

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

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9.	Aqneursa	levacetylleucine	混悬剂 Suspension	治疗尼曼匹克疾病 C 型 To treat Niemann-Pick disease type C	IntraBio Inc.
10.	Aqvesme [#]	mitapivat	片剂 Tablet	用于成人 α -或 β -地中海贫血的贫血治疗 Treatment of anemia in adults with alpha- or beta-thalassemia	Agios Pharmaceuticals, Inc.
11.	Attruby; Beyontra	acoramidis	片剂 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 To treat cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis	BridgeBio Pharma, Inc.
12.	Aucatzyl	obecabtagene autoleucel	注射剂 Injection	治疗复发性或难治性 B-细胞前体急性淋巴细胞白血病 Treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia	Autolus GmbH
13.	Avmapki Fakzynja Co-Pack	avutometinib; defactinib	胶囊、片剂 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 To treat KRAS-mutated recurrent low-grade serous ovarian cancer after prior systemic therapy	Verastem Oncology
14.	Awikli; 诺和期; 依柯胰岛素注射液	insulin icodec	注射剂 Injection	治疗成人 2 型糖尿病 To treat type 2 diabetes mellitus	Novo Nordisk A/S
15.	Beqvez	fidanacogene elaparvovec	注射剂 Injection	治疗 B 型血友病 Treatment of hemophilia B	Pfizer Inc.
16.	Bimzelx	bimekizumab	注射剂 Injection	治疗适合全身治疗或光疗的成人中重度斑块型银屑病 To treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	UCB, Inc.

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17.	Bizengri	zenocutuzumab	注射剂 Injection	治疗非小细胞肺癌及胰腺癌 To treat non-small cell lung cancer and pancreatic adenocarcinoma	Merus N.V.
18.	Blujepa	gepotidacin	片剂 Tablet	治疗非复杂性尿路感染 To treat uncomplicated urinary tract infections	GlaxoSmithKline
19.	Brenzavvy	bexagliflozin	片剂 Tablet	改善 2 型糖尿病成人患者的血糖控制 To improve glycemic control in adults with type 2 diabetes mellitus	Theracos Inc.
20.	Breyanzi	lisocabtagene maraleucel	注射剂 Injection	治疗复发性或难治性大 B 细胞淋巴瘤 Treatment of relapsed or refractory (r/r) large B-cell lymphoma (LBCL)	Juno Therapeutics (Bristol Myers Squibb)
21.	Brinsupri	brensocatib	片剂 Tablet	治疗非纤维囊肿型支气管扩张 To treat non-cystic fibrosis bronchiectasis	Insmed Incorporated
22.	Briumvi	ublituximab	注射剂 Injection	治疗成人复发性多发性硬化症 To treat relapsing forms of multiple sclerosis	TG Therapeutics, Inc.
23.	Cardamyst	etripamil	吸入制剂 Inhalation	治疗阵发性室上性心搏过速 To treat episodes of paroxysmal supraventricular tachycardia	Milestone Pharmaceuticals Inc.
24.	Carvykti	ciltacabtagene autoleucel	注射剂 Injection	治疗复发性或难治性多发性骨髓瘤 To Treat relapsed/refractory multiple myeloma (RRMM)	Legend Biotech Corporation; Janssen Biotech, Inc.
25.	Casgevy	exagamglogene autotemcel	注射剂 Injection	用于治疗 β -地中海贫血及镰刀型红血球疾病 Treatment of beta thalassaemia and sickle cell disease	Vertex Pharmaceuticals (Ireland) Limited
26.	Cobenfy	xanomeline; trospium chloride	胶囊 Capsule	治疗精神分裂症 To treat schizophrenia	Bristol-Myers Squibb Company

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27.	Cosela	trilaciclib	注射剂 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 To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan containing regimen for extensive-stage small cell lung cancer (ES-SCLC)	G1 Therapeutics, Inc.
28.	Crenessity	crinecerfont	胶囊、溶液剂 Capsule; Solution	治疗典型先天性肾上腺增生症 To treat classic congenital adrenal hyperplasia	Neurocrine Biosciences, Inc.
29.	Datroway	datopotamab deruxtecan	注射剂 Injection	用于接受过内分泌治疗及化疗但无法切除或转移性荷尔蒙受体阳性、HER2 阴性的乳腺癌 To treat unresectable or metastatic, HR-positive, HER2-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease	Daiichi Sankyo, Inc.
30.	Dawnzera	donidalorsen	注射剂 Injection	用于预防遗传性血管性水肿的发作 To prevent attacks of hereditary angioedema	Ionis Pharmaceuticals Inc.
31.	Daxxify	daxibotulinumtoxin A	注射剂 Injection	治疗与皱眉肌和/或降眉肌活动相关的中度至重度眉间皱纹 To treat moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity	Revance Therapeutics Inc.
32.	Daybue	trofinetide	溶液剂 Solution	治疗雷特综合征 To treat Rett syndrome	Acadia Pharmaceuticals Inc.

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33.	Defencath	taurolidine heparin	注射剂 Injection	用于降低通过中心静脉导管接受长期血液透析的肾功能衰竭成年患者的导管相关血液感染的发生率 To reduce the incidence of catheter-related bloodstream infections (CRBSI) in adults with kidney failure receiving chronic hemodialysis through a central venous catheter	CorMedix Inc.
34.	Duvyzat	givinostat	混悬剂 Suspension	治疗 6 岁及以上患者的杜氏肌营养不良症 To treat Duchenne muscular dystrophy in individuals aged 6 years and older	Italfarmaco S.A.; ITF Therapeutics, LLC
35.	Ebglyss	lebrikizumab	注射剂 Injection	治疗中度至重度异位性皮炎 To treat moderate-to-severe atopic dermatitis	Eli Lilly and Company
36.	Ebvallo	tabelecleucel	注射剂 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 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
37.	Ekterly	sebetralstat	片剂 Tablet	治疗遗传性血管性水肿急性发作 To treat acute attacks of hereditary angioedema	KalVista Pharmaceuticals, Inc.
38.	Elfabrio	pegunigalsidase alfa	注射剂 Injection	作为酶替代疗法用于治疗法布里病的成人患者 Enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease	Protalix BioTherapeutics Inc.
39.	Elrexio	elranatamab	注射剂 Injection	治疗复发或难治性多发性骨髓瘤 To treat relapsed or refractory multiple myeloma	Pfizer Inc.

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40.	Elucirem	gadopiclenol	注射剂 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 To detect and visualize lesions, together with MRI, with abnormal vascularity in the central nervous system and the body	Guerbet
41.	Emrelis	telisotuzumab vedotin	注射剂 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 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.
42.	Enflonsia	clesrovimab	注射剂 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 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
43.	Enjaymo	sutimlimab	注射剂 Injection	减少冷凝集素病溶血引起的输血需求 To decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease	Bioverativ Therapeutics Inc.

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44.	Enzeshu ; 恩泽舒；注射用苏维 西塔单抗	suvemcitug (sevacizumab)	注射剂 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 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
45.	Exblifep	cefepime; enmetazobactam	注射剂 Injection	治疗复杂性泌尿道感染 To treat complicated urinary tract infections	Orchid Pharma
46.	Exdensur	depemokimab	注射剂 Injection	作为附加的维持治疗，用于治疗以嗜酸性粒细胞表 型为特征的重度哮喘 To treat severe asthma characterized by an eosinophilic phenotype as an add-on maintenance therapy	GSK
47.	Exxua	gepirone	片剂 Tablet	治疗忧郁症 To treat major depressive disorder	Mission Pharmacal Company
48.	Ezmekly	mirdametinib	胶囊、片剂 Capsules、 Tablets	治疗神经纤维瘤病 1 型 Treatment of plexiform neurofibromas in patients with neurofibromatosis type 1	Springworks Therapeutics Ireland Limited
49.	Filspari	sparsentan	片剂 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 To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression	Ligand Pharmaceuticals Inc. ; Traverse Therapeutics Inc. ; Bristol Myers Squibb
50.	Filsuvez	birch triterpenes	凝胶 Gel	用于营养失养型及接合型表皮分解性水疱相关的伤 口	Lichtenheldt GmbH

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				To treat wounds associated with dystrophic and junctional epidermolysis bullosa	
51.	Gohibic	vilobelimab	注射剂 Injection	治疗新冠病毒引起的急性呼吸窘迫综合征 To treat acute respiratory distress syndrome (ARDS) caused by SARS-CoV-2	Almac Pharma Services Ltd
52.	Gomekli	mirdametinib	胶囊、混悬剂 Capsule、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 To treat neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection	SpringWorks Therapeutics, Inc.
53.	Grafapex	treosulfan	注射剂 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症 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
54.	Hemgenix	etranacogene dezaparvovec	注射剂 Injection	治疗 B 型血友病 Treatment of hemophilia B	CSL Behring LLC
55.	Hernexeos	zongertinib	片剂 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 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.

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56.	Hyrnuo	sevabertinib	片剂 Tablet	治疗肿瘤具有 HER2 酪氨酸激酶结构域活化突变，且已接受过全身性治疗的局部晚期或转移性非鳞状非小细胞肺癌患者 To treat locally advanced or metastatic non-squamous non-small cell lung cancer with tumors that have activating HER2 tyrosine kinase domain activating mutations in patients who received a systemic therapy	Bayer HealthCare Pharmaceuticals, Inc.
57.	Imaavy	nipocalimab	注射剂 Injection	治疗全身性重症肌无力 To treat generalized myasthenia gravis	Janssen Biotech, Inc.
58.	Imdelltra	tarlatamab	注射剂 Injection	治疗晚期小细胞肺癌 To treat extensive stage small cell lung cancer	Amgen Inc.
59.	Inpefa	sotagliflozin	片剂 Tablet	治疗心脏衰竭 To treat heart failure	Lexicon Pharms Inc.
60.	Iomervu	iomeprol	注射剂 Injection	用作放射线造影剂 For use as a radiographic contrast agent	Bracco Diagnostic Inc.; BIPSO GmbH
61.	Iqirvo	elafibranor	片剂 Tablet	联合熊脱氧胆酸用于治疗原发性胆源性胆管炎 To treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid	Ipsen Biopharmaceuticals, Inc.
62.	Ixchiq	chikungunya vaccine (live)	注射剂 Injection	预防成人基孔肯尼亚病 Prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years and older	Valneva Austria GmbH
63.	Izervay	avacincaptad pegol	注射剂 Injection	治疗黄斑病变引发的地图样萎缩症 To treat geographic atrophy secondary to age-related macular degeneration	IVERIC bio, Inc.
64.	Jascayd；博优维；那米司特片	nerandomilast	片剂 Tablet	治疗特发性肺纤维化 To treat idiopathic pulmonary fibrosis	Boehringer Ingelheim Pharmaceuticals, Inc.

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65.	Jaypirca	pirtobrutinib	片剂 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 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
66.	Jesduvroq	daprodustat	片剂 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 To treat anemia caused by chronic kidney disease for adults on dialysis for at least four months	GlaxoSmithKline
67.	Joenja	leniolisib	片剂 Tablet	治疗活化磷酸肌醇 3-激酶 δ 综合症 To treat activated phosphoinositide 3-kinase delta syndrome	Pharming Group NV ; Novartis
68.	Journavx	suzetrigine	片剂 Tablet	治疗中到重度急性疼痛 To treat moderate to severe acute pain	Vertex Pharmaceuticals Incorporated
69.	Kavigale	sipavibart	注射剂 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 Pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older	AstraZeneca AB
70.	Kimmtrak	tebentafusp	注射剂 Injection	治疗不可切除或转移性葡萄膜黑色素瘤 To treat unresectable or metastatic uveal melanoma	Immunocore Ltd
71.	Kisunla	donanemab	注射剂 Injection	治疗阿尔茨海默症 To treat Alzheimer's disease	Eli Lilly and Company
72.	Komzifti	ziftomenib	胶囊 Capsule	治疗具有核磷蛋白 1 突变的复发或难治性急性髓系白血病成人患者 To treat adults with relapsed or refractory acute	Kura Oncology, Inc.

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				myeloid leukemia with nucleophosmin 1 mutation	
73.	Korsuva ; Kapruvia	difelikefalin	注射剂 Injection	治疗慢性肾病导致的中度至重度瘙痒 To treat moderate-to-severe pruritus associated with chronic kidney disease	Cara Therapeutics
74.	Kostaive	zapomeran	注射剂 Injection	预防成人新冠病毒感染 To prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older	Arcturus Therapeutics Europe B.V.
75.	Krazati	adagrasib	片剂 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 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.
76.	Kygevvi	doxecitine; doxribtimine	粉剂 Powder	治疗胸苷激酶 2 缺乏症 To treat thymidine kinase 2 deficiency	UCB
77.	Kymriah	tisagenlecleucel	注射剂 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 Treatment of relapsed or refractory (r/r) acute lymphocytic leukemia (ALL) or relapsed or refractory (r/r) large B-cell lymphoma (LBCL)	Novartis
78.	Lamzede	velmanase alfa	散剂、注射剂 Powder、Injection	治疗α-甘露糖苷贮积症 Treatment of alpha-mannosidosis	Chiesi Farmaceutici SPA
79.	Lazcluze	lazertinib	片剂 Tablet	治疗非小细胞肺癌 To treat non-small cell lung cancer (NSCLC)	Janssen Biotech, Inc.
80.	Leqselvi	deuruxolitinib	片剂 Tablet	治疗严重斑秃 To treat severe alopecia areata	Sun Pharmaceutical Industries, Inc.

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81.	Lerochol	lerodalcibep	注射剂 Injection	降低成人高胆固醇血症患者的低密度脂蛋白胆固醇，作为饮食和运动的辅助治疗 To reduce low-density lipoprotein cholesterol in adults with hypercholesterolemia, as an adjunct to diet and exercise	LIB Therapeutics
82.	Letybo	letibotulinumtoxin A	注射剂 Injection	暂时性改善出现的中度至重度皱眉纹 To temporarily improve the appearance of moderate-to-severe glabellar lines	Hugel, Inc.
83.	Livdelzi	seladelpar	胶囊 Capsule	治疗原发性胆汁性胆管炎 To treat primary biliary cholangitis (PBC)	Gilead Sciences, Inc.
84.	Loargys	pegzilarginase	注射剂 Injection	治疗 2 岁及以上患者的高精氨酸血症 To treat people from 2 years of age with hyperargininemia	Immedica Pharma AB Unimedica AB
85.	Locametz	gallium Ga 68 gozetotide	注射剂 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 Detection of prostate-specific membrane antigen (PSMA)-positive lesions with positron emission tomography (PET) in patients with prostate cancer	Novartis Pharmaceuticals UK Limited
86.	Lumisight	pegulicianine	注射剂 Injection	作为光学成像剂用于检测癌组织 To use as an optical imaging agent for the detection of cancerous tissue	Lumicell, Inc.
87.	Lupkynis	voclosporin	胶囊 Capsule	治疗狼疮性肾炎 To treat lupus nephritis	Aurinia Pharmaceuticals Inc.
88.	Lynkuet	elinzanetant	胶囊 Capsule	治疗更年期引起的中度至重度血管舒缩症状 Treatment of moderate to severe vasomotor symptoms due to menopause.	Bayer HealthCare Pharmaceuticals Inc.

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89.	Lynozyfic	linvoseltamab	注射剂 Injection	治疗复发性及难治性多发性骨髓瘤 Treatment of patients with relapsed and refractory multiple myeloma	Regeneron Ireland DAC
90.	Lytgobi	futibatinib	片剂 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 To treat intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements	Taiho Oncology
91.	Miebo	perfluoro-hexyloctane	眼用溶液 Ophthalmic solution	治疗干眼病的症状 To treat signs and symptoms of dry eye disease	Novaliq GmbH
92.	Miplyffa	arimoclomol	胶囊 Capsule	治疗尼曼匹克疾病 C 型 To treat Niemann-Pick disease type C	Zevra Denmark A/S
93.	Modeyso	dordaviprone	胶囊 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 To treat diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy	Jazz Pharmaceuticals, Inc.
94.	mResvia	Respiratory Syncytial Virus mRNA	注射剂 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 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.
95.	Myqorzo ; 星舒平 ; 阿夫凯泰片	aficamten	片剂 Tablet	治疗症状性梗阻性肥厚型心肌病 To treat symptomatic obstructive hypertrophic cardiomyopathy	Cytokinetics
96.	Nemluvio	nemolizumab	注射剂 Injection	治疗结节性痒疹 To treat prurigo nodularis	Galderma Laboratories, L.P.

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
97.	Nereus [#]	tradipitant	胶囊 Capsule	预防成人晕动病 For the prevention of motion sickness in adults	Vanda Pharmaceuticals Inc.
98.	NexoBrid	anacaulase	凝胶 Gel	去除成人深度部分或全层热烧伤的焦痂 To remove eschar in adults with deep partial thickness or full thickness thermal burns	Mediowound, Ltd
99.	Ngenla	somatrogon	注射剂 Injection	治疗因生长激素分泌不足而导致的生长障碍 Management of a growth disorder due to growth hormone deficiency	OPKO Health Inc. Pfizer Inc.
100.	Niktimvo	axatilimab	注射剂 Injection	治疗慢性移植物抗宿主病 To treat chronic graft-versus-host disease (cGVHD)	Incyte Corporation
101.	Nulibry	fosdenopterin	散剂、注射剂 Powder、 Injection	降低 A 型钼辅因子缺乏症 (MoCD) 患者的死亡风险 To reduce the risk of mortality in molybdenum cofactor deficiency Type A	Sentynl Therapeutics, Inc.
102.	Nuzolvece	zoliflodacin	颗粒剂 Granules	治疗由淋病奈瑟球菌引起的单纯性泌尿生殖道淋病 To treat uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae	Entasis Therapeutics
103.	Ogsiveo	nirogacestat	片剂 Tablet	治疗需要使用全身治疗的进展性硬纤维瘤成年患者 To treat adults with progressing desmoid tumors who require systemic treatment	SpringWorks Therapeutics, Inc.
104.	Ojemda	tovorafenib	片剂、混悬剂 Tablet、 Suspension	治疗复发性或难治性儿童低级别胶质瘤 To treat relapsed or refractory pediatric low-grade glioma	Day One Biopharmaceuticals, Inc.; Quotient Sciences – Philadelphia LLC
105.	Omlonti	omidenepag	眼用溶液 Ophthalmic solution	降低开角型青光眼或高眼压症患者的眼压 To reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Santen Pharmaceutical Co., Ltd

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
106.	OmvoH	mirikizumab	注射剂 Injection	治疗溃疡性结肠炎 To treat ulcerative colitis	Eli Lilly
107.	Opdualag	nivolumab; relatlimab	注射剂 Injection	治疗不可切除或转移性黑色素瘤 To treat unresectable or metastatic melanoma	Bristol Myers Squibb
108.	Ordspono	odronextamab	注射剂 Injection	治疗滤泡性淋巴瘤或弥漫性大 B 细胞淋巴瘤 To treat follicular lymphoma or diffuse large B-cell lymphoma (DLBCL)	Regeneron Ireland DAC
109.	Orlynvah	sulopenem et Zadroxil, probenecid	片剂 Tablet	治疗非复杂性尿路感染 To treat uncomplicated urinary tract infections	Iterum Therapeutics
110.	Piaskey	crovalimab	注射剂 Injection	治疗阵发性睡眠性血红蛋白尿症 Treatment of paroxysmal nocturnal hemoglobinuria (PNH)	Roche Pharma (Schweiz) AG
111.	Pombiliti	cipaglucosidase alfa	注射剂 Injection	治疗迟发性庞贝氏症 Treatment of late-onset Pompe disease	Amicus Therapeutics Inc.
112.	Pyrukynd	mitapivat	片剂 Tablet	治疗丙酮酸激酶缺乏症的溶血性贫血 To treat hemolytic anemia in pyruvate kinase deficiency	Agios Pharmaceuticals Inc.
113.	Qalsody	tofersen	注射剂 Injection	治疗具有 SOD1 基因突变的成人肌萎缩侧索硬化症 To treat amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation	Ionis Pharmaceuticals Inc. ; Biogen Inc.
114.	Quviviq	daridorexant	片剂 Tablet	治疗失眠 To treat insomnia	Actelion Ltd ; Idorsia Ltd
115.	Penpulimab ; 安尼可 ; 派安普利单抗注射液	penpulimab	注射剂 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 In combination with either cisplatin or carboplatin and gemcitabine, to treat adults with recurrent or	Akeso Biopharma Co., Ltd.

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				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	
116.	Rapiblyk	landiolol	注射剂 Injection	治疗室上性心搏过速 To treat supraventricular tachycardia	AOP Orphan Pharmaceuticals GmbH
117.	Redemplo	plozasiran	注射剂 Injection	用于降低家族性乳糜微粒血症综合征成人患者的甘油三酯 To reduce triglycerides in adults with familial chylomicronemia syndrome	Arrowhead Pharmaceuticals, Inc.
118.	Relyvrio	sodium phenylbutyrate;taur ursodiol	混悬剂 Suspension	治疗肌萎缩侧索硬化症 To treat amyotrophic lateral sclerosis (ALS)	Amylyx Pharmaceuticals
119.	Revuforj	revumenib	片剂 Tablet	治疗复发性或难治性急性白血病 To treat relapsed or refractory acute leukemia	Syndax Pharmaceuticals, Inc.
120.	Reyvow	lasmiditan	片剂 Tablet	治疗偏头痛 Treatment of migraine	Eli Lilly
121.	Rezdiffra	resmetirom	片剂 Tablet	治疗成人非酒精性脂肪性肝炎和中晚期肝纤维化 To treat noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced liver scarring	Madrigal Pharmaceuticals, Inc.; UPM Pharmaceuticals
122.	Rezlidhia	olutasidenib	胶囊 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 To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation	Rigel Pharms Inc.
123.	Rezzayo	rezafungin	注射剂 Injection	治疗念珠菌血症和侵袭性念珠菌病 To treat candidemia and invasive candidiasis	Cidara Therapeutics Inc.; Seachaid Pharmaceuticals Inc.

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
124.	Riulvy	tegomil fumarate	胶囊 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 Treatment of adults and children from 13 years of age with relapsing remitting multiple sclerosis	Neuraxpharm Pharmaceuticals, S.L.
125.	Rivfloza	nedosiran	注射剂 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 To lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function	Novo Nordisk Inc; Pyramid Laboratories
126.	Roctavian	valoctocogene roxaparvovec	注射剂 Injection	治疗 A 型血友病 Treatment of Hemophilia A	BioMarin Pharmaceutical Inc.
127.	Rolvedon	eflapeg rastim	注射剂 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 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
128.	Romvimza	vimseltinib	胶囊 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 To treat symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity	Deciphera Pharmaceuticals, LLC
129.	Rystiggo	rozanolixizumab	注射剂 Injection	治疗全身性重症肌无力 Treatment of generalized myasthenia gravis	UCB Pharmaceuticals
130.	Rytelo	imetelstat	注射剂 Injection	治疗患有低风险至中等-1 风险的骨髓增生异常综合症	Geron Corporation; Catalent Indiana, LLC;

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				To treat low- to intermediate-1-risk myelodysplastic syndromes (MDS)	Patheon Italia, S.p.A
131.	Ryzneuta	efbemalenograstim alfa	注射剂 Injection	治疗嗜中性粒细胞减少症 To treat neutropenia	Evive Biotechnology Singapore Pte. Ltd.
132.	Sephience	sepiapterin	散剂 Powder	治疗成人及儿童苯丙酮尿症引起的高苯丙氨酸血症 Treatment of hyperphenylalaninemia in adults and children with phenylketonuria (PKU)	PTC Therapeutics International Limited
133.	Siiltibcy	rdESAT-6; rCFP-10	注射剂 Injection	用于诊断结核分枝杆菌感染 To detect infection and disease caused by Mycobacterium tuberculosis	Serum Life Science Europe GmbH Bilthoven Biologicals B.V.
134.	Sofdra	sofpironium	凝胶 Gel	治疗原发性腋窝多汗症 To treat primary axillary hyperhidrosis	Botanix SB Inc.
135.	Sohonos	palovarotene	胶囊 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 To reduce the volume of new heterotopic ossification in adults and pediatric patients with fibrodysplasia ossificans progressiva (FOP)	Ipsen Biopharmaceuticals, Inc.
136.	Sunlenca	lenacapavir	注射剂 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 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.
137.	Skyclarys	omaveloxolone	胶囊 Capsule	治疗弗里德里希共济失调 To treat Friedrich's ataxia	Reata Pharmaceuticals Inc.
138.	Tecartus	brexucabtagene autoleucel	注射剂 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	Kite (Gilead Sciences Inc.)

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				Treatment of relapsed or refractory (r/r) acute lymphocytic leukemia (ALL) or relapsed or refractory (r/r) mantle cell lymphoma (MCL)	
139.	Tecelra	afamitresgene autoleucel	注射剂 Injection	治疗成人不可切除或转移性滑膜瘤 Treatment of adults with unresectable or metastatic synovial sarcoma	Adaptimmune, LLC
140.	Tibsovo	ivosidenib	片剂 Tablet	治疗 IDH1 突变型急性粒细胞白血病、IDH1 突变型胆管癌 To treat IDH1-mutated AML、IDH1-mutated cholangiocarcinoma	Laboratoires Servier
141.	Tryngolza	olezarsen	注射剂 Injection	治疗家族性高乳糜微粒血症综合征 To treat familial chylomicronemia syndrome	Ionis Pharmaceuticals Inc.
142.	Tryptyr	acoltremon	眼用溶液 ophthalmic solution	治疗干眼症的征象及症状 To treat the signs and symptoms of dry eye disease	Alcon Inc.
143.	Tryvio	aprocitentan	片剂 Tablet	治疗高血压 To treat hypertension	Idorsia Pharmaceuticals US Inc.
144.	Tymlos; Eladynos	abaloparatide	注射剂 Injection	治疗骨质疏松症 Treatment of osteoporosis	Radius Health Inc.
145.	Tzield	teplizumab	注射剂 Injection	延缓第 3 期 1 型糖尿病的发作 To delay the onset of stage 3 type 1 diabetes	Provention Bio Inc.
146.	Unloxcyt	cosibelimab	注射剂 Injection	治疗皮肤鳞状细胞癌 To treat cutaneous squamous cell carcinoma	Checkpoint Therapeutics, Inc.
147.	Vafseo	vadadustat	片剂 Tablet	治疗慢性肾脏疾病导致之贫血 To treat anemia due to chronic kidney disease	Akebia Therapeutics, Inc.

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
148.	Vanrafia	atrasentan	片剂 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 To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression	Novartis Pharmaceuticals Corporation
149.	Veopoz	pozelimab	注射剂 Injection	治疗 1 岁及以上患者的 CD55 缺乏蛋白丢失性肠病 (CHAPLE 病) To treat patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease	Regeneron Pharmaceuticals, Inc.
150.	Vivjoa	oteseconazole	胶囊 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 To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential	Mycovia Pharmaceuticals
151.	Vizz	aceclidine	眼用溶液 Ophthalmic solution	治疗老花眼 To treat presbyopia	LENZ Therapeutics, Inc.
152.	Vonjo	pacritinib	胶囊 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 To treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets	CTI BioPharma
153.	Voydeya	danicopan	片剂 Tablet	治疗阵发性夜间血红蛋白尿症患者的血管外溶血 To treat extravascular hemolysis with paroxysmal nocturnal hemoglobinuria	Alexion Europe SAS

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
154.	Voyxact	sibeprenlimab	注射剂 Injection	用于降低原发性免疫球蛋白 A 肾病变患者的蛋白尿 To reduce proteinuria in primary immunoglobulin A nephropathy	Otsuka Pharmaceutical Company, Ltd.
155.	Vtama	tapinarof	乳膏 Cream	治疗斑块状银屑病 To treat plaque psoriasis	Dermavant Sciences
156.	Vyjuvek	beremagene geperpavec	混悬剂、凝胶 Suspension, 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 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
157.	Vyvgart	efgartigimod alfa	注射剂 Injection	治疗全身性重症肌无力 To treat generalized myasthenia gravis	Argenx BV
158.	Wainua; Wainzua	eplontersen	注射剂 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 To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis	AstraZeneca Pharmaceuticals LP
159.	Wayrilz	rilzabrutinib	片剂 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 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 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
160.	Xacduro	sulbactam; durlobactam	注射剂 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 To treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex	Entasis Therapeutics Holdings Inc.
161.	Xenoview	hyperpolarized Xe-129	吸入制剂 Inhalation	辅助评估肺功能及肺部成像 To evaluate pulmonary function and imaging	Polarean Inc.
162.	Xenpozyme	olipudase alfa	注射剂 Injection	治疗酸性鞘磷脂酶缺乏症 To treat acid sphingomyelinase deficiency	Sanofi S.A.
163.	Xolremdi	mavorixafor	胶囊 Capsule	治疗 WHIM 综合症 To treat WHIM syndrome	X4 Pharmaceuticals, Inc.
164.	Yartemlea [#]	narsoplimab	注射剂 Injection	治疗成人及 2 岁及以上患者的造血干细胞移植相关血栓性微血管病 Treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy	Omeros Corporation
165.	Yorvipath	palopegteriparatide	注射剂 Injection	治疗副甲状腺功能低下症 To treat hypoparathyroidism	Ascendis Pharma Bone Diseases A/S
166.	Yselyt	linzagolix	片剂 Tablet	治疗子宫肌瘤 To treat uterine fibroids	Theramex Ireland Limited
167.	Zavzpret	zavegepant	喷剂 Spray	治疗偏头痛 To treat migraine	Pfizer Inc.
168.	Zegfrovy ; 舒沃哲 ; 舒沃替尼片	sunvozertinib	片剂 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 Treatment of adult patients with locally	迪哲 (江苏) 医药股份有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations	
169.	Zelsuvmi	berdazimer	凝胶 Gel	治疗传染性软疣 To treat molluscum contagiosum	EPIH SPV, LLC
170.	Zilbrysq	zilucoplan	注射剂 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 To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive	UCB, Inc.
171.	Zokinvy	lonafarnib	胶囊 Capsule	治疗哈钦森-吉尔福德早衰综合症 Treatment of Hutchinson-Gilford progeria syndrome	Eiger Biopharmaceuticals
172.	Ztalmy	ganaxolone	混悬剂 Suspension	治疗细胞周期蛋白依赖性激酶样 5 缺乏症的癫痫发作 To treat seizures in cyclin-dependent kinase-like 5 deficiency disorder	Marinus Pharmaceuticals Inc.; Purdue Neuroscience Corp
173.	Zurzuvae	zuranolone	胶囊 Capsule	治疗产后抑郁症 To treat postpartum depression	Biogen Inc.
174.	Zycubo [#]	copper histidinate	注射剂 Injection	治疗儿童患者的孟克斯病 Treatment of Menkes disease in pediatric patients	Sentynl Therapeutics, Inc.
175.	Zynlonta	loncastuximab tesirine	注射剂 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) To treat diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBCL)	ADC Therapeutics SA

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
176.	Zynyz	retifanlimab	注射剂 Injection	治疗转移性或复发性局部晚期默克尔细胞癌 To treat metastatic or recurrent locally advanced Merkel cell carcinoma	Incyte Corp ; MacroGenics Inc.
177.	戈芮宁；注射用维拉 昔酶β	velaglucerase β	注射剂 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 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
178.	地达西尼胶囊	dimdazenil	胶囊 Capsule	失眠的短期治疗 Short-term treatment of insomnia	浙江京新药业股份有限公司
179.	因他瑞；林普利塞片	linperlisib	片剂 Tablet	治疗复发性或难治性滤泡性淋巴瘤成人患者 Treatment of adults with relapsed or refractory follicular lymphoma	上海瓊黎药业有限公司
180.	艾比特；苹果酸法米 替尼胶囊	famitinib malate	胶囊 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 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

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
181.	艾心安；注射用瑞卡西单抗	recaticimab	注射剂 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 On the basis of dietary control, in combination with statins or other lipid lowering therapy for the treatment of adult patients with primary 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	广东恒瑞医药有限公司
182.	艾速达；硫酸埃玛替尼片	ivarmacitinib sulfate	片剂 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 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

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
183.	艾瑞凯；戈来雷塞片	glecirasib	片剂 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 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
184.	艾瑞璟；泽美妥司他片	zeprumetostat	片剂 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 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
185.	艾泽利；瑞拉芙普α注射液 [#]	retlirafusp alfa	注射剂 Injection	联合氟尿嘧啶类和铂类药物用于 PD-L1 阳性 (CPS≥1) 的局部晚期不可切除、复发或转移性胃及胃食管结合部腺癌的一线治疗 In combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of PD-L1-positive (CPS ≥1) locally advanced unresectable, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma	苏州盛迪亚生物医药有限公司
186.	汝佳宁；盐酸来罗西利片	lerociclib hydrochloride	片剂 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 Treatment of advanced or metastatic HR-positive, HER2-negative breast cancer. In combination with aromatase inhibitors as initial	Genor Biopharma(USA), Inc.

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				endocrine therapy. In combination with fulvestrant, particularly in patients who have progressed on prior endocrine therapy.	
187.	伊速达；玛舒拉沙韦片	suraxavir marboxil	片剂 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 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
188.	伏罗尼布片	vorolanib	片剂 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 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
189.	百悦达；索托克拉片 [#]	sonrotoclax	片剂 Tablet	用于既往经过至少包含布鲁顿酪氨酸激酶抑制剂在内的一种系统治疗的成人慢性淋巴细胞白血病/小淋巴细胞淋巴瘤患者、既往接受过至少两种系统性治疗（含布鲁顿氏酪氨酸激酶抑制剂）的复发或难治性套细胞淋巴瘤成人患者 For adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (SLL) who have received at least one prior systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor; and for adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior systemic therapies, including a Bruton's tyrosine kinase (BTK) inhibitor	百济神州(苏州)生物科技有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
190.	先诺欣； 先诺特韦片/利托那韦片	ritonavir; simnotrelvir	片剂 Tablet	治疗新冠病毒感染 Treatment of COVID-19 infection	先声药业有限公司
191.	安久卫； 安奈拉唑钠肠溶片	anaprazole sodium	片剂 Tablet	治疗十二指肠溃疡 Treatment of duodenal ulcer	轩竹生物科技股份有限公司
192.	安洛晴；枸橼酸依奉阿克胶囊	envonalkib	胶囊 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 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
193.	安佑平；菲诺利单抗注射液	finotonlimab	注射剂 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 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
194.	安方宁；格索雷塞片	garsorasib	片剂 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 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
195.	安达静；夫那奇珠单抗注射液	vunakizumab	注射剂 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 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

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
196.	沙艾特；注射用埃普奈明	aponermin	注射剂 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 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
197.	阿兹夫定片	azvudine	片剂 Tablet	治疗新冠病毒感染 Treatment of COVID-19 infection	河南真实生物科技有限公司
198.	阿得贝利单抗注射液	adebrelimab	注射剂 Injection	治疗小细胞肺癌 Treatment of small cell lung cancer	江苏恒瑞医药股份有限公司
199.	贝塔宁；枸橼酸倍维巴肽注射液	bevifibatide citrate	注射剂 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 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
200.	贝特琳；注射用盐酸伊吡诺司他	ifupinostat hydrochloride	注射剂 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 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

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
201.	贝捷迈；盐酸匹米替尼胶囊	pimicotinib	胶囊 Capsule	用于治疗手术切除可能会导致功能受限或出现较严重并发症的症状性腱鞘巨细胞瘤（TGCT）成年患者 For the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) where surgical resection is likely to result in functional limitation or severe morbidity/complications	默克雪兰诺（北京）医药有限公司
202.	伯瑞替尼肠溶胶囊	bozitinib	胶囊 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 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
203.	利生妥；利沙托克拉片	lisaftoclax	片剂 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 Treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) in patients who have previously received at least one prior systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor	苏州亚盛药业有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
204.	君适达；昂戈瑞西单抗注射液	ongeracicimab	注射剂 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 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
205.	宜诺欣；佐来曲替尼片	zurletrectinib	片剂 Tablet	用于符合下列条件的成人和 12 岁以上青少年实体瘤患者：携带神经营养酪氨酸受体激酶（NTRK）融合基因且不包括已知获得性耐药突变，患有局部晚期、转移性疾病或手术切除可能导致严重并发症的患者，以及无满意替代治疗或既往治疗失败的患者 For the treatment of adult and adolescent patients aged 12 years and older with solid tumors who have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, who have locally advanced or metastatic disease or where surgical resection is likely to result in severe morbidity, and who have no satisfactory	北京诺诚健华医药科技有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				alternative treatments or who have progressed following prior treatment	
206.	依达方； 依沃西单抗注射液	ivonescimab	注射剂 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 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
207.	东英贺；艾考磷布韦片	encofosbuvir	片剂 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 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

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
208.	东卫卓；磷酸蔡坦司韦胶囊	netanasvir phosphate	胶囊 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 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
209.	东泽安；奥洛格列净胶囊 [#]	Olorigliflozin	胶囊 Capsule	用于改善成人 2 型糖尿病患者的血糖控制 For improving glycemic control in adult patients with type 2 diabetes mellitus	宜昌东阳光长江药业股份有限公司
210.	佳泰莱；芦康沙妥珠单抗注射液	sacituzumab tirumotecan	注射剂 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 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
211.	昂伟达；盐酸司美那非片	simenafil hydrochloride	片剂 Tablet	治疗勃起功能障碍 Treatment of erectile dysfunction	苏州旺山旺水生物医药股份有限公司
212.	金立希；赛立奇单抗注射液	xeligekimab	注射剂 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 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

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
213.	金蓓欣；注射用伏欣奇拜单抗	firsekibart	注射剂 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 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
214.	美佑恒；注射用维贝柯妥塔单抗	becotatug vedotin	注射剂 Injection	治疗既往经至少二线系统化疗和 PD-1/PD-L1 抑制剂治疗失败的复发/转移性鼻咽癌的成人患者 To treat adult patients with recurrent/metastatic nasopharyngeal carcinoma who have progressed after at least two prior lines of systemic chemotherapy and PD-1/PD-L1 inhibitor therapy	乐普生物科技股份有限公司
215.	思美宁；苯磺酸克利加巴林胶囊	crisugabalin besilate	胶囊 Capsule	治疗糖尿病性周围神经病理性疼痛 To treat peripheral neuropathic pain	海思科医药集团股份有限公司
216.	思舒静；安瑞克芬注射液	anrikefon	注射剂 Injection	用于治疗腹部手术后的轻至中度疼痛 Treatment of mild to moderate pain following abdominal surgery	海思科医药集团股份有限公司
217.	派达康；维培那肽注射液	visepegenatide	注射剂 Injection	用于成人 2 型糖尿病患者的血糖控制 For glycemic control in adult patients with type 2 diabetes	派格生物医药（杭州）股份有限公司
218.	派舒宁；塞纳-马恩省帕利胶囊	senaparib	胶囊 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 Maintenance treatment of adult patients with	上海英派药业有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 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	
219.	科泰莱；塔戈利单抗注射液	tagitanlimab	注射剂 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 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
220.	科露平；妥拉美替尼胶囊	tunlametinib	胶囊 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 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
221.	津立生；纳卢梭拜单抗注射液	narlumosbart	注射剂 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 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
222.	信立汀；苯甲酸福格列汀片	fotagliptin benzoate	片剂 Tablet	改善成人 2 型糖尿病患者的血糖控制 To improve glycemic control in patients with type 2 diabetes mellitus	深圳信立泰药业股份有限公司
223.	信立安；戊二酸利那拉生酯胶囊	linaprazan glurate	胶囊 Capsule	用于反流性食管炎 Treatment of gastroesophageal reflux disease	上海生诺医药科技有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
224.	信妥安；苹果酸司妥吉仑片	sitokiren	片剂 Tablet	治疗原发性高血压 For the treatment of primary hypertension	上海上药信谊药厂有限公司
225.	信美悦；匹康奇拜单抗注射液	picankibart	注射剂 Injection	用于适合系统性治疗的中重度斑块状银屑病成人患者 For the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy	信达生物医药科技（杭州）有限公司
226.	信玖凝；波哌达可基注射液	dalnacogene ponparvovec	注射剂 Injection	治疗中重度 B 型血友病成年患者 Treatment of adult patients with moderate to severe hemophilia B	上海信致医药科技有限公司
227.	重组人源抗狂犬病毒单抗	ormutivimab	注射剂 Injection	治疗狂犬病病毒感染 Treatment of rabies virus infection	华北制药集团新药研究开发有限责任公司
228.	恒凯莱；雷尼基奥仑赛注射液	ranicabtagene autoleucel	注射剂 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 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 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).	上海恒润达生生物科技股份有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
229.	佩金；拓培非格司亭注射液	telpegfilgrastim	注射剂 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 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
230.	倍长平；考格列汀片	coflogliptin	片剂 Tablet	改善成人 2 型糖尿病患者的血糖控制 To improve glycemic control in patients with type 2 diabetes mellitus	海思科医药集团股份有限公司
231.	倍稳； 盐酸凯普拉生片	keverprazan hydrochloride	片剂 Tablet	治疗十二指肠溃疡、反流性食管炎 Treatment of duodenal ulcer, reflux esophagitis	江苏柯菲平医药股份有限公司
232.	海纳安；氘恩扎鲁胺软胶囊	deuenzalutamide	胶囊 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 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
233.	海益坦；谷美替尼片	glumetinib	片剂 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 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
234.	高瑞哲；戈利昔替尼胶囊	golidocitinib	胶囊 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 To treat relapsed/refractory peripheral T-Cell	迪哲（江苏）医药股份有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				lymphoma (r/r PTCL) in patients whose disease has advanced following a minimum of one previous systemic therapy or who were refractory to this	
235.	轩悦宁；吡洛西利片	bireociclib	片剂 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 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
236.	轩菲宁；地罗阿克片	dirozalkib	片剂 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 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
237.	泰妥妥；盐酸妥诺达非片	tunodafil hydrochloride	片剂 Tablet	治疗勃起功能障碍 Treatment of erectile dysfunction	扬子江药业集团有限公司
238.	盛捷维；磷酸森格列汀片	cetagliptin phosphate	片剂 Tablet	改善成人 2 型糖尿病患者的血糖控制 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
239.	启欣可；伊鲁阿克片	iruplinalkib	片剂 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	齐鲁制药有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				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	
240.	莫米司特片	mufemilast	片剂 Tablet	用于治疗符合接受光疗或系统治疗指征的中度至重度斑块状银屑病的成人患者 For the treatment of adult patients with moderate to severe plaque psoriasis who are eligible for phototherapy or systemic therapy	赣州和美药业股份有限公司
241.	培莫沙肽注射液	pegmolesatide	注射剂 Injection	治疗慢性肾病引起的贫血 Treatment of anemia due to chronic kidney disease	江苏豪森药业集团有限公司
242.	康悦达；普奇拜单抗注射液	stapokibart	注射剂 Injection	治疗中度至重度异位性皮炎 Treatment of moderate to severe atopic dermatitis	成都康诺行生物医药科技有限公司
243.	康美纳；酒石酸泰瑞西利胶囊	tibremciclib tartrate	胶囊 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 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
244.	惠优静；脯氨酸加格列净片	henagliflozin	片剂 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 Monotherapy or as add-on therapy to metformin to improve glycemic control	惠升生物制药股份

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
245.	达伯乐；己二酸他雷替尼胶囊	taletrectinib	胶囊 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 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
246.	复邦德；艾诺米替片	ainuovirine; lamivudine; tenofovir disoproxil fumarate	片剂 Tablet	治疗未接受过治疗的 HIV-1 感染成人患者 Treatment of treatment-naïve adults with HIV-1 infection	江苏艾迪药业股份有限公司
247.	复妥宁；枸橼酸伏维西利胶囊	fovinaciclib citrate	胶囊 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 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
248.	普利得凯；普基奥仑赛注射液	puzolcabtogene autoleucel	注射剂 Injection	治疗 CD19 阳性的难治或复发性急性 B 淋巴细胞白血病患者 To treat patients with CD19-positive refractory or relapsed acute B-cell lymphoblastic leukemia	重庆精准生物技术有限公司
249.	普佑恒；普特利单抗注射液	pucotenlimab	注射剂 Injection	治疗 MSI-H 或 dMMR 实体瘤；黑色素瘤 Treatment of MSI-H or dMMR solid tumors; melanoma	乐普生物科技股份有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
250.	华堂宁； 多格列艾汀片	dorzagliatin	片剂 Tablet	治疗 2 型糖尿病 Treatment of Type 2 diabetes	华领医药技术（上海）有限公司
251.	华优诺；立贝韦塔单抗注射液 [#]	libevitug	注射剂 Injection	用于治疗伴有或不伴有代偿期肝硬化的慢性丁型肝炎病毒（HDV）感染成年患者 For the treatment of adult patients with chronic hepatitis delta virus (HDV) infection, with or without compensated cirrhosis	华辉安健（北京）生物科技有限公司
252.	开坦尼； 卡度尼利单抗注射液	cadonilimab	注射剂 Injection	治疗宫颈癌 To treat cervical cancer	康方药业有限公司
253.	景助达； 恩替司他片	entinostat	片剂 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 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
254.	奥壹新；利厄替尼片	limertinib	片剂 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 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

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
255.	奥格特韦钠胶囊	olgotrelvir	胶囊 Capsule	用于治疗轻中型新型冠状病毒感染 (COVID-19) 的成年患者 Treatment of adult patients with mild to moderate COVID-19 infection	浙江艾森药业有限公司
256.	奥特康唑胶囊	oteseconazole	胶囊 Capsule	治疗重度外阴阴道假丝酵母菌病 (VVC) To treat vulvovaginal candidiasis (VVC)	eVENUS Pharmaceutical Laboratories Inc.
257.	舒泰莱；注射用博度曲妥珠单抗	trastuzumab botidotin	注射剂 Injection	用于既往接受过一种或一种以上抗 HER2 药物治疗的不可切除或转移性 HER2 阳性成人乳腺癌患者 For the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have previously received one or more anti-HER2 therapies	四川科伦博泰生物医药股份有限公司
258.	爱达罗；依若奇单抗注射液	ebdarokimab	注射剂 Injection	治疗成人中度至重度斑块状银屑病 Treatment of moderate-to-severe plaque psoriasis in adult	中山康方生物医药有限公司
259.	新舒沐；甲磺酸普雷福韦片	pradefovir mesylate	片剂 Tablet	治疗成人慢性乙型肝炎 Treatment of adult patients with chronic hepatitis B infection	西安葛蓝新通制药有限公司
260.	新替妥；斯泰度塔单抗注射液	siltartoxatug	注射剂 Injection	用于破伤风紧急预防 Emergency prevention of post-traumatic tetanus	珠海泰诺麦博制药股份有限公司
261.	善泽平；普卢格列汀片	prusogliptin	片剂 Tablet	用于改善成人 2 型糖尿病患者的血糖控制 To improve glycemic control in patients with type 2 diabetes mellitus	石药集团欧意药业有限公司
262.	瑞玛比嗪注射液	Relmapirazin	注射剂 Injection	与特定的经皮肾小球滤过率测量设备配合使用，评估患者的肾小球滤过率 Use in conjunction with specific transcutaneous glomerular filtration rate measurement	杭州中美华东制药有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				equipment to assess the patient's glomerular filtration rate	
263.	瑞必达； 甲磺酸瑞齐替尼胶囊	rezivertinib	胶囊 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 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
264.	瑞坦宁；注射用磷罗 拉匹坦帕洛诺司琼	fosrclonazepam palonosetron	注射剂 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 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
265.	瑞格列汀二甲双胍片	retagliptin; metformin	片剂 Tablet	用于改善成人 2 型糖尿病患者的血糖控制 To improve glycemic control in patients with type 2 diabetes mellitus	山东盛迪医药有限公司
266.	瑞维鲁胺片	rezvilutamide	片剂 Tablet	治疗高肿瘤负荷的转移性激素敏感性前列腺癌 (mHSPC) 患者 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 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
267.	圣瑞沙；甲磺酸瑞厄替尼片	rilertinib mesylate	片剂 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 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
268.	圣诺迪；奥磷布韦片	alfosbuvir	片剂 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） To treat chronic HCV infection in adults (genotypes 1, 2, 3, 6)	南京圣和药业股份有限公司
269.	玛帕西沙韦胶囊	pixavir marboxil	胶囊 Capsule	用于 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 For the treatment of uncomplicated influenza A and B in adolescents and adults aged 12 years and older	健康元药业集团股份有限公司
270.	汉斯状；斯鲁利单抗注射液	serplulimab	注射剂 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 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
271.	迈粒生；注射用阿格司亭α	albipagrastim alfa	注射剂 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 to decrease the incidence of infection, as manifested by febrile neutropenia, in adult	江苏泰康生物医药有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
				patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	
272.	迈瑞东；马来酸美凡厄替尼片	mifanertinib maleate	片剂 Tablet	用于表皮生长因子受体(EGFR)21 号外显子 L858R 置换突变的局部晚期或转移性非小细胞肺癌(NSCLC) 成人患者的一线治疗 For first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 21 L858R substitution mutation	杭州中美华东制药有限公司
273.	睿铂生；艾米迈托赛注射液	amimetrocel	注射剂 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 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
274.	赛坦欣；库莫西利胶囊	culmerciclib	胶囊 Capsule	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激素受体（HR）阳性、人表皮生长因数受体 2（HER2）阴性的局部晚期或转移性乳腺癌成人患者 In combination with fulvestrant for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in adult patients who have disease progression following prior endocrine therapy	正大天晴药业集团股份有限公司

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
275.	泽普平；盐酸吉卡昔替尼片	gecacitinib hydrochloride	片剂 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 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
276.	赛美纳；甲磺酸贝福替尼胶囊	befotertinib	胶囊 Capsule	治疗 EGFR T790M 突变阳性的转移性非小细胞肺癌 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
277.	赛恺泽；泽沃基奥仑赛注射液	zevorcabtagene autoleucel	注射剂 Injection	治疗复发性或难治性多发性骨髓瘤 To Treat relapsed/refractory multiple myeloma (RRMM)	科济生物医药（上海）有限公司
278.	盐酸凯普拉生注射液；盐酸凯普拉生片	carenoprazan hydrochloride	片剂;注射剂 Tablet ; Injection	治疗十二指肠溃疡、反流性食道炎 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：01/2026

#最新獲國家藥監局、美國 FDA 或歐盟 EMA 批准上市的新藥

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