

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.	Attruby; Beyonttra	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.
11.	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
12.	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
13.	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
14.	Beqvez	fidanacogene elaparvovec	注射剂 Injection	治疗 B 型血友病 Treatment of hemophilia B	Pfizer Inc.
15.	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.
16.	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.

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17.	Blujepa	gepotidacin	片剂 Tablet	治疗非复杂性尿路感染 To treat uncomplicated urinary tract infections	GlaxoSmithKline
18.	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.
19.	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)
20.	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.
21.	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.
22.	Casgevy	exagamglogene autotemcel	注射剂 Injection	Treatment of beta thalassaemia and sickle cell disease 用于治疗β-地中海贫血及镰刀型红血球疾病	Vertex Pharmaceuticals (Ireland) Limited
23.	Cobenfy	xanomeline; trospium chloride	胶囊 Capsule	治疗精神分裂症 To treat schizophrenia	Bristol-Myers Squibb Company
24.	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.

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25.	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.
26.	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.
27.	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.
28.	Daybue	trofinetide	溶液剂 Solution	治疗雷特综合征 To treat Rett syndrome	Acadia Pharmaceuticals Inc.
29.	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.
30.	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
31.	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

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32.	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
33.	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.
34.	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.
35.	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
36.	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.
37.	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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38.	Ensacove	ensartinib	胶囊 Capsule	治疗非小细胞肺癌 To treat non-small cell lung cancer	Xcovery Holdings, Inc.
39.	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
40.	Exxua	gepirone	片剂 Tablet	治疗忧郁症 To treat major depressive disorder	Mission Pharmacal Company
41.	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
42.	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
43.	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 To treat wounds associated with dystrophic and junctional epidermolysis bullosa	Lichtenheldt GmbH
44.	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
45.	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.

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46.	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
47.	Hemgenix	etranacogene dezaparvovec	注射剂 Injection	治疗 B 型血友病 Treatment of hemophilia B	CSL Behring LLC
48.	Imaavy [#]	nipocalimab	注射剂 Injection	治疗全身性重症肌无力 To treat generalized myasthenia gravis	Janssen Biotech, Inc.
49.	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.
50.	Inpefa	sotagliflozin	片剂 Tablet	治疗心脏衰竭 To treat heart failure	Lexicon Pharms Inc.
51.	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
52.	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.
53.	Itovebi	inavolisib	片剂 Tablet	治疗局部晚期或转移性乳癌 To treat locally advanced or metastatic breast cancer	Genentech USA, Inc.
54.	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

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55.	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.
56.	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
57.	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
58.	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
59.	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
60.	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
61.	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
62.	Kisunla	donanemab	注射剂 Injection	治疗阿尔茨海默症 To treat Alzheimer's disease	Eli Lilly and Company

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63.	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
64.	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.
65.	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.
66.	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
67.	Lamzedo	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
68.	Lazcluze	lazertinib	片剂 Tablet	治疗非小细胞肺癌 To treat non-small cell lung cancer (NSCLC)	Janssen Biotech, Inc.
69.	Leqselvi	deuruxolitinib	片剂 Tablet	治疗严重斑秃 To treat severe alopecia areata	Sun Pharmaceutical Industries, Inc.
70.	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.
71.	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.

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72.	Livtency	maribavir	片剂 Tablet	治疗移植后的巨细胞病毒 (CMV) 感染 To treat post-transplant cytomegalovirus (CMV) infection	Takeda Pharmaceuticals USA
73.	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
74.	Locametz	gallium Ga 68 gozetotide	注射剂 Injection	用于正电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
75.	Lumisight	pegulicanine	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.
76.	Lupkynis	voclosporin	胶囊 Capsule	治疗狼疮性肾炎 To treat lupus nephritis	Aurinia Pharmaceuticals Inc.
77.	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
78.	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
79.	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

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80.	Miplyffa	arimoclomol	胶囊 Capsule	治療尼曼匹克疾病 C 型 To treat Niemann-Pick disease type C	Zevra Denmark A/S
81.	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.
82.	Nemluvio	nemolizumab	注射剂 Injection	治疗结节性痒疹 To treat prurigo nodularis	Galderma Laboratories, L.P.
83.	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
84.	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.
85.	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
86.	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.
87.	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.
88.	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

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89.	Omlonti	omidenepag	眼用溶液 Ophthalmic solution	降低开角型青光眼或高血压症患者的眼压 To reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Santen Pharmaceutical Co., Ltd
90.	Omvoh	mirikizumab	注射剂 Injection	治疗溃疡性结肠炎 To treat ulcerative colitis	Eli Lilly
91.	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
92.	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
93.	Orlynvah	sulopenem etzadroxil, probenecid	片剂 Tablet	治疗非复杂性尿路感染 To treat uncomplicated urinary tract infections	Iterum Therapeutics
94.	Piasky	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
95.	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.
96.	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.
97.	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.
98.	Qfitlia	fitusiran	注射剂 Injection	用于 A 型及 B 型血友病人以避免或减少出血事件 To prevent or reduce the frequency of bleeding episodes in hemophilia A or B	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
99.	Quviviq	daridorexant	片剂 Tablet	治疗失眠 To treat insomnia	Actelion Ltd ; Idorsia Ltd
100.	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 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.
101.	Rapiblyk	landiolol	注射剂 Injection	治疗室上性心搏过速 To treat supraventricular tachycardia	AOP Orphan Pharmaceuticals GmbH
102.	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
103.	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.
104.	Reyvow	lasmiditan	片剂 Tablet	治疗偏头痛 Treatment of migraine	Eli Lilly
105.	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

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.	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.
107.	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.
108.	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.
109.	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
110.	Roctavian	valoctocogene roxaparvovec	注射剂 Injection	治疗 A 型血友病 Treatment of Hemophilia A	BioMarin Pharmaceutical Inc.
111.	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
112.	Romvimza	vimseltinib	胶囊 Capsule	用于治疗患有症状性腱鞘巨细胞瘤的成年患者。对于这些患者而言，手术切除可能会导致严重的功能障碍或疾病的恶化	Deciphera Pharmaceuticals, 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 symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity	
113.	Rystiggo	rozanolixizumab	注射剂 Injection	治疗全身性重症肌无力 Treatment of generalized myasthenia gravis	UCB Pharmaceuticals
114.	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 To treat low- to intermediate-1-risk myelodysplastic syndromes (MDS)	Geron Corporation; Catalent Indiana, LLC; Patheon Italia, S.p.A
115.	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.
116.	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
117.	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.
118.	Sofdra	sofpironium	凝胶 Gel	治疗原发性腋窝多汗症 To treat primary axillary hyperhidrosis	Botanix SB Inc.
119.	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.

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
120.	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.
121.	Skyclarys	omaveloxolone	胶囊 Capsule	治疗弗里德里希共济失调 To treat Friedrich's ataxia	Reata Pharmaceuticals Inc.
122.	Talvey	talquetamab	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	Janssen Biotech, Inc.
123.	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 Treatment of relapsed or refractory (r/r) acute lymphocytic leukemia (ALL) or relapsed or refractory (r/r) mantle cell lymphoma (MCL)	Kite (Gilead Sciences Inc.)
124.	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
125.	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
126.	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.
127.	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.

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128.	Tryvio	aprocitentan	片剂 Tablet	治疗高血压 To treat hypertension	Idorsia Pharmaceuticals US Inc.
129.	Tymlos; Eladynos	abaloparatide	注射剂 Injection	治疗骨质疏松症 Treatment of osteoporosis	Radius Health Inc.
130.	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.
131.	Unloxcyt	cosibelimab	注射剂 Injection	治疗皮肤鳞状细胞癌 To treat cutaneous squamous cell carcinoma	Checkpoint Therapeutics, Inc.
132.	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.
133.	Vanflyta	quizartinib	片剂 Tablet	治疗急性髓细胞白血病 Treatment for newly diagnosed acute myeloid leukemia	Daiichi Sankyo, Inc.
134.	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
135.	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.
136.	Veozah	fezolinetant	片剂 Tablet	治疗更年期引起的中度至重度潮热 To treat moderate to severe hot flashes caused by menopause	Ogeda SA ; Astellas Pharma Inc.

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137.	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
138.	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
139.	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
140.	Vtama	tapinarof	乳膏 Cream	治疗斑块状银屑病 To treat plaque psoriasis	Dermavant Sciences
141.	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
142.	Vyloy	zolbetuximab	注射剂 Injection	治疗胃及胃食管交界处腺癌 To treat gastric or gastroesophageal junction adenocarcinoma	Astellas Pharma US, Inc.
143.	Vyvgart	efgartigimod alfa	注射剂 Injection	治疗全身性重症肌无力 To treat generalized myasthenia gravis	Argenx BV

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144.	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
145.	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.
146.	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.
147.	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.
148.	Xolremdi	mavorixafor	胶囊 Capsule	治疗 WHIM 综合症 To treat WHIM syndrome	X4 Pharmaceuticals, Inc.
149.	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
150.	Yselty	linzagolix	片剂 Tablet	治疗子宫肌瘤 To treat uterine fibroids	Theramex Ireland Limited
151.	Zavzpret	zavegepant	喷剂 Spray	治疗偏头痛 To treat migraine	Pfizer Inc.
152.	Zelsuvmi	berdazimer	凝胶 Gel	治疗传染性软疣 To treat molluscum contagiosum	EPIH SPV, LLC

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153.	Ziihera ; 百赫安 ; 注射用泽尼达妥单抗 [#]	zanidatamab	注射剂 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 Treatment of adults with previously treated, unresectable locally advanced or metastatic HER2-positive biliary tract cancer	Jazz Pharmaceuticals Ireland Limited ; 百济神州 (苏州) 生物科技有限公司
154.	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.
155.	Zokinvy	lonafarnib	胶囊 Capsule	治疗哈钦森-吉尔福德早衰综合征 Treatment of Hutchinson-Gilford progeria syndrome	Eiger Biopharmaceuticals
156.	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
157.	Zurzuvae	zuranolone	胶囊 Capsule	治疗产后抑郁症 To treat postpartum depression	Biogen Inc.
158.	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
159.	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.

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160.	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）生物科技公司
161.	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
162.	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
163.	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
164.	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	广东恒瑞医药有限公司

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
				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	
165.	艾速达；硫酸埃玛昔替尼片	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
166.	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
167.	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 endocrine therapy. In combination with fulvestrant, particularly in patients who have progressed on prior endocrine therapy.	Genor Biopharma(USA), Inc.

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168.	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
169.	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
170.	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
171.	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
172.	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
173.	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

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
174.	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
175.	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
176.	安睿威；昂拉地韦片 [#]	onradivir	片剂 Tablet	用于成人单纯性甲型流感患者的治疗 Treatment of adult patients with simple influenza A	广东众生睿创生物科技有限公司
177.	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
178.	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
179.	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

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
180.	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
181.	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
182.	君适达；昂戈瑞西单抗注射液	ongerlicimab	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

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.	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
184.	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
185.	东卫卓；磷酸萘坦司韦胶囊	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

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
186.	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
187.	怡诺轻；依苏帕格鲁肽α注射液	supaglutide	注射剂 Injection	用于成人 2 型糖尿病患者的血糖控制 For glycemic control in adults with type 2 diabetes mellitus	上海银诺医药技术有限公司
188.	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
189.	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
190.	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
191.	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 advanced epithelial high-grade ovarian,	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
				fallopian tube, or primary peritoneal cancer who achieved a complete or partial response after the completion of first-line platinum-based chemotherapy	
192.	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
193.	科露平；妥拉美替尼胶囊	tunlametinib	胶囊 Capsule	Treatment of advanced melanoma carrying neuroblastoma ras viral oncogene homolog (NRAS) mutations who have previously undergone PD-1/PD-L1 treatment 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	上海科州药物研发有限公司
194.	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
195.	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
196.	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
197.	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
198.	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
199.	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
200.	倍长平；考格列汀片	cofroglipitin	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
201.	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
202.	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

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
203.	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
204.	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 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
205.	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
206.	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
207.	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	
208.	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
209.	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
210.	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
211.	达伯特；氟泽雷塞片	fulzerasib	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成人患者 Treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harboring the KRAS G12C mutation who have received at least one systemic therapy	信达生物科技有限公司
212.	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

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.	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 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
214.	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
215.	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
216.	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
217.	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
218.	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

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
219.	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
220.	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
221.	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.
222.	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
223.	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

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.	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
225.	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
226.	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
227.	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
228.	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
229.	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
230.	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
231.	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
232.	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
233.	迈粒生；注射用阿格司亭 $\alpha^{\#}$	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 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 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药企 Pharmaceutical company
234.	睿铂生；艾米迈托赛注射液	amimestrocel	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
235.	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
236.	泽瑞尼；盐酸佐利替尼片	zorifertinib hydrochloride	片剂 Tablet	用于具有表皮生长因子受体（EGFR）19 号外显子缺失或外显子 21（L858R）置换突变，并伴有中枢神经系统（CNS）转移的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 non-small cell lung cancer (NSCLC) harboring EGFR exon 19 deletion or exon 21 L858R substitution mutations and central nervous system (CNS) metastases	江苏晨泰医药科技有限公司
237.	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

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
238.	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
239.	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

资料截至：5/2025

Commercial names are listed in alphabetical/strokes order

#最新獲國家藥監局、美國 FDA 或歐盟 EMA 批准上市的新藥

Latest new drug approved for marketing by NMPA, USFDA and EMA