 43. | Exblifep                     | cefepime;<br>enmetazobactam | 注射剂<br>Injection  | 治疗复杂性泌尿道感染<br>To treat complicated urinary tract infections                                                                                                                                                                                                                                                   | Orchid Pharma                |

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|-----|-------------------------|-----------------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 44. | Exxua                   | gepirone                    | 片剂<br>Tablet                     | 治疗忧郁症<br>To treat major depressive disorder                                                                                                                                                                                                                  | Mission Pharmacal Company                                                             |
| 45. | Ezmekly                 | mirdametinib                | 胶囊、片剂<br>Capsules、<br>Tablets    | 治疗神经纤维瘤病 1 型<br>Treatment of plexiform neurofibromas in patients with neurofibromatosis type 1                                                                                                                                                               | Springworks Therapeutics Ireland Limited                                              |
| 46. | Filspari                | sparsentan                  | 片剂<br>Tablet                     | 减少患有原发性免疫球蛋白 A 肾病且有疾病快速进展风险的成人患者的蛋白尿<br>To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression                                                                                                       | Ligand Pharmaceuticals Inc. ;<br>Traverse Therapeutics Inc. ;<br>Bristol Myers Squibb |
| 47. | Filsuvez                | birch triterpenes           | 凝胶<br>Gel                        | 用于营养失养型及接合型表皮分解性水疱相关的伤口<br>To treat wounds associated with dystrophic and junctional epidermolysis bullosa                                                                                                                                                   | Lichtenheldt GmbH                                                                     |
| 48. | Gohibic                 | vilobelimab                 | 注射剂<br>Injection                 | 治疗新冠病毒引起的急性呼吸窘迫综合征<br>To treat acute respiratory distress syndrome (ARDS) caused by SARS-CoV-2                                                                                                                                                               | Almac Pharma Services Ltd                                                             |
| 49. | Gomekli                 | mirdametinib                | 胶囊、混悬剂<br>Capsule、<br>Suspension | 用于治疗患有 1 型神经纤维瘤病且患有症状性丛状神经纤维瘤且无法完全切除的患者<br>To treat neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection                                                                                      | SpringWorks Therapeutics, Inc.                                                        |
| 50. | Grafapex                | treosulfan                  | 注射剂<br>Injection                 | 与氟达拉滨联合使用，作为异基因造血干细胞移植的准备方案，用于患有急性髓细胞白血病或骨髓增生异常综合征<br>For use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) for acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) | Medac GmbH                                                                            |

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| 51. | Hemgenix                | etranacogene dezaparvovec   | 注射剂<br>Injection  | 治疗 B 型血友病<br>Treatment of hemophilia B                                                                                                                                                                                                                                                                   | CSL Behring LLC                            |
| 52. | Hernexeos               | zongertinib                 | 片剂<br>Tablet      | 用于治疗具有 HER2 酪氨酸激酶结构域激活突变且已接受过全身治疗的不可切除或转移性非鳞状非小细胞肺癌成人患者<br>To treat adults with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy | Boehringer Ingelheim Pharmaceuticals, Inc. |
| 53. | Imaavy                  | nipocalimab                 | 注射剂<br>Injection  | 治疗全身性重症肌无力<br>To treat generalized myasthenia gravis                                                                                                                                                                                                                                                     | Janssen Biotech, Inc.                      |
| 54. | Imdelltra               | tarlatamab                  | 注射剂<br>Injection  | 治疗晚期小细胞肺癌<br>To treat extensive stage small cell lung cancer                                                                                                                                                                                                                                             | Amgen Inc.                                 |
| 55. | Inpefa                  | sotagliflozin               | 片剂<br>Tablet      | 治疗心脏衰竭<br>To treat heart failure                                                                                                                                                                                                                                                                         | Lexicon Pharms Inc.                        |
| 56. | Iomervu                 | iomeprol                    | 注射剂<br>Injection  | 用作放射线造影剂<br>For use as a radiographic contrast agent                                                                                                                                                                                                                                                     | Bracco Diagnostic Inc.;<br>BIPSO GmbH      |
| 57. | Iqirvo                  | elafibranor                 | 片剂<br>Tablet      | 联合熊脱氧胆酸用于治疗原发性胆源性胆管炎<br>To treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid                                                                                                                                                                                              | Ipsen Biopharmaceuticals, Inc.             |
| 58. | Ixchiq                  | chikungunya vaccine (live)  | 注射剂<br>Injection  | 预防成人基孔肯尼亚病<br>Prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years and older                                                                                                                                                                                                | Valneva Austria GmbH                       |
| 59. | Izervay                 | avacincaptad pegol          | 注射剂<br>Injection  | 治疗黄斑病变引发的地图样萎缩症<br>To treat geographic atrophy secondary to age-related macular degeneration                                                                                                                                                                                                             | IVERIC bio, Inc.                           |

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|-----|-------------------------|-----------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| 60. | Jaypirca                | pirtobrutinib               | 片剂<br>Tablet      | 用于治疗已接受过至少两种全身治疗（包括 BTK 抑制剂）的成人的复发性或难治性套细胞淋巴瘤<br>To treat relapsed or refractory mantle cell lymphoma in adults who have had at least two lines of systemic therapy, including a BTK inhibitor | Loxo Oncology Inc. ; Eli Lilly      |
| 61. | Jesduvroq               | daprodustat                 | 片剂<br>Tablet      | 用于治疗已接受至少四个月透析的成人慢性肾病引起的贫血<br>To treat anemia caused by chronic kidney disease for adults on dialysis for at least four months                                                                 | GlaxoSmithKline                     |
| 62. | Joenja                  | leniolisib                  | 片剂<br>Tablet      | 治疗活化磷酸肌醇 3-激酶 $\delta$ 综合症<br>To treat activated phosphoinositide 3-kinase delta syndrome                                                                                                      | Pharming Group NV ; Novartis        |
| 63. | Journavx                | suzetrigine                 | 片剂<br>Tablet      | 治疗中到重度急性疼痛<br>To treat moderate to severe acute pain                                                                                                                                           | Vertex Pharmaceuticals Incorporated |
| 64. | Kavigale                | sipavibart                  | 注射剂<br>Injection  | 用于成人及 12 岁或以上青少年作为新冠病毒暴露前的预防用药<br>Pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older                                                                     | AstraZeneca AB                      |
| 65. | Kimmtrak                | tebentafusp                 | 注射剂<br>Injection  | 治疗不可切除或转移性葡萄膜黑色素瘤<br>To treat unresectable or metastatic uveal melanoma                                                                                                                        | Immunocore Ltd                      |
| 66. | Kisunla                 | donanemab                   | 注射剂<br>Injection  | 治疗阿尔茨海默症<br>To treat Alzheimer's disease                                                                                                                                                       | Eli Lilly and Company               |
| 67. | Korsuva ; Kapruvia      | difelikefalin               | 注射剂<br>Injection  | 治疗慢性肾病导致的中度至重度瘙痒<br>To treat moderate-to-severe pruritus associated with chronic kidney disease                                                                                                | Cara Therapeutics                   |

| 项目  | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form          | 适应症<br>Indication(s)                                                                                                                                                                                    | 药企<br>Pharmaceutical company        |
|-----|-------------------------|-----------------------------|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| 68. | Kostaive                | zapomeran                   | 注射剂<br>Injection           | 预防成人新冠病毒感染<br>To prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older                                                                                                         | Arcturus Therapeutics Europe B.V.   |
| 69. | Krazati                 | adagrasib                   | 片剂<br>Tablet               | 用于治疗已接受过至少一种全身治疗的成人 KRAS G12C 突变的局部晚期或转移性非小细胞肺癌<br>To treat KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer in adults who have received at least one prior systemic therapy | Mirati Therapeutics Inc.            |
| 70. | Kymriah                 | tisagenlecleucel            | 注射剂<br>Injection           | 治疗复发性或难治性急性淋巴细胞白血病、复发性或难治性大 B 细胞淋巴瘤<br>Treatment of relapsed or refractory (r/r) acute lymphocytic leukemia (ALL) or relapsed or refractory (r/r) large B-cell lymphoma (LBCL)                          | Novartis                            |
| 71. | Lamzedo                 | velmanase alfa              | 散剂、注射剂<br>Powder、Injection | 治疗α-甘露糖苷贮积症<br>Treatment of alpha-mannosidosis                                                                                                                                                          | Chiesi Farmaceutici SPA             |
| 72. | Lazcluze                | lazertinib                  | 片剂<br>Tablet               | 治疗非小细胞肺癌<br>To treat non-small cell lung cancer (NSCLC)                                                                                                                                                 | Janssen Biotech, Inc.               |
| 73. | Leqselvi                | deuruxolitinib              | 片剂<br>Tablet               | 治疗严重斑秃<br>To treat severe alopecia areata                                                                                                                                                               | Sun Pharmaceutical Industries, Inc. |
| 74. | Letybo                  | letibotulinumtoxin A        | 注射剂<br>Injection           | 暂时性改善出现的中度至重度皱眉纹<br>To temporarily improve the appearance of moderate-to-severe glabellar lines                                                                                                         | Hugel, Inc.                         |
| 75. | Livdelzi                | seladelpar                  | 胶囊<br>Capsule              | 治疗原发性胆汁性胆管炎<br>To treat primary biliary cholangitis (PBC)                                                                                                                                               | Gilead Sciences, Inc.               |
| 76. | Livtency                | maribavir                   | 片剂<br>Tablet               | 治疗移植后的巨细胞病毒 (CMV) 感染<br>To treat post-transplant cytomegalovirus (CMV) infection                                                                                                                        | Takeda Pharmaceuticals USA          |

| 项目  | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form           | 适应症<br>Indication(s)                                                                                                                                                                | 药企<br>Pharmaceutical company        |
|-----|-------------------------|-----------------------------|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| 77. | Loargys                 | pegzilarginase              | 注射剂<br>Injection            | 治疗 2 岁及以上患者的高精氨酸血症<br>To treat people from 2 years of age with hyperargininemia                                                                                                     | Immedica Pharma AB<br>Unimedica AB  |
| 78. | Locametz                | gallium Ga 68 gozetotide    | 注射剂<br>Injection            | 用于正子断层扫描中辨识前列腺癌患者中前列腺特异性膜抗原阳性病变<br>Detection of prostate-specific membrane antigen (PSMA)-positive lesions with positron emission tomography (PET) in patients with prostate cancer | Novartis Pharmaceuticals UK Limited |
| 79. | Lumisight               | pegulicanine                | 注射剂<br>Injection            | 作为光学成像剂用于检测癌组织<br>To use as an optical imaging agent for the detection of cancerous tissue                                                                                          | Lumicell, Inc.                      |
| 80. | Lupkynis                | voclosporin                 | 胶囊<br>Capsule               | 治疗狼疮性肾炎<br>To treat lupus nephritis                                                                                                                                                 | Aurinia Pharmaceuticals Inc.        |
| 81. | Lynozyfic               | linvoseltamab               | 注射剂<br>Injection            | 治疗复发性及难治性多发性骨髓瘤<br>Treatment of patients with relapsed and refractory multiple myeloma                                                                                              | Regeneron Ireland DAC               |
| 82. | Lytgobi                 | futibatinib                 | 片剂<br>Tablet                | 治疗含有成纤维细胞生长因子受体 2 (FGFR2) 基因融合或其他重排的肝内胆管癌<br>To treat intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements    | Taiho Oncology                      |
| 83. | Miebo                   | perfluoro-hexyloctane       | 眼用溶液<br>Ophthalmic solution | 治疗干眼病的症状<br>To treat signs and symptoms of dry eye disease                                                                                                                          | Novaliq GmbH                        |
| 84. | Miplyffa                | arimoclomol                 | 胶囊<br>Capsule               | 治疗尼曼匹克疾病 C 型<br>To treat Niemann-Pick disease type C                                                                                                                                | Zevra Denmark A/S                   |

| 项目  | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s)      | 剂型<br>Dosage Form          | 适应症<br>Indication(s)                                                                                                                                            | 药企<br>Pharmaceutical company    |
|-----|-------------------------|----------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| 85. | Modeyso                 | dordaviprone                     | 胶囊<br>Capsule              | 治疗 H3 K27M 突变且既往接受过治疗后病情出现进展的弥漫性中线神经胶质瘤<br>To treat diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy       | Jazz Pharmaceuticals, Inc.      |
| 86. | mResvia                 | Respiratory Syncytial Virus mRNA | 注射剂<br>Injection           | 预防 60 岁及以上人群因呼吸道合胞病毒引起的下呼吸道疾病<br>Prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in adults 60 years of age and older | Moderna Biotech Spain, S.L.     |
| 87. | Nemluvio                | nemolizumab                      | 注射剂<br>Injection           | 治疗结节性痒疹<br>To treat prurigo nodularis                                                                                                                           | Galderma Laboratories, L.P.     |
| 88. | NexoBrid                | anacaulase                       | 凝胶<br>Gel                  | 去除成人深度部分或全层热烧伤的焦痂<br>To remove eschar in adults with deep partial thickness or full thickness thermal burns                                                     | Mediowound, Ltd                 |
| 89. | Ngenla                  | somatrogon                       | 注射剂<br>Injection           | 治疗因生长激素分泌不足而导致的生长障碍<br>Management of a growth disorder due to growth hormone deficiency                                                                         | OPKO Health Inc.<br>Pfizer Inc. |
| 90. | Niktimvo                | axatilimab                       | 注射剂<br>Injection           | 治疗慢性移植物抗宿主病<br>To treat chronic graft-versus-host disease (cGVHD)                                                                                               | Incyte Corporation              |
| 91. | Nulibry                 | fosdenopterin                    | 散剂、注射剂<br>Powder、Injection | 降低 A 型钼辅因子缺乏症 ( MoCD ) 患者的死亡风险<br>To reduce the risk of mortality in molybdenum cofactor deficiency Type A                                                      | Sentynl Therapeutics, Inc.      |
| 92. | Ogsiveo                 | nirogacestat                     | 片剂<br>Tablet               | 治疗需要使用全身治疗的进展性硬纤维瘤成年患者<br>To treat adults with progressing desmoid tumors who require systemic treatment                                                        | SpringWorks Therapeutics, Inc.  |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s)             | 剂型<br>Dosage Form               | 适应症<br>Indication(s)                                                                                                      | 药企<br>Pharmaceutical company                                              |
|------|-------------------------|-----------------------------------------|---------------------------------|---------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| 93.  | Ojemda                  | tovorafenib                             | 片剂、混悬剂<br>Tablet、<br>Suspension | 治疗复发性或难治性儿童低级别胶质瘤<br>To treat relapsed or refractory pediatric low-grade glioma                                           | Day One Biopharmaceuticals, Inc.;<br>Quotient Sciences – Philadelphia LLC |
| 94.  | Omlonti                 | omidenepag                              | 眼用溶液<br>Ophthalmic solution     | 降低开角型青光眼或高眼压症患者的眼压<br>To reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension | Santen Pharmaceutical Co., Ltd                                            |
| 95.  | OmvoH                   | mirikizumab                             | 注射剂<br>Injection                | 治疗溃疡性结肠炎<br>To treat ulcerative colitis                                                                                   | Eli Lilly                                                                 |
| 96.  | Opdualag                | nivolumab;<br>relatlimab                | 注射剂<br>Injection                | 治疗不可切除或转移性黑色素瘤<br>To treat unresectable or metastatic melanoma                                                            | Bristol Myers Squibb                                                      |
| 97.  | Ordspono                | odronextamab                            | 注射剂<br>Injection                | 治疗滤泡性淋巴瘤或弥漫性大 B 细胞淋巴瘤<br>To treat follicular lymphoma or diffuse large B-cell lymphoma (DLBCL)                            | Regeneron Ireland DAC                                                     |
| 98.  | Orlynvah                | sulopenem<br>et zadroxil,<br>probenecid | 片剂<br>Tablet                    | 治疗非复杂性尿路感染<br>To treat uncomplicated urinary tract infections                                                             | Iterum Therapeutics                                                       |
| 99.  | Piaskey                 | crovalimab                              | 注射剂<br>Injection                | 治疗阵发性睡眠性血红蛋白尿症<br>Treatment of paroxysmal nocturnal hemoglobinuria (PNH)                                                  | Roche Pharma (Schweiz) AG                                                 |
| 100. | Pombiliti               | cipaglucosidase<br>alfa                 | 注射剂<br>Injection                | 治疗迟发性庞贝氏症<br>Treatment of late-onset Pompe disease                                                                        | Amicus Therapeutics Inc.                                                  |
| 101. | Pyrukynd                | mitapivat                               | 片剂<br>Tablet                    | 治疗丙酮酸激酶缺乏症的溶血性贫血<br>To treat hemolytic anemia in pyruvate kinase deficiency                                               | Agios Pharmaceuticals Inc.                                                |
| 102. | Qalsody                 | tofersen                                | 注射剂<br>Injection                | 治疗具有 SOD1 基因突变的成人肌萎缩侧索硬化症<br>To treat amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation               | Ionis Pharmaceuticals Inc. ;<br>Biogen Inc.                               |

| 项目   | 商品名称<br>Commercial Name      | 主成分<br>Active Ingredient(s)         | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                                                                 | 药企<br>Pharmaceutical company                        |
|------|------------------------------|-------------------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| 103. | Quviviq                      | daridorexant                        | 片剂<br>Tablet      | 治疗失眠<br>To treat insomnia                                                                                                                                                                                                                                                                                                                                            | Actelion Ltd ; Idorsia Ltd                          |
| 104. | Penpulimab ; 安尼可 ; 派安普利单抗注射液 | penpulimab                          | 注射剂<br>Injection  | 与顺铂或卡铂和吉西他滨联合用药，用于复发或转移性非角化性鼻咽癌成人患者；单药治疗用于接受过铂类化疗且至少接受过一种其他先前治疗的转移性非角化性鼻咽癌成人患者<br>In combination with either cisplatin or carboplatin and gemcitabine, to treat adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC), or as a single agent while on or after platinum-based chemotherapy and at least one other prior line of therapy | Akeso Biopharma Co., Ltd.                           |
| 105. | Rapiblyk                     | landiolol                           | 注射剂<br>Injection  | 治疗室上性心搏过速<br>To treat supraventricular tachycardia                                                                                                                                                                                                                                                                                                                   | AOP Orphan Pharmaceuticals GmbH                     |
| 106. | Relyvrio                     | sodium phenylbutyrate;taur ursodiol | 混悬剂<br>Suspension | 治疗肌萎缩侧索硬化症<br>To treat amyotrophic lateral sclerosis (ALS)                                                                                                                                                                                                                                                                                                           | Amylyx Pharmaceuticals                              |
| 107. | Revuforj                     | revumenib                           | 片剂<br>Tablet      | 治疗复发性或难治性急性白血病<br>To treat relapsed or refractory acute leukemia                                                                                                                                                                                                                                                                                                     | Syndax Pharmaceuticals, Inc.                        |
| 108. | Reyvow                       | lasmiditan                          | 片剂<br>Tablet      | 治疗偏头痛<br>Treatment of migraine                                                                                                                                                                                                                                                                                                                                       | Eli Lilly                                           |
| 109. | Rezdiffra                    | resmetirom                          | 片剂<br>Tablet      | 治疗成人非酒精性脂肪性肝炎和中晚期肝纤维化<br>To treat noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced liver scarring                                                                                                                                                                                                                                         | Madrigal Pharmaceuticals, Inc.; UPM Pharmaceuticals |
| 110. | Rezlidhia                    | olutasidenib                        | 胶囊<br>Capsule     | 治疗成人患有易感异柠檬酸脱氢酶-1 (IDH1) 突变的复发性或难治性急性髓系白血病<br>To treat adults with relapsed or refractory acute                                                                                                                                                                                                                                                                      | Rigel Pharms Inc.                                   |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                | 药企<br>Pharmaceutical company                               |
|------|-------------------------|-----------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
|      |                         |                             |                   | myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation                                                                                                                                                                      |                                                            |
| 111. | Rezzayo                 | rezafungin                  | 注射剂<br>Injection  | 治疗念珠菌血症和侵袭性念珠菌病<br>To treat candidemia and invasive candidiasis                                                                                                                                                                                     | Cidara Therapeutics Inc.;<br>Seachaid Pharmaceuticals Inc. |
| 112. | Riulvy                  | tegomil fumarate            | 胶囊<br>Capsule     | 治疗 13 岁及以上儿童及成人复发缓解型的多发性硬化症<br>Treatment of adults and children from 13 years of age with relapsing remitting multiple sclerosis                                                                                                                    | Neuraxpharm<br>Pharmaceuticals, S.L.                       |
| 113. | Rivfloza                | nedosiran                   | 注射剂<br>Injection  | 用于降低 9 岁及以上儿童和成人 1 型原发性高草酸尿症(PH1)患者的尿草酸水平<br>To lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function                                                               | Novo Nordisk Inc;<br>Pyramid Laboratories                  |
| 114. | Roctavian               | valoctocogene roxaparvovec  | 注射剂<br>Injection  | 治疗 A 型血友病<br>Treatment of Hemophilia A                                                                                                                                                                                                              | BioMarin Pharmaceutical Inc.                               |
| 115. | Rolvedon                | eflapeg rastim              | 注射剂<br>Injection  | 降低接受骨髓抑制抗癌药物的非髓系恶性肿瘤患者与发烧性中性粒细胞减少症相关的感染发生率<br>To decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia | Spectrum Pharmaceuticals                                   |
| 116. | Romvimza                | vimseltinib                 | 胶囊<br>Capsule     | 用于治疗患有症状性且手术切除可能会导致严重的功能障碍或疾病的恶化的腱鞘巨细胞瘤<br>To treat symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity                                        | Deciphera Pharmaceuticals,<br>LLC                          |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                               | 药企<br>Pharmaceutical company                                          |
|------|-------------------------|-----------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| 117. | Rystiggo                | rozanolixizumab             | 注射剂<br>Injection  | 治疗全身性重症肌无力<br>Treatment of generalized myasthenia gravis                                                                                                                                           | UCB Pharmaceuticals                                                   |
| 118. | Rytelo                  | imetelstat                  | 注射剂<br>Injection  | 治疗患有低风险至中等-1 风险的骨髓增生异常综合症<br>To treat low- to intermediate-1-risk myelodysplastic syndromes (MDS)                                                                                                  | Geron Corporation;<br>Catalent Indiana, LLC;<br>Patheon Italia, S.p.A |
| 119. | Ryzneuta                | efbemalenograstim alfa      | 注射剂<br>Injection  | 治疗嗜中性粒细胞减少症<br>To treat neutropenia                                                                                                                                                                | Evive Biotechnology Singapore Pte. Ltd.                               |
| 120. | Sephience               | sepiapterin                 | 散剂<br>Powder      | 治疗成人及儿童苯丙酮尿症引起的高苯丙氨酸血症<br>Treatment of hyperphenylalaninemia in adults and children with phenylketonuria (PKU)                                                                                     | PTC Therapeutics International Limited                                |
| 121. | Siiltibcy               | rdESAT-6;<br>rCFP-10        | 注射剂<br>Injection  | 用于诊断结核分枝杆菌感染<br>To detect infection and disease caused by Mycobacterium tuberculosis                                                                                                               | Serum Life Science Europe GmbH<br>Bilthoven Biologicals B.V.          |
| 122. | Sofdra                  | sofpironium                 | 凝胶<br>Gel         | 治疗原发性腋窝多汗症<br>To treat primary axillary hyperhidrosis                                                                                                                                              | Botanix SB Inc.                                                       |
| 123. | Sohonos                 | palovarotene                | 胶囊<br>Capsule     | 减少患有进行性骨化性纤维发育不良的成人和儿童的异养骨化<br>To reduce the volume of new heterotopic ossification in adults and pediatric patients with fibrodysplasia ossificans progressiva (FOP)                              | Ipsen Biopharmaceuticals, Inc.                                        |
| 124. | Sunlenca                | lenacapavir                 | 注射剂<br>Injection  | 治疗因耐药、不耐受或安全考虑而无法用其他可用治疗方法的多重耐药性 HIV 病毒感染<br>Treatment of multi-drug resistant HIV in people with HIV who have limited treatment options due to safety, intolerance, and resistance considerations | Gilead Sciences, Inc.                                                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form           | 适应症<br>Indication(s)                                                                                                                                                      | 药企<br>Pharmaceutical company    |
|------|-------------------------|-----------------------------|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| 125. | Skyclarys               | omaveloxolone               | 胶囊<br>Capsule               | 治疗弗里德里希共济失调<br>To treat Friedrich's ataxia                                                                                                                                | Reata Pharmaceuticals Inc.      |
| 126. | Tecartus                | brexucabtagene autoleucel   | 注射剂<br>Injection            | 治疗复发性或难治性急性淋巴细胞白血病、复发性或难治性套细胞淋巴瘤<br>Treatment of relapsed or refractory (r/r) acute lymphocytic leukemia (ALL) or relapsed or refractory (r/r) mantle cell lymphoma (MCL) | Kite<br>(Gilead Sciences Inc.)  |
| 127. | Tecelra                 | afamitresgene autoleucel    | 注射剂<br>Injection            | 治疗成人不可切除或转移性滑膜瘤<br>Treatment of adults with unresectable or metastatic synovial sarcoma                                                                                   | Adaptimmune, LLC                |
| 128. | Tibsovo                 | ivosidenib                  | 片剂<br>Tablet                | 治疗 IDH1 突变型急性粒细胞白血病、IDH1 突变型胆管癌<br>To treat IDH1-mutated AML、IDH1-mutated cholangiocarcinoma                                                                              | Laboratoires Servier            |
| 129. | Tryngolza               | olezarsen                   | 注射剂<br>Injection            | 治疗家族性高乳糜微粒血症综合征<br>To treat familial chylomicronemia syndrome                                                                                                             | Ionis Pharmaceuticals Inc.      |
| 130. | Tryptyr                 | acoltremon                  | 眼用溶液<br>ophthalmic solution | 治疗干眼症的征象及症状<br>To treat the signs and symptoms of dry eye disease                                                                                                         | Alcon Inc.                      |
| 131. | Tryvio                  | aprocitentan                | 片剂<br>Tablet                | 治疗高血压<br>To treat hypertension                                                                                                                                            | Idorsia Pharmaceuticals US Inc. |
| 132. | Tymlos;<br>Eladynos     | abaloparatide               | 注射剂<br>Injection            | 治疗骨质疏松症<br>Treatment of osteoporosis                                                                                                                                      | Radius Health Inc.              |
| 133. | Tziel                   | teplizumab                  | 注射剂<br>Injection            | 延缓第 3 期 1 型糖尿病的发作<br>To delay the onset of stage 3 type 1 diabetes                                                                                                        | Provention Bio Inc.             |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active<br>Ingredient(s) | 剂型<br>Dosage Form           | 适应症<br>Indication(s)                                                                                                                                                                      | 药企<br>Pharmaceutical company         |
|------|-------------------------|--------------------------------|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| 134. | Unloxcyt                | cosibelimab                    | 注射剂<br>Injection            | 治疗皮肤鳞状细胞癌<br>To treat cutaneous squamous cell carcinoma                                                                                                                                   | Checkpoint Therapeutics, Inc.        |
| 135. | Vafseo                  | vadadustat                     | 片剂<br>Tablet                | 治疗慢性肾脏疾病导致之贫血<br>To treat anemia due to chronic kidney disease                                                                                                                            | Akebia Therapeutics, Inc.            |
| 136. | Vanrafia                | atrasentan                     | 片剂<br>Tablet                | 用于降低病情快速进展风险且患有原发性免疫球蛋白 A 肾病成人的蛋白尿<br>To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression                                      | Novartis Pharmaceuticals Corporation |
| 137. | Veopoz                  | pozelimab                      | 注射剂<br>Injection            | 治疗 1 岁及以上患者的 CD55 缺乏蛋白丢失性肠病 (CHAPLE 病)<br>To treat patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease                       | Regeneron Pharmaceuticals, Inc.      |
| 138. | Vivjoa                  | oteseconazole                  | 胶囊<br>Capsule               | 降低有复发性外阴阴道念珠菌病(RVVC)病史且无生殖潜力的女性的 RVVC 发病率<br>To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential | Mycovia Pharmaceuticals              |
| 139. | Vizz                    | aceclidine                     | 眼用溶液<br>Ophthalmic solution | 治疗老花眼<br>To treat presbyopia                                                                                                                                                              | LENZ Therapeutics, Inc.              |
| 140. | Vonjo                   | pacritinib                     | 胶囊<br>Capsule               | 治疗血小板低的成人中度或高危原发性或继发性骨髓纤维化<br>To treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets                                                          | CTI BioPharma                        |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form            | 适应症<br>Indication(s)                                                                                                                                                                                    | 药企<br>Pharmaceutical company   |
|------|-------------------------|-----------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 141. | Voydeya                 | danicopan                   | 片剂<br>Tablet                 | 治疗阵发性夜间血红蛋白尿症患者的血管外溶血<br>To treat extravascular hemolysis with paroxysmal nocturnal hemoglobinuria                                                                                                      | Alexion Europe SAS             |
| 142. | Vtama                   | tapinarof                   | 乳膏<br>Cream                  | 治疗斑块状银屑病<br>To treat plaque psoriasis                                                                                                                                                                   | Dermavant Sciences             |
| 143. | Vyjuvek                 | beremagene<br>geperpavec    | 混悬剂、凝胶<br>Suspension,<br>Gel | 治疗患有营养不良性大疱性表皮松解症且伴有 VII 型胶原α1 链(COL7A1)基因突变的患者的伤口<br>Treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene | Krystal Biotech Netherlands BV |
| 144. | Vyvgart                 | efgartigimod alfa           | 注射剂<br>Injection             | 治疗全身性重症肌无力<br>To treat generalized myasthenia gravis                                                                                                                                                    | Argenx BV                      |
| 145. | Wainua; Wainzua         | eplontersen                 | 注射剂<br>Injection             | 治疗遗传性转甲状腺素蛋白介导的淀粉样变性多发性神经病<br>To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis                                                                                                  | AstraZeneca Pharmaceuticals LP |
| 146. | Wayrilz <sup>#</sup>    | rilzabrutinib               | 片剂<br>Tablet                 | 用于治疗对免疫球蛋白、抗 D 疗法或皮质类固醇治疗反应不足的慢性免疫性血小板减少症<br>To treat persistent or chronic immune thrombocytopenia that has not sufficiently responded to immunoglobulins, anti-D therapy or corticosteroids           | Genzyme Corporation            |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form  | 适应症<br>Indication(s)                                                                                                                                                                                                          | 药企<br>Pharmaceutical company       |
|------|-------------------------|-----------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| 147. | Xacduro                 | sulbactam;<br>durlobactam   | 注射剂<br>Injection   | 治疗由鲍曼不动杆菌-醋酸钙复合体敏感分离株引起的医院获得性细菌性肺炎和呼吸机相关细菌性肺炎<br>To treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex | Entasis Therapeutics Holdings Inc. |
| 148. | Xenoview                | hyperpolarized Xe-129       | 吸入制剂<br>Inhalation | 辅助评估肺功能及肺部成像<br>To evaluate pulmonary function and imaging                                                                                                                                                                    | Polarean Inc.                      |
| 149. | Xenpozyme               | olipudase alfa              | 注射剂<br>Injection   | 治疗酸性鞘磷脂酶缺乏症<br>To treat acid sphingomyelinase deficiency                                                                                                                                                                      | Sanofi S.A.                        |
| 150. | Xolremdi                | mavorixafor                 | 胶囊<br>Capsule      | 治疗 WHIM 综合症<br>To treat WHIM syndrome                                                                                                                                                                                         | X4 Pharmaceuticals, Inc.           |
| 151. | Yorvipath               | palopegteriparatide         | 注射剂<br>Injection   | 治疗副甲状腺功能低下症<br>To treat hypoparathyroidism                                                                                                                                                                                    | Ascendis Pharma Bone Diseases A/S  |
| 152. | Yselty                  | linzagolix                  | 片剂<br>Tablet       | 治疗子宫肌瘤<br>To treat uterine fibroids                                                                                                                                                                                           | Theramex Ireland Limited           |
| 153. | Zavzpret                | zavegepant                  | 喷剂<br>Spray        | 治疗偏头痛<br>To treat migraine                                                                                                                                                                                                    | Pfizer Inc.                        |
| 154. | Zegfrovy ;<br>舒沃哲；舒沃替尼片 | sunvozertinib               | 片剂<br>Tablet       | 治疗带有表皮生长因子受体外显子 20 插入突变型的局部晚期或转移性非小细胞肺癌的成人患者<br>Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations   | 迪哲（江苏）医药股份有限公司                     |
| 155. | Zelsuvmi                | berdazimer                  | 凝胶<br>Gel          | 治疗传染性软疣<br>To treat molluscum contagiosum                                                                                                                                                                                     | EPIH SPV, LLC                      |

| 项目   | 商品名称<br>Commercial Name   | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                 | 药企<br>Pharmaceutical company                                   |
|------|---------------------------|-----------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| 156. | Ziihera ; 百赫安 ; 注射用泽尼达妥单抗 | zanidatamab                 | 注射剂<br>Injection  | 用于既往接受过治疗的 HER2 高表达的不可切除局部晚期或转移性胆道癌患者<br>Treatment of adults with previously treated, unresectable locally advanced or metastatic HER2-positive biliary tract cancer | Jazz Pharmaceuticals Ireland Limited ;<br>百济神州 ( 苏州 ) 生物科技有限公司 |
| 157. | Zilbrysq                  | zilucoplan                  | 注射剂<br>Injection  | 治疗抗乙酰胆碱受体抗体阳性的成人患者的全身性重症肌无力<br>To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive                         | UCB, Inc.                                                      |
| 158. | Zokinvy                   | lonafarnib                  | 胶囊<br>Capsule     | 治疗哈钦森-吉尔福德早衰综合征<br>Treatment of Hutchinson-Gilford progeria syndrome                                                                                                 | Eiger Biopharmaceuticals                                       |
| 159. | Ztalmy                    | ganaxolone                  | 混悬剂<br>Suspension | 治疗细胞周期蛋白依赖性激酶样 5 缺乏症的癫痫发作<br>To treat seizures in cyclin-dependent kinase-like 5 deficiency disorder                                                                 | Marinus Pharmceuticals Inc.;<br>Purdue Neuroscience Corp       |
| 160. | Zurzuvae                  | zuranolone                  | 胶囊<br>Capsule     | 治疗产后抑郁症<br>To treat postpartum depression                                                                                                                            | Biogen Inc.                                                    |
| 161. | Zynlonta                  | loncastuximab tesirine      | 注射剂<br>Injection  | 治疗弥漫性大 B 细胞淋巴瘤 (DLBCL)及高级别 B 细胞淋巴瘤 (HGBL)<br>To treat diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBCL)                                   | ADC Therapeutics SA                                            |
| 162. | Zynyz                     | retifanlimab                | 注射剂<br>Injection  | 治疗转移性或复发性局部晚期默克尔细胞癌<br>To treat metastatic or recurrent locally advanced Merkel cell carcinoma                                                                       | Incyte Corp ; MacroGenics Inc.                                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                            | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 163. | 戈芮宁；注射用维拉替酶β            | velaglucerase β             | 注射剂<br>Injection  | 用于 12 岁及以上青少年和成人 I 型和 III 型戈谢病患者的长期酶替代治疗<br>Treatment of adolescents aged 12 and above and adults with type I and type III Gaucher disease.                                                                                                                                                                                     | 北海康成（上海）生物科技有限公司             |
| 164. | 地达西尼胶囊                  | dimdazenil                  | 胶囊<br>Capsule     | 失眠的短期治疗<br>Short-term treatment of insomnia                                                                                                                                                                                                                                                                                     | 浙江京新药业股份有限公司                 |
| 165. | 因他瑞；林普利塞片               | linperlisib                 | 片剂<br>Tablet      | 治疗复发性或难治性滤泡性淋巴瘤成人患者<br>Treatment of adults with relapsed or refractory follicular lymphoma                                                                                                                                                                                                                                      | 上海瓊黎药业有限公司                   |
| 166. | 艾比特；苹果酸法米替尼胶囊           | famitinib malate            | 胶囊<br>Capsule     | 联合注射用卡瑞利珠单抗用于既往接受含铂化疗治疗失败但未接受过贝伐珠单抗治疗的复发或转移性宫颈癌患者<br>In combination with injectable carelizumab for patients with recurrent or metastatic cervical cancer who have failed platinum-containing chemotherapy but have not received bevacizumab treatment                                                                          | 江苏恒瑞医药股份有限公司                 |
| 167. | 艾心安；注射用瑞卡西单抗            | recaticimab                 | 注射剂<br>Injection  | 在控制饮食的基础上，与他汀类药物、或者与他汀类药物及其它降脂疗法联合用药，用于接受中等或以上剂量他汀类药物治疗仍无法达到低密度脂蛋白胆固醇(LDL-C)目标的原发性高胆固醇血症和混合型血脂异常的成人患者；单药用于非家族性高胆固醇血症和混合型血脂异常的成人患者，以降低低密度脂蛋白胆固醇(LDL-C)、总胆固醇(TC)、载脂蛋白 B (ApoB)水平<br>On the basis of dietary control, in combination with statins or other lipid lowering therapy for the treatment of adult patients with primary | 广东恒瑞医药有限公司                   |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                                                                                             | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|      |                         |                             |                   | hypercholesterolemia and mixed dyslipidemia, who fail to achieve low-density lipoprotein cholesterol (LDL-C) goals after receiving moderate or higher doses of statins treatment; Monotherapy for adult patients with non-familial hypercholesterolemia and mixed dyslipidemia to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), and apolipoprotein B (ApoB) levels |                              |
| 168. | 艾速达；硫酸埃玛昔替尼片            | ivarmacitinib sulfate       | 片剂<br>Tablet      | 用于对一种或多种 TNF 抑制剂疗效不佳或不耐受的活动性强直性脊柱炎成人患者<br>Treatment of adult patients with active ankylosing spondylitis who have poor efficacy or intolerance to one or more TNF inhibitor                                                                                                                                                                                                                      | 江苏恒瑞医药股份有限公司                 |
| 169. | 艾瑞凯；戈来雷塞片               | glecirasib                  | 片剂<br>Tablet      | 用于至少接受过一种系统性治疗的 KRAS G12C 突变型的晚期非小细胞肺癌(NSCLC)成人患者<br>Treatment of adult patients with non-small cell lung cancer (NSCLC) harboring KRAS G12C mutations who have received at least one prior systemic therapy                                                                                                                                                                                     | 上海艾力斯医药科技股份有限公司              |
| 170. | 艾瑞璟；泽美妥司他片 <sup>#</sup> | zeprumetostat               | 片剂<br>Tablet      | 用于既往接受过至少一种系统性治疗的复发或难治外周 T 细胞淋巴瘤成人患者<br>Treatment for adult patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL) who have received at least one prior line of systemic therapy                                                                                                                                                                                             | 江苏恒瑞医药股份有限公司                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                                                      | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 171. | 汝佳宁；盐酸来罗西利片             | lerociclib hydrochloride    | 片剂<br>Tablet      | 用于激素受体阳性、人表皮生长因子受体 2 阴性局部晚期或转移性乳腺癌成人患者；与芳香化酶抑制剂联合使用作为初始内分泌治疗；与氟维司群联合用于既往接受内分泌治疗后疾病进展的患者<br>Treatment of advanced or metastatic HR-positive, HER2-negative breast cancer. In combination with aromatase inhibitors as initial endocrine therapy. In combination with fulvestrant, particularly in patients who have progressed on prior endocrine therapy. | Genor Biopharma(USA), Inc.   |
| 172. | 伊速达；玛舒拉沙韦片              | suraxavir marboxil          | 片剂<br>Tablet      | 用于既往健康的 12 岁及以上青少年和成人单纯性甲型和乙型流感患者的治疗，不包括存在流感相关并发症高风险的患者<br>Treatment of influenza A and B in individuals aged 12 and above. However, it is not indicated for patients at high risk of flu-related complications.                                                                                                                                          | 江西科睿药业有限公司                   |
| 173. | 伏罗尼布片                   | vorolanib                   | 片剂<br>Tablet      | 与依维莫司联合，用于既往接受过酪氨酸激酶抑制剂治疗失败的晚期肾细胞癌患者<br>In combination with everolimus, for patients with advanced renal cell carcinoma who have failed prior treatment with a tyrosine kinase inhibitor                                                                                                                                                                  | 贝达药业股份有限公司                   |
| 174. | 先诺欣；<br>先诺特韦片/利托那韦片     | ritonavir;<br>simnotrelvir  | 片剂<br>Tablet      | 治疗新冠病毒感染<br>Treatment of COVID-19 infection                                                                                                                                                                                                                                                                                                               | 先声药业有限公司                     |
| 175. | 安久卫；<br>安奈拉唑钠肠溶片        | anaprazole sodium           | 片剂<br>Tablet      | 治疗十二指肠溃疡<br>Treatment of duodenal ulcer                                                                                                                                                                                                                                                                                                                   | 轩竹生物科技股份有限公司                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                              | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 176. | 安洛晴；枸橼酸依奉阿克胶囊           | envonalkib                  | 胶囊<br>Capsule     | 治疗未经过间变性淋巴瘤激酶抑制剂治疗的 ALK 阳性的局部晚期或转移性非小细胞肺癌<br>Treatment of anaplastic lymphoma kinase (ALK)-positive patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not been treated with ALK inhibitors | 正大天晴药业集团股份有限公司               |
| 177. | 安佑平；菲诺利单抗注射液            | finotonlimab                | 注射剂<br>Injection  | 与含铂化疗联合用于复发性和/或转移性头颈部鳞状细胞癌<br>Treatment of recurrent and/or metastatic head and neck squamous cell carcinoma in combination with platinum-based chemotherapy                                                                      | 神州细胞工程有限公司                   |
| 178. | 安方宁；格索雷塞片               | garsorasib                  | 片剂<br>Tablet      | 用于治疗已接受过至少一种全身治疗的成人 KRAS G12C 突变的局部晚期或转移性非小细胞肺癌<br>To treat KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer in adults who have received at least one prior systemic therapy                           | 上海正大天晴医药科技开发有限公司             |
| 179. | 安达静；夫那奇珠单抗注射液           | vunakizumab                 | 注射剂<br>Injection  | 治疗适合系统治疗或光疗的中度至重度斑块状银屑病成人患者<br>Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy                                                                       | 苏州盛迪亚生物医药有限公司                |
| 180. | 沙艾特；注射用埃普奈明             | aponermin                   | 注射剂<br>Injection  | 治疗接受过至少 2 种系统性治疗方案的复发或难治性多发性骨髓瘤成人患者<br>Treatment of adult patients with relapsed or refractory multiple myeloma after two or more systemic therapies                                                                              | 武汉海特生物制药股份有限公司               |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                       | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 181. | 阿兹夫定片                   | azvudine                    | 片剂<br>Tablet      | 治疗新冠病毒感染<br>Treatment of COVID-19 infection                                                                                                                                                                                                                                                | 河南真实生物科技有限公司                 |
| 182. | 阿得贝利单抗注射液               | adebrelimab                 | 注射剂<br>Injection  | 治疗小细胞肺癌<br>Treatment of small cell lung cancer                                                                                                                                                                                                                                             | 江苏恒瑞医药股份有限公司                 |
| 183. | 贝塔宁；枸橼酸倍维巴肽注射液          | bevifibatide citrate        | 注射剂<br>Injection  | 用于进行经皮冠状动脉介入术（包括进行冠状动脉内支架置入术）的急性冠脉综合征患者，以降低急性闭塞、支架内血栓、无复流和慢血流发生的风险<br>For patients with acute coronary syndrome undergoing percutaneous coronary intervention (including coronary stent implantation) to reduce the risk of acute occlusion, in-stent thrombosis, no-reflow, and slow flow | 百奥泰生物制药股份有限公司                |
| 184. | 贝特琳；注射用盐酸伊吡诺司他          | ifupinostat hydrochloride   | 注射剂<br>Injection  | 用于既往接受过至少两线系统性治疗的复发或难治性弥漫性大 B 细胞淋巴瘤成人患者<br>Treatment for relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) in patients who have received at least two prior systemic therapies                                                                                              | 广州必贝特医药股份有限公司                |
| 185. | 伯瑞替尼肠溶胶囊                | bozitinib                   | 胶囊<br>Capsule     | 治疗具有间质-上皮转化因子（MET）外显子 14 跳变的局部晚期或转移性非小细胞肺癌患者<br>To treat patients with MET exon 14 skipping non-small cell lung cancer (NSCLC)                                                                                                                                                             | 北京浦润奥生物科技有限责任公司              |
| 186. | 利生妥；利沙托克拉片              | lisaftoclax                 | 片剂<br>Tablet      | 用于既往经过至少包含布鲁顿酪氨酸激酶（BTK）抑制剂在内的一种系统治疗的成人慢性淋巴细胞白血病（CLL）/小淋巴细胞淋巴瘤（SLL）患者<br>Treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma                                                                                                                                               | 苏州亚盛药业有限公司                   |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                                                                                                                                               | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|      |                         |                             |                   | (CLL/SLL) in patients who have previously received at least one prior systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor                                                                                                                                                                                                                                                                                                       |                              |
| 187. | 君适达；昂戈瑞西单抗注射液           | ongeriticimab               | 注射剂<br>Injection  | 在控制饮食的基础上，与他汀类药物、或者与他汀类药物和依折麦布联合用药，用于在接受中等剂量或中等剂量以上他汀类药物治疗，仍无法达到低密度脂蛋白胆固醇（LDL-C）目标的原发性高胆固醇血症（非家族性）和混合型血脂异常的成人患者<br>Based on dietary control, in combination with statins or statins and ezetimibe for the treatment of adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia, who fail to achieve low-density lipoprotein cholesterol (LDL-C) goals after receiving moderate or higher doses of statins treatment | 上海君实生物医药科技股份有限公司             |
| 188. | 依达方；<br>依沃西单抗注射液        | ivonescimab                 | 注射剂<br>Injection  | 联合培美曲塞和卡铂，用于经表皮生长因子受体酪氨酸激酶抑制剂治疗后进展的 EGFR 基因突变阳性的局部晚期或转移性非鳞状非小细胞肺癌<br>Combined with pemetrexed and carboplatin chemotherapy in treating EGFR mutation in locally advanced positive non-squamous non-small cell lung cancer (NSCLC) patients who have progressed after treatment of EGFR tyrosine kinase inhibitor                                                                                                                                   | 康方赛诺医药有限公司                   |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                               | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 189. | 东英贺；艾考磷布韦片              | encofosbuvir                | 片剂<br>Tablet      | 与磷酸萘坦司韦胶囊联用，治疗初治或经干扰素治疗的基因 1、2、3、6 型成人慢性丙型肝炎病毒感染，可合并或不合并代偿性肝硬化<br>In combination with netanasvir phosphate capsules to treat chronic hepatitis C virus (HCV) infection in adults with genotypes 1, 2, 3, and 6 who are treatment-naïve or have been treated with interferon, with or without compensated cirrhosis | 宜昌东阳光长江药业股份有限公司              |
| 190. | 东卫卓；磷酸萘坦司韦胶囊            | netanasvir phosphate        | 胶囊<br>Capsule     | 用于与艾考磷布韦片联用，治疗初治或经干扰素治疗的基因 1、2、3、6 型成人慢性丙型肝炎病毒感染，可合并或不合并代偿性肝硬化<br>In combination with yiqibuvir tablets to treat chronic hepatitis C virus (HCV) infection in adults with genotypes 1, 2, 3, and 6 who are treatment-naïve or have been treated with interferon, with or without compensated cirrhosis             | 广东东阳光药业股份有限公司                |
| 191. | 佳泰莱；芦康沙妥珠单抗注射液          | sacituzumab tirumotecan     | 注射剂<br>Injection  | 用于既往至少接受过 2 种系统治疗（其中至少 1 种治疗针对晚期或转移性阶段）的不可切除的局部晚期或转移性三阴性乳腺癌成人患者<br>Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) who have received at least 2 prior systemic therapies, including at least 1 in the advanced or metastatic setting             | 四川科伦博泰生物医药股份有限公司             |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                       | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 192. | 昂伟达；盐酸司美那非片             | simenafil hydrochloride     | 片剂<br>Tablet      | 治疗勃起功能障碍<br>Treatment of erectile dysfunction                                                                                                                                                                                                                                                              | 苏州旺山旺水生物医药股份有限公司             |
| 193. | 金立希；赛立奇单抗注射液            | xeligekimab                 | 注射剂<br>Injection  | 治疗适合系统治疗或光疗的中度至重度斑块状银屑病成人患者<br>Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy                                                                                                                                                | 重庆智翔金泰生物制药股份有限公司             |
| 194. | 金禧欣；注射用伏欣奇拜单抗           | firsekibart                 | 注射剂<br>Injection  | 用于对非甾体类抗炎药和/或秋水仙碱禁忌、不耐受或缺乏疗效的，以及不适合反复使用类固醇激素的成人痛风性关节炎急性发作<br>For patients with acute episodes of gout arthritis in adults who are contraindicated, intolerant, or lack curative effects with nonsteroidal anti-inflammatory drugs and/or colchicine, and who are not suitable for repeated use of steroids | 长春金赛药业有限责任公司                 |
| 195. | 思美宁；苯磺酸克利加巴林胶囊          | crisugabalin besilate       | 胶囊<br>Capsule     | 治疗糖尿病性周围神经病理性疼痛<br>To treat peripheral neuropathic pain                                                                                                                                                                                                                                                    | 海思科医药集团股份有限公司                |
| 196. | 思舒静；安瑞克芬注射液             | anrikefon                   | 注射剂<br>Injection  | 用于治疗腹部手术后的轻至中度疼痛<br>Treatment of mild to moderate pain following abdominal surgery                                                                                                                                                                                                                         | 海思科医药集团股份有限公司                |
| 197. | 派舒宁；塞纳-马恩省帕利胶囊          | senaparib                   | 胶囊<br>Capsule     | 用于晚期上皮性卵巢癌、输卵管癌或原发性腹膜癌成人患者在一线含铂化疗达到完全缓解或部分缓解后的维持治疗<br>Maintenance treatment of adult patients with                                                                                                                                                                                                         | 上海英派药业有限公司                   |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                            | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|      |                         |                             |                   | advanced epithelial high-grade ovarian, fallopian tube, or primary peritoneal cancer who achieved a complete or partial response after the completion of first-line platinum-based chemotherapy |                              |
| 198. | 科泰莱；塔戈利单抗注射液            | tagitanlimab                | 注射剂<br>Injection  | 用于既往接受过二线及以上化疗失败的复发或转移性鼻咽癌患者的治疗<br>Treatment of patients with recurrent or metastatic nasopharyngeal cancer (NPC) who have previously failed second-line or higher chemotherapy                 | 四川科伦博泰生物医药股份有限公司             |
| 199. | 科露平；妥拉美替尼胶囊             | tunlametinib                | 胶囊<br>Capsule     | 治疗曾接受抗 PD-1/PD-L1 治疗的 NRAS 突变的晚期黑色素瘤患者<br>Treatment of advanced melanoma carrying neuroblastoma ras viral oncogene homolog (NRAS) mutations who have previously undergone PD-1/PD-L1 treatment  | 上海科州药物研发有限公司                 |
| 200. | 津立生；纳卢梭拜单抗注射液           | narlumosbart                | 注射剂<br>Injection  | 治疗不可手术切除或手术切除可能导致严重功能障碍的骨巨细胞瘤成人患者<br>Treatment for adult patients with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity        | 上海津曼特生物科技有限公司                |
| 201. | 信立汀；苯甲酸福格列汀片            | fotagliptin benzoate        | 片剂<br>Tablet      | 改善成人 2 型糖尿病患者的血糖控制<br>To improve glycemic control in patients with type 2 diabetes mellitus                                                                                                     | 深圳信立泰药业股份有限公司                |
| 202. | 信立安；戊二酸利那拉生酯胶囊          | linaprazan glurate          | 胶囊<br>Capsule     | 用于反流性食管炎<br>Treatment of gastroesophageal reflux disease                                                                                                                                        | 上海生诺医药科技有限公司                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 203. | 信玖凝；波哌达可基注射液            | dalnacogene ponparvovec     | 注射剂<br>Injection  | 治疗中重度 B 型血友病成年患者<br>Treatment of adult patients with moderate to severe hemophilia B                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 上海信致医药科技有限公司                 |
| 204. | 信尔美；玛仕度肽注射液             | mazdutide                   | 注射剂<br>Injection  | 用于在控制饮食和增加体力活动基础上对成人患者的长期体重控制，初始体重指数（BMI）为：BMI≥28 kg/m <sup>2</sup> （肥胖）；或 BMI≥24 kg/m <sup>2</sup> （超重），并伴有至少一种体重相关的合并症（例如高血糖、高血压、血脂异常、脂肪肝、阻塞性睡眠呼吸暂停综合症等）<br>As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial Body Mass Index (BMI) of BMI≥28 kg/m <sup>2</sup> (obesity) or BMI≥24 kg/m <sup>2</sup> (overweight) in the presence of at least one weight-related comorbid condition (e.g., hyperglycemia, hypertension, dyslipidemia, fatty liver, or obstructive sleep apnea syndrome and etc.) | 信达生物制药（苏州）有限公司               |
| 205. | 重组人源抗狂犬病毒单抗             | ormutivimab                 | 注射剂<br>Injection  | 治疗狂犬病病毒感染<br>Treatment of rabies virus infection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 华北制药集团新药研究开发有限责任公司           |
| 206. | 恒凯莱；雷尼基奥仑赛注射液           | ranicabtagene autoleucel    | 注射剂<br>Injection  | 治疗经过二线或以上系统性治疗后成人复发或难治性大 B 细胞淋巴瘤，包括弥漫性大 B 细胞淋巴瘤非特指型、滤泡性淋巴瘤转化的弥漫性大 B 细胞淋巴瘤、伴 MYC 和 BCL2 重排的高级别 B 细胞淋巴瘤、高级别 B 细胞淋巴瘤非特指型<br>Treatment of adult patients with relapsed or refractory large B-cell lymphoma (r/r LBCL) who have received two or more lines of systemic therapy. This includes diffuse large B-cell                                                                                                                                                                                                                                                                             | 上海恒润达生生物科技股份有限公司             |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                          | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|      |                         |                             |                   | lymphoma, not otherwise specified (DLBCL, NOS); diffuse large B-cell lymphoma transformed from follicular lymphoma; high-grade B-cell lymphoma with MYC and BCL2 rearrangements and high-grade B-cell lymphoma, not otherwise specified (HGBL, NOS).                                                          |                              |
| 207. | 佩金；拓培非格司亭注射液            | telpegfilgrastim            | 注射剂<br>Injection  | 降低非髓性恶性肿瘤患者在接受容易引起发热性中性粒细胞减少症的骨髓抑制性抗癌药物治疗时以发热性中性粒细胞减少症为表现的感染发生率<br>To reduce the incidence of infections manifesting as febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs that predispose to febrile neutropenia                                      | 厦门特宝生物工程股份有限公司               |
| 208. | 倍长平；考格列汀片               | cofroglipitin               | 片剂<br>Tablet      | 改善成人 2 型糖尿病患者的血糖控制<br>To improve glycemic control in patients with type 2 diabetes mellitus                                                                                                                                                                                                                   | 海思科医药集团股份有限公司                |
| 209. | 倍稳；<br>盐酸凯普拉生片          | keverprazan hydrochloride   | 片剂<br>Tablet      | 治疗十二指肠溃疡、反流性食管炎<br>Treatment of duodenal ulcer, reflux esophagitis                                                                                                                                                                                                                                            | 江苏柯菲平医药股份有限公司                |
| 210. | 海纳安；氘恩扎鲁胺软胶囊            | deuenzalutamide             | 胶囊<br>Capsule     | 用于接受醋酸阿比特龙及化疗后出现疾病进展，且既往未接受新型雄激素受体抑制剂的转移性去势抵抗性前列腺癌成人患者<br>Treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) who have disease progression after receiving abiraterone acetate and chemotherapy, and who have not previously received novel androgen receptor inhibitors | 海创药业股份有限公司                   |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                                                                                                                           | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 211. | 海益坦；谷美替尼片               | glumetinib                  | 片剂<br>Tablet      | 用于具有间质-上皮转化因子外显子 14 跳变的局部晚期或转移性非小细胞肺癌<br>Treatment of patients with locally advanced or metastatic non-small cell lung cancer with MET exon 14 skipping mutation METex14                                                                                                                                                                                                                                                       | 上海海和药物研究开发股份有限公司             |
| 212. | 高瑞哲；戈利昔替尼胶囊             | golidocitinib               | 胶囊<br>Capsule     | 既往至少接受过一线系统性治疗的复发或难治的外周 T 细胞淋巴瘤<br>To treat relapsed/refractory peripheral T-Cell lymphoma (r/r PTCL) in patients whose disease has advanced following a minimum of one previous systemic therapy or who were refractory to this                                                                                                                                                                                               | 迪哲（江苏）医药股份有限公司               |
| 213. | 轩悦宁；吡洛西利片               | bireociclib                 | 片剂<br>Tablet      | 用于激素受体（HR）阳性、人表皮生长因子受体 2（HER2）阴性的晚期或转移性乳腺癌成人患者；与氟维司群联合用于既往接受内分泌治疗后出现疾病进展的患者；单药用于既往转移性阶段接受过两种及以上内分泌治疗和一种化疗后出现疾病进展的患者<br>For patients with HR+/HER2- breast cancer: in combination with fulvestrant for patients whose disease has progressed after previous endocrine therapy, and as monotherapy for patients who have progressed after receiving two or more endocrine therapies and one chemotherapy in the metastatic stage | 轩竹生物科技股份有限公司                 |
| 214. | 轩菲宁；地罗阿克片 <sup>#</sup>  | dirozalkib                  | 片剂<br>Tablet      | 用于未经过间变性淋巴瘤激酶抑制剂治疗的 ALK 阳性的局部晚期或转移性非小细胞肺癌<br>Treatment of patients with ALK-positive, locally advanced, or metastatic non-small cell lung cancer (NSCLC) who have not previously received ALK inhibitor therapy                                                                                                                                                                                                                | 轩竹生物科技股份有限公司                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                         | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 215. | 泰妥妥；盐酸妥诺达非片             | tunodafil hydrochloride     | 片剂<br>Tablet      | 治疗勃起功能障碍<br>Treatment of erectile dysfunction                                                                                                                                                                                                                                                                | 扬子江药业集团有限公司                  |
| 216. | 盛捷维；磷酸森格列汀片             | cetagliptin phosphate       | 片剂<br>Tablet      | 改善成人 2 型糖尿病患者的血糖控制<br>To improve glycemic control in patients with type 2 diabetes mellitus                                                                                                                                                                                                                  | 盛世泰科生物医药技术（苏州）股份有限公司         |
| 217. | 启欣可；伊鲁阿克片               | iruplinalkib                | 片剂<br>Tablet      | 既往接受过克唑替尼治疗后疾病进展或对克唑替尼不耐受的间变性淋巴瘤激酶（ALK）阳性的局部晚期或转移性非小细胞肺癌（NSCLC）患者的治疗<br>Treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed after prior treatment with crizotinib or who are intolerant to crizotinib | 齐鲁制药有限公司                     |
| 218. | 培莫沙肽注射液                 | pegmolesatide               | 注射剂<br>Injection  | 治疗慢性肾病引起的贫血<br>Treatment of anemia due to chronic kidney disease                                                                                                                                                                                                                                             | 江苏豪森药业集团有限公司                 |
| 219. | 康悦达；普奇拜单抗注射液            | stapokibart                 | 注射剂<br>Injection  | 治疗中度至重度异位性皮炎<br>Treatment of moderate to severe atopic dermatitis                                                                                                                                                                                                                                            | 成都康诺行生物医药科技有限公司              |
| 220. | 康美纳；酒石酸泰瑞西利胶囊           | tibremciclib tartrate       | 胶囊<br>Capsule     | 联合氟维司群，适用于既往接受内分泌治疗后进展的激素受体（HR）阳性、人表皮生长因子受体 2（HER2）阴性的局部晚期或转移性成年乳腺癌患者<br>In combination with fulvestrant for adult patients with HR+/HER2- locally advanced or metastatic breast cancer who have progressed following prior endocrine therapy                                                                | 贝达药业股份有限公司                   |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s)                                  | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                 | 药企<br>Pharmaceutical company |
|------|-------------------------|--------------------------------------------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 221. | 惠优静；脯氨酸加格列净片            | henagliflozin                                                | 片剂<br>Tablet      | 单药治疗或与盐酸二甲双胍联合使用改善成人 2 型糖尿病患者的血糖控制<br>Monotherapy or as add-on therapy to metformin to improve glycemic control                                                                                                                                                                                                      | 惠升生物制药股份                     |
| 222. | 达伯乐；己二酸他雷替尼胶囊           | taletrectinib                                                | 胶囊<br>Capsule     | 用于经 ROS1-TKI 治疗后进展的 ROS1 阳性局部晚期或转移性非小细胞肺癌（NSCLC）成人患者<br>Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who have been previously treated with ROS1 TKIs                                                                                             | 葆元生物医药科技（杭州）有限公司             |
| 223. | 复邦德；艾诺米替片               | ainuovirine;<br>lamivudine;<br>tenofovir disoproxil fumarate | 片剂<br>Tablet      | 治疗未接受过治疗的 HIV-1 感染成人患者<br>Treatment of treatment-naïve adults with HIV-1 infection                                                                                                                                                                                                                                   | 江苏艾迪药业股份有限公司                 |
| 224. | 复妥宁；枸橼酸伏维西利胶囊           | fovinaciclib citrate                                         | 胶囊<br>Capsule     | 联合氟维司群，适用于既往接受内分泌治疗后出现疾病进展的激素受体阳性、人表皮生长因子 2 阴性的复发或转移性成年乳腺癌患者<br>Treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative relapsed or metastatic adult breast cancer patients with disease progression after previous endocrine therapy, in combination with fulvestrant | 锦州奥鸿药业有限责任公司                 |
| 225. | 普佑恒；普特利单抗注射液            | pucotenlimab                                                 | 注射剂<br>Injection  | 治疗 MSI-H 或 dMMR 实体瘤；黑色素瘤<br>Treatment of MSI-H or dMMR solid tumors; melanoma                                                                                                                                                                                                                                        | 乐普生物科技股份有限公司                 |
| 226. | 华堂宁；多格列艾汀片              | dorzagliatin                                                 | 片剂<br>Tablet      | 治疗 2 型糖尿病<br>Treatment of Type 2 diabetes                                                                                                                                                                                                                                                                            | 华领医药技术（上海）有限公司               |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                               | 药企<br>Pharmaceutical company            |
|------|-------------------------|-----------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| 227. | 开坦尼；<br>卡度尼利单抗注射液       | cadonilimab                 | 注射剂<br>Injection  | 治疗宫颈癌<br>To treat cervical cancer                                                                                                                                                                                                                                                                  | 康方药业有限公司                                |
| 228. | 景助达；<br>恩替司他片           | entinostat                  | 片剂<br>Tablet      | 联合芳香化酶抑制剂用于治疗激素受体阳性、人类表皮生长因子受体-2 阴性，经内分泌治疗复发或进展的局部晚期或转移性乳腺癌<br>In combination with aromatase inhibitors, for patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer who have relapsed or progressed after endocrine therapy | 泰州亿腾景昂药业股份有限公司                          |
| 229. | 奥壹新；利厄替尼片               | limertinib                  | 片剂<br>Tablet      | 用于既往经表皮生长因子酪氨酸激酶抑制剂治疗时或治疗后出现疾病进展，并且经检测确认存在 EGFR T790M 突变阳性的局部晚期或转移性非小细胞肺癌<br>Treatment for patients with locally advanced or metastatic/recurrent non-small cell lung cancer (NSCLC) with confirmed EGFR T790M mutation who progressed on or after EGFR TKI therapy                                | 江苏奥赛康药业有限公司                             |
| 230. | 奥特康唑胶囊                  | oteseconazole               | 胶囊<br>Capsule     | 治疗重度外阴阴道假丝酵母菌病 ( VVC )<br>To treat vulvovaginal candidiasis (VVC)                                                                                                                                                                                                                                  | eVENUS Pharmaceutical Laboratories Inc. |
| 231. | 爱达罗；依若奇单抗注射液            | ebdarokimab                 | 注射剂<br>Injection  | 治疗成人中度至重度斑块状银屑病<br>Treatment of moderate-to-severe plaque psoriasis in adult                                                                                                                                                                                                                       | 中山康方生物医药有限公司                            |
| 232. | 新舒沐；甲磺酸普雷福韦片            | pradefovir mesylate         | 片剂<br>Tablet      | 治疗成人慢性乙型肝炎<br>Treatment of adult patients with chronic hepatitis B infection                                                                                                                                                                                                                       | 西安葛蓝新通制药有限公司                            |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s)    | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                  | 药企<br>Pharmaceutical company |
|------|-------------------------|--------------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 233. | 新替妥；斯泰度塔单抗注射液           | siltartoxatug                  | 注射剂<br>Injection  | 用于破伤风紧急预防<br>Emergency prevention of post-traumatic tetanus                                                                                                                                                                                                           | 珠海泰诺麦博制药股份有限公司               |
| 234. | 善泽平；普卢格列汀片              | prusogliptin                   | 片剂<br>Tablet      | 用于改善成人 2 型糖尿病患者的血糖控制<br>To improve glycemic control in patients with type 2 diabetes mellitus                                                                                                                                                                         | 石药集团欧意药业有限公司                 |
| 235. | 瑞必达；<br>甲磺酸瑞齐替尼胶囊       | rezivertinib                   | 胶囊<br>Capsule     | 用于既往经表皮生长因子受体酪氨酸激酶抑制剂治疗时或治疗后出现疾病进展，并且经检测确认存在 EGFR T790M 突变阳性的局部晚期或转移性非小细胞肺癌<br>Treatment for patients with locally advanced or metastatic/recurrent non-small cell lung cancer (NSCLC) with confirmed EGFR T790M mutation who progressed on or after EGFR TKI therapy | 上海倍而达药业有限公司                  |
| 236. | 瑞坦宁；注射用磷罗拉匹坦帕洛诺司琼       | fosrclonazepam<br>palonosetron | 注射剂<br>Injection  | 用于预防成人高度致吐性化疗引起的急性和迟发性恶心及呕吐<br>prevention of acute and delayed nausea and vomiting caused by highly emetogenic chemotherapy (HEC) in adults                                                                                                                           | 福建盛迪医药有限公司                   |
| 237. | 瑞格列汀二甲双胍片               | retagliptin;<br>metformin      | 片剂<br>Tablet      | 用于改善成人 2 型糖尿病患者的血糖控制<br>To improve glycemic control in patients with type 2 diabetes mellitus                                                                                                                                                                         | 山东盛迪医药有限公司                   |
| 238. | 瑞维鲁胺片                   | rezvolutamide                  | 片剂<br>Tablet      | 治疗高肿瘤负荷的转移性激素敏感性前列腺癌 (mHSPC) 患者<br>Treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC) with high tumor burden                                                                                                                             | 江苏恒瑞医药股份有限公司                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form | 适应症<br>Indication(s)                                                                                                                                                                                                                                                                                                         | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 239. | 圣瑞沙；甲磺酸瑞厄替尼片            | rilertinib mesylate         | 片剂<br>Tablet      | 用于既往经表皮生长因子受体酪氨酸激酶抑制剂治疗时或治疗后出现疾病进展，并且经检测确认存在EGFR T790M 突变阳性的局部晚期或转移性非小细胞肺癌<br>Treatment for patients with locally advanced or metastatic/recurrent non-small cell lung cancer (NSCLC) with confirmed EGFR T790M mutation who progressed on or after EGFR TKI therapy                                                         | 南京圣和药业股份有限公司                 |
| 240. | 圣诺迪；奥磷布韦片               | alfosbuvir                  | 片剂<br>Tablet      | 治疗成人慢性丙型肝炎病毒感染（基因1型、2型、3型、6型）<br>To treat chronic HCV infection in adults (genotypes 1, 2, 3, 6)                                                                                                                                                                                                                             | 南京圣和药业股份有限公司                 |
| 241. | 汉斯状；斯鲁利单抗注射液            | serplulimab                 | 注射剂<br>Injection  | 治疗鳞状非小细胞肺癌、转移性非鳞状非小细胞肺癌、晚期实体瘤<br>Treatment of squamous non-small cell lung cancer; metastatic non-squamous non-small cell lung cancer; advanced solid tumors                                                                                                                                                                 | 上海复宏汉霖生物技术股份有限公司             |
| 242. | 迈粒生；注射用阿格司亭α            | albipagrastim alfa          | 注射剂<br>Injection  | 用于成年非髓性恶性肿瘤患者在接受容易引起发热性中性粒细胞减少症的骨髓抑制性抗癌药物治疗时，降低以发热性中性粒细胞减少症为表现的感染发生率<br>to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia | 江苏泰康生物医药有限公司                 |

| 项目   | 商品名称<br>Commercial Name | 主成分<br>Active Ingredient(s) | 剂型<br>Dosage Form               | 适应症<br>Indication(s)                                                                                                                                                                                                                                                      | 药企<br>Pharmaceutical company |
|------|-------------------------|-----------------------------|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 243. | 睿铂生；艾米迈托赛注射液            | amimestrocel                | 注射剂<br>Injection                | 用于治疗 14 岁以上消化道受累为主的激素治疗失败的急性移植物抗宿主病<br>Treatment of patients over 14 years old with acute graft-versus-host disease with predominant gastrointestinal involvement who have failed hormone therapy                                                                         | 铂生卓越生物科技（北京）有限公司             |
| 244. | 泽普平；盐酸吉卡昔替尼片            | gecacitinib hydrochloride   | 片剂<br>Tablet                    | 用于中危或高危骨髓纤维化包括原发性骨髓纤维化、真性红细胞增多症继发性骨髓纤维化及原发性血小板增多症继发性骨髓纤维化的成人患者<br>Treatment of intermediate- and high-risk myelofibrosis, including primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF), and post-essential thrombocythemia myelofibrosis (PET-MF) | 苏州泽璟生物制药股份有限公司               |
| 245. | 赛美纳；甲磺酸贝福替尼胶囊           | befotertinib                | 胶囊<br>Capsule                   | 治疗 EGFR T790M 突变阳性的转移性非小细胞肺癌<br>Treatment of EGFR T790M mutation-positive metastatic non-small cell lung cancer                                                                                                                                                           | 益方生物科技（上海）股份有限公司             |
| 246. | 赛恺泽；泽沃基奥仑赛注射液           | zevorcabtagene autoleucel   | 注射剂<br>Injection                | 治疗复发性或难治性多发性骨髓瘤<br>To Treat relapsed/refractory multiple myeloma (RRMM)                                                                                                                                                                                                   | 科济生物医药（上海）有限公司               |
| 247. | 盐酸凯普拉生注射液；盐酸凯普拉生片       | carenoprazan hydrochloride  | 片剂;注射剂<br>Tablet ;<br>Injection | 治疗十二指肠溃疡、反流性食道炎<br>Treatment of duodenal ulcer, reflux esophagitis                                                                                                                                                                                                        | 江苏柯菲平医药股份有限公司                |

\*按商品名称的字母/笔划排序

Commercial names are listed in alphabetical/strokes order

资料截至：9/2025

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