

具條件可供本澳醫療機構使用及在澳門申請註冊上市的新藥
(已獲國家藥監局、美國 FDA 或歐盟 EMA 批准上市的新藥)

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)

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
1.	Abecma	idecabtagene vicleucel	注射劑 Injection	治療復發性或難治性多發性骨髓瘤 To Treat relapsed/refractory multiple myeloma (RRMM)	Celgene Corporation (Bristol Myers Squibb)
2.	Akeega	niraparib; abiraterone acetate	片劑 Tablet	治療成人 BRCA1/2 突變的轉移性去勢抗性前列腺癌 Treatment of metastatic castration-resistant prostate cancer with BRCA1/2 mutations in adults	Janssen Pharmaceuticals
3.	Alhemo	concizumab	注射劑 Injection	用於 A 型及 B 型血友病人作為常規預防以避免出血 事件 For routine prophylaxis to prevent bleeding episodes in hemophilia A and B	Novo Nordisk Inc.
4.	Alyftrek	Vanzacaftor; tezacaftor; deutivacaftor	片劑 Tablet	治療囊性纖維化 To treat cystic fibrosis	Vertex Pharmaceuticals Incorporated
5.	Agamree	vamorolone	溶液劑 Solution	治療裘馨氏肌肉失養症 To treat Duchenne muscular dystrophy	Santhera Pharmaceuticals
6.	Amvuttra	vutrisiran	注射劑 Injection	治療遺傳性澱粉樣蛋白疾病所導致的多發性神經病變 To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis	AInylam Pharms Inc.
7.	Andembry	garadacimab	注射劑 Injection	預防遺傳性血管性水腫發作 Prevention of recurrent attacks of hereditary angioedema (HAE)	CSL Behring GmbH
8.	Anktiva	nogapendekin alfa	注射劑 Injection	治療膀胱癌 To treat bladder cancer	Altor BioScience, LLC

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
9.	Aqneursa	levacetylleucine	混懸劑 Suspension	治療尼曼匹克疾病 C 型 To treat Niemann-Pick disease type C	IntraBio Inc.
10.	Attruby; Beyonttra	acoramidis	片劑 Tablet	治療伴有心肌病的野生型或變異型轉甲狀腺素蛋白介導的澱粉樣變性 To treat cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis	BridgeBio Pharma, Inc.
11.	Aucatzyl	obecabtagene autoleucel	注射劑 Injection	治療復發性或難治性 B-細胞前體急性淋巴細胞白血病 Treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia	Autolus GmbH
12.	Avmapki Fakzynja Co-Pack	avutometinib; defactinib	膠囊、片劑 Capsule、Tablet	治療既往接受過全身治療的 KRAS 突變復發性低級別漿液性卵巢癌 To treat KRAS-mutated recurrent low-grade serous ovarian cancer after prior systemic therapy	Verastem Oncology
13.	Awikli; 諾和期; 依柯胰島素注射液	insulin icodec	注射劑 Injection	治療成人 2 型糖尿病 To treat type 2 diabetes mellitus	Novo Nordisk A/S
14.	Beqvez	fidanacogene elaparvovec	注射劑 Injection	治療 B 型血友病 Treatment of hemophilia B	Pfizer Inc.
15.	Bimzelx	bimekizumab	注射劑 Injection	治療適合全身治療或光療的成人中重度斑塊型銀屑病 To treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	UCB, Inc.
16.	Bizengri	zenocutuzumab	注射劑 Injection	治療非小細胞肺癌及胰腺癌 To treat non-small cell lung cancer and pancreatic adenocarcinoma	Merus N.V.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
17.	Blujepa	gepotidacin	片劑 Tablet	治療非複雜性尿路感染 To treat uncomplicated urinary tract infections	GlaxoSmithKline
18.	Brenzavvy	bexagliflozin	片劑 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	注射劑 Injection	治療復發性或難治性大 B 細胞淋巴瘤 Treatment of relapsed or refractory (r/r) large B-cell lymphoma (LBCL)	Juno Therapeutics (Bristol Myers Squibb)
20.	Briumvi	ublituximab	注射劑 Injection	治療成人復發性多發性硬化症 To treat relapsing forms of multiple sclerosis	TG Therapeutics, Inc.
21.	Carvykti	ciltacabtagene autoleucel	注射劑 Injection	治療復發性或難治性多發性骨髓瘤 To Treat relapsed/refractory multiple myeloma (RRMM)	Legend Biotech Corporation; Janssen Biotech, Inc.
22.	Casgevy	exagamglogene autotemcel	注射劑 Injection	Treatment of beta thalassemia and sickle cell disease 用於治療β-地中海貧血及鐮刀型紅血球疾病	Vertex Pharmaceuticals (Ireland) Limited
23.	Cobenfy	xanomeline; trospium chloride	膠囊 Capsule	治療精神分裂症 To treat schizophrenia	Bristol-Myers Squibb Company
24.	Cosela	trilaciclib	注射劑 Injection	在廣泛期小細胞肺癌 (ES-SCLC) 的含鉑/依托泊苷方案或含拓撲替康方案之前給藥時，可降低成人患者化療引起的骨髓抑制的發生率 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.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
25.	Crenessity	crinecerfont	膠囊、溶液劑 Capsule; Solution	治療典型先天性腎上腺增生症 To treat classic congenital adrenal hyperplasia	Neurocrine Biosciences, Inc.
26.	Datroway	datopotamab deruxtecan	注射劑 Injection	用於接受過內分泌治療及化療但無法切除或轉移性荷爾蒙受體陽性、HER2 陰性的乳腺癌 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	注射劑 Injection	治療與皺眉肌和/或降眉肌活動相關的中度至重度眉間皺紋 To treat moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity	Revance Therapeutics Inc.
28.	Daybue	trofinetide	溶液劑 Solution	治療雷特綜合症 To treat Rett syndrome	Acadia Pharmaceuticals Inc.
29.	Defencath	taurolidine heparin	注射劑 Injection	用於降低通過中心靜脈導管接受長期血液透析的腎功能衰竭成年患者的導管相關血液感染的發生率 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	混懸劑 Suspension	治療 6 歲及以上患者的杜氏肌營養不良症 To treat Duchenne muscular dystrophy in individuals aged 6 years and older	Italfarmaco S.A.; ITF Therapeutics, LLC
31.	Ebglyss	lebrikizumab	注射劑 Injection	治療中度至重度異位性皮膚炎 To treat moderate-to-severe atopic dermatitis	Eli Lilly and Company

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
32.	Ebvallo	tabelecleucel	注射劑 Injection	治療既往至少接受過一種治療的復發性或難治性 EBV 陽性的移植後淋巴增殖性疾病的兩歲及以上兒童和成人患者 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	注射劑 Injection	作為酶替代療法用於治療法布裏病的成人患者 Enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease	Protalix BioTherapeutics Inc.
34.	Elrexio	elranatamab	注射劑 Injection	治療復發或難治性多發性骨髓瘤 To treat relapsed or refractory multiple myeloma	Pfizer Inc.
35.	Elucirem	gadopiclenol	注射劑 Injection	於 MRI 過程中用作檢測中樞神經系統和身體的異常血管病變 To detect and visualize lesions, together with MRI, with abnormal vascularity in the central nervous system and the body	Guerbet
36.	Emrelis	telisotuzumab vedotin	注射劑 Injection	治療先前接受過全身治療且具高 c-Met 蛋白過表達的局部晚期或轉移性的非小細胞肺癌 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.	Enflonsia [#]	clesrovimab	注射劑 Injection	預防新生兒及嬰兒在呼吸道合胞病毒感染季節出生或進入第一個感染季節的嬰兒的下呼吸道疾病 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

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
38.	Enjaymo	sutimlimab	注射劑 Injection	減少冷凝集素病溶血引起的輸血需求 To decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease	Bioverativ Therapeutics Inc.
39.	Exblifep	cefepime; enmetazobactam	注射劑 Injection	治療複雜性泌尿道感染 To treat complicated urinary tract infections	Orchid Pharma
40.	Exxua	gepirone	片劑 Tablet	治療憂鬱症 To treat major depressive disorder	Mission Pharmacal Company
41.	Ezmekly	mirdametinib	膠囊、片劑 Capsule、 Tablet	治療神經纖維瘤病 1 型 Treatment of plexiform neurofibromas in patients with neurofibromatosis type 1	Springworks Therapeutics Ireland Limited
42.	Filspari	sparsentan	片劑 Tablet	減少患有原發性免疫球蛋白 A 腎病且有疾病快速進展風險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. ; Travere Therapeutics Inc. ; Bristol Myers Squibb
43.	Filsuvez	birch triterpenes	凝膠 Gel	用於營養失養型及接合型表皮分解性水皰相關的傷口 To treat wounds associated with dystrophic and junctional epidermolysis bullosa	Lichtenheldt GmbH
44.	Gohibic	vilobelimab	注射劑 Injection	治療新冠病毒引起的急性呼吸窘迫綜合症 To treat acute respiratory distress syndrome (ARDS) caused by SARS-CoV-2	Almac Pharma Services Ltd
45.	Gomekli	mirdametinib	膠囊、混懸劑 Capsule、 Suspension	用於治療患有 1 型神經纖維瘤病且患有症狀性叢狀神經纖維瘤且無法完全切除的患者 To treat neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection	SpringWorks Therapeutics, Inc.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
46.	Grafapex	treosulfan	注射劑 Injection	與氟達拉濱聯合使用，作為異基因造血幹細胞移植的準備方案，用於患有急性髓細胞白血病或骨髓增生異常綜合症 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	注射劑 Injection	治療 B 型血友病 Treatment of hemophilia B	CSL Behring LLC
48.	Imaavy	nipocalimab	注射劑 Injection	治療全身性重症肌無力 To treat generalized myasthenia gravis	Janssen Biotech, Inc.
49.	Imdelltra	tarlatamab	注射劑 Injection	治療晚期小細胞肺癌 To treat extensive stage small cell lung cancer	Amgen Inc.
50.	Inpefa	sotagliflozin	片劑 Tablet	治療心臟衰竭 To treat heart failure	Lexicon Pharms Inc.
51.	Iomervu	iomeprol	注射劑 Injection	用作放射線造影劑 For use as a radiographic contrast agent	Bracco Diagnostic Inc.; BIPSO GmbH
52.	Iqirvo	elafibranor	片劑 Tablet	聯合熊去氧膽酸用於治療原發性膽汁性膽管炎 To treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid	Ipsen Biopharmaceuticals, Inc.
53.	Itovebi	inavolisib	片劑 Tablet	治療局部晚期或轉移性乳癌 To treat locally advanced or metastatic breast cancer	Genentech USA, Inc.
54.	Ixchiq	chikungunya vaccine (live)	注射劑 Injection	預防成人基孔肯雅病 Prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years and older	Valneva Austria GmbH

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
55.	Izervay	avacincaptad pegol	注射劑 Injection	治療黃斑病變引發的地圖樣萎縮症 To treat geographic atrophy secondary to age-related macular degeneration	IVERIC bio, Inc.
56.	Jaypirca	pirtobrutinib	片劑 Tablet	用於治療已接受過至少兩種全身治療（包括 BTK 抑制劑）的成人的復發性或難治性套細胞淋巴瘤 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	片劑 Tablet	用於治療已接受至少四個月透析的成人慢性腎病引起的貧血 To treat anemia caused by chronic kidney disease for adults on dialysis for at least four months	GlaxoSmithKline
58.	Joenja	leniolisib	片劑 Tablet	治療活化磷酸肌醇 3-激酶 δ 綜合症 To treat activated phosphoinositide 3-kinase delta syndrome	Pharming Group NV ; Novartis
59.	Journavx	suzetrigine	片劑 Tablet	治療中到重度急性疼痛 To treat moderate to severe acute pain	Vertex Pharmaceuticals Incorporated
60.	Kavigale	sipavibart	注射劑 Injection	用於成人及 12 歲或以上青少年作為新冠病毒暴露前的預防用藥 Pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older	AstraZeneca AB
61.	Kimmtrak	tebentafusp	注射劑 Injection	治療不可切除或轉移性葡萄膜黑色素瘤 To treat unresectable or metastatic uveal melanoma	Immunocore Ltd
62.	Kisunla	donanemab	注射劑 Injection	治療阿爾茨海默症 To treat Alzheimer's disease	Eli Lilly and Company

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
63.	Korsuva ; Kapruvia	difelikefalin	注射劑 Injection	治療慢性腎病導致的中度至重度瘙癢 To treat moderate-to-severe pruritus associated with chronic kidney disease	Cara Therapeutics
64.	Kostaive	zapomeran	注射劑 Injection	預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	片劑 Tablet	用於治療已接受過至少一種全身治療的成人 KRAS G12C 突變的局部晚期或轉移性非小細胞肺癌 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	注射劑 Injection	治療復發性或難治性急性淋巴細胞白血病、復發性或難治性大 B 細胞淋巴瘤 Treatment of relapsed or refractory (r/r) acute lymphocytic leukemia (ALL) or relapsed or refractory (r/r) large B-cell lymphoma (LBCL)	Novartis
67.	Lamzede	velmanase alfa	散劑、注射劑 Powder、Injection	治療α-甘露糖苷貯積症 Treatment of alpha-mannosidosis	Chiesi Farmaceutici SPA
68.	Lazcluze	lazertinib	片劑 Tablet	治療非小細胞肺癌 To treat non-small cell lung cancer (NSCLC)	Janssen Biotech, Inc.
69.	Leqselvi	deuruxolitinib	片劑 Tablet	治療嚴重斑禿 To treat severe alopecia areata	Sun Pharmaceutical Industries, Inc.
70.	Letybo	letibotulinumtoxin A	注射劑 Injection	暫時性改善出現的中度至重度皺眉紋 To temporarily improve the appearance of moderate-to-severe glabellar lines	Hugel, Inc.
71.	Livdelzi	seladelpar	膠囊 Capsule	治療原發性膽汁性膽管炎 To treat primary biliary cholangitis (PBC)	Gilead Sciences, Inc.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
72.	Livtency	maribavir	片劑 Tablet	治療移植後的巨細胞病毒 (CMV) 感染 To treat post-transplant cytomegalovirus (CMV) infection	Takeda Pharmaceuticals USA
73.	Loargys	pegzilarginase	注射劑 Injection	治療 2 歲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	注射劑 Injection	用於正子斷層掃描中辨識前列腺癌患者中前列腺特異性膜抗原陽性病變 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	pegulicianine	注射劑 Injection	作為光學成像劑用於檢測癌組織 To use as an optical imaging agent for the detection of cancerous tissue	Lumicell, Inc.
76.	Lupkynis	voclosporin	膠囊 Capsule	治療狼瘡性腎炎 To treat lupus nephritis	Aurinia Pharmaceuticals Inc.
77.	Lynozytic	linvoseltamab	注射劑 Injection	治療復發性及難治性多發性骨髓瘤 Treatment of patients with relapsed and refractory multiple myeloma	Regeneron Ireland DAC
78.	Lytgobi	futibatinib	片劑 Tablet	治療含有成纖維細胞生長因子受體 2 (FGFR2) 基因融合或其他重排的肝內膽管癌 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	治療乾眼病的症狀 To treat signs and symptoms of dry eye disease	Novaliq GmbH

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
80.	Miplyffa	arimoclomol	膠囊 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	注射劑 Injection	預防 60 歲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	注射劑 Injection	治療結節性癢疹 To treat prurigo nodularis	Galderma Laboratories, L.P.
83.	NexoBrid	anacaulase	凝膠 Gel	去除成人深度部分或全層熱燒傷的焦痂 To remove eschar in adults with deep partial thickness or full thickness thermal burns	Mediowound, Ltd
84.	Ngenla	somatrogon	注射劑 Injection	治療因生長激素分泌不足而導致的生長障礙 Management of a growth disorder due to growth hormone deficiency	OPKO Health Inc. Pfizer Inc.
85.	Niktimvo	axatilimab	注射劑 Injection	治療慢性移植抗宿主病 To treat chronic graft-versus-host disease (cGVHD)	Incyte Corporation
86.	Nulibry	fosdenopterin	散劑、注射劑 Powder、Injection	降低 A 型鉬輔因子缺乏症 (MoCD) 患者的死亡風險 To reduce the risk of mortality in molybdenum cofactor deficiency Type A	Sentynl Therapeutics, Inc.
87.	Ogsiveo	nirogacestat	片劑 Tablet	治療需要使用全身治療的進展性硬纖維瘤成年患者 To treat adults with progressing desmoid tumors who require systemic treatment	SpringWorks Therapeutics, Inc.
88.	Ojemda	tovorafenib	片劑、混懸劑 Tablet、Suspension	治療復發性或難治性兒童低級別膠質瘤 To treat relapsed or refractory pediatric low-grade glioma	Day One Biopharmaceuticals, Inc.; Quotient Sciences – Philadelphia LLC

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
89.	Omlonti	omidenepag	眼用溶液 Ophthalmic solution	降低開角型青光眼或高眼壓症患者的眼壓 To reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Santen Pharmaceutical Co., Ltd
90.	OmvoH	mirikizumab	注射劑 Injection	治療潰瘍性結腸炎 To treat ulcerative colitis	Eli Lilly
91.	Opdualag	nivolumab ; relatlimab	注射劑 Injection	治療不可切除或轉移性黑色素瘤 To treat unresectable or metastatic melanoma	Bristol Myers Squibb
92.	Ordspono	odronextamab	注射劑 Injection	治療濾泡性淋巴瘤或瀰漫性大 B 細胞淋巴瘤 To treat follicular lymphoma or diffuse large B-cell lymphoma (DLBCL)	Regeneron Ireland DAC
93.	Orlynvah	sulopenem et zadroxil, probenecid	片劑 Tablet	治療非複雜性尿路感染 To treat uncomplicated urinary tract infections	Iterum Therapeutics
94.	Piaskey	crovalimab	注射劑 Injection	治療陣發性睡眠性血紅蛋白尿症 Treatment of paroxysmal nocturnal hemoglobinuria (PNH)	Roche Pharma (Schweiz) AG
95.	Pombiliti	cipaglucosidase alfa	注射劑 Injection	治療遲發性龐貝氏症 Treatment of late-onset Pompe disease	Amicus Therapeutics Inc.
96.	Pyrukynd	mitapivat	片劑 Tablet	治療丙酮酸激酶缺乏症的溶血性貧血 To treat hemolytic anemia in pyruvate kinase deficiency	Agios Pharmaceuticals Inc.
97.	Qalsody	tofersen	注射劑 Injection	治療具有 SOD1 基因突變的成人肌萎縮側索硬化症 To treat amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation	Ionis Pharmaceuticals Inc. ; Biogen Inc.
98.	Qfitlia	fitusiran	注射劑 Injection	用於 A 型及 B 型血友病人以避免或減少出血事件 To prevent or reduce the frequency of bleeding episodes in hemophilia A or B	Genzyme Corporation

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
99.	Quviviq	daridorexant	片劑 Tablet	治療失眠 To treat insomnia	Actelion Ltd ; Idorsia Ltd
100.	Penpulimab ; 安尼可 ; 派安普利單抗注射液	penpulimab	注射劑 Injection	與順鉑或卡鉑和吉西他濱聯合用藥，用於復發或轉移性非角化性鼻咽癌成人患者；單藥治療用於接受過鉑類化療且至少接受過一種其他先前治療的轉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	注射劑 Injection	治療室上性心搏過速 To treat supraventricular tachycardia	AOP Orphan Pharmaceuticals GmbH
102.	Relyvrio	sodium phenylbutyrate;taur ursodiol	混懸劑 Suspension	治療肌萎縮側索硬化症 To treat amyotrophic lateral sclerosis (ALS)	Amylyx Pharmaceuticals
103.	Revuforj	revumenib	片劑 Tablet	治療復發性或難治性急性白血病 To treat relapsed or refractory acute leukemia	Syndax Pharmaceuticals, Inc.
104.	Reyvow	lasmiditan	片劑 Tablet	治療偏頭痛 Treatment of migraine	Eli Lilly
105.	Rezdiffra	resmetirom	片劑 Tablet	治療成人非酒精性脂肪性肝炎和中晚期肝纖維化 To treat noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced liver scarring	Madrigal Pharmaceuticals, Inc.; UPM Pharmaceuticals

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
106.	Rezlidhia	olutasidenib	膠囊 Capsule	治療成人患有易感異檸檬酸脫氫酶-1 (IDH1) 突變的復發性或難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	注射劑 Injection	治療念珠菌血症和侵襲性念珠菌病 To treat candidemia and invasive candidiasis	Cidara Therapeutics Inc.; Seachaid Pharmaceuticals Inc.
108.	Riulvy	tegomil fumarate	膠囊 Capsule	治療 13 歲及以上兒童及成人復發緩解型的多發性硬化症 Treatment of adults and children from 13 years of age with relapsing remitting multiple sclerosis	Neuraxpharm Pharmaceuticals, S.L.
109.	Rivfloza	nedosiran	注射劑 Injection	用於降低 9 歲及以上兒童和成人 1 型原發性高草酸尿症(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	注射劑 Injection	治療 A 型血友病 Treatment of Hemophilia A	BioMarin Pharmaceutical Inc.
111.	Rolvedon	eflapegrastim	注射劑 Injection	降低接受骨髓抑制抗癌藥物的非髓系惡性腫瘤患者與發燒性中性粒細胞減少症相關的感染發生率 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	膠囊 Capsule	用於治療患有症狀性且手術切除可能會導致嚴重的功能障礙或疾病的惡化的髓鞘巨細胞瘤	Deciphera Pharmaceuticals, LLC

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 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	注射劑 Injection	治療全身性重症肌無力 Treatment of generalized myasthenia gravis	UCB Pharmaceuticals
114.	Rytelo	imetelstat	注射劑 Injection	治療患有低風險至中等-1 風險的骨髓增生異常綜合症 To treat low- to intermediate-1-risk myelodysplastic syndromes (MDS)	Geron Corporation; Catalent Indiana, LLC; Patheon Italia, S.p.A
115.	Ryzneuta	efbemalenograstim alfa	注射劑 Injection	治療嗜中性粒細胞減少症 To treat neutropenia	Evive Biotechnology Singapore Pte. Ltd.
116.	Sephience	sepiapterin	散劑 Powder	治療成人及兒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	注射劑 Injection	用於診斷結核分枝桿菌感染 To detect infection and disease caused by Mycobacterium tuberculosis	Serum Life Science Europe GmbH Bilthoven Biologicals B.V.
118.	Sofdra	sofpironium	凝膠 Gel	治療原發性腋窩多汗症 To treat primary axillary hyperhidrosis	Botanix SB Inc.
119.	Sohonos	palovarotene	膠囊 Capsule	減少患有進行性骨化性纖維發育不良的成人和兒童的異養骨化 To reduce the volume of new heterotopic ossification in adults and pediatric patients with fibrodysplasia ossificans progressiva (FOP)	Ipsen Biopharmaceuticals, Inc.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
120.	Sunlenca	lenacapavir	注射劑 Injection	治療因耐藥、不耐受或安全考慮而無法用其他可用治療方法的多重耐藥性 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	膠囊 Capsule	治療弗裏德裏希共濟失調 To treat Friedrich's ataxia	Reata Pharmaceuticals Inc.
122.	Talvey	talquetamab	注射劑 Injection	治療復發或難治性多發性骨髓瘤 To treat relapsed or refractory multiple myeloma	Janssen Biotech, Inc.
123.	Tecartus	brexucabtagene autoleucel	注射劑 Injection	治療復發性或難治性急性淋巴細胞白血病、復發性或難治性套細胞淋巴瘤 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	注射劑 Injection	治療成人不可切除或轉移性滑膜瘤 Treatment of adults with unresectable or metastatic synovial sarcoma	Adaptimmune, LLC
125.	Tibsovo	ivosidenib	片劑 Tablet	治療 IDH1 突變型急性粒細胞白血病、IDH1 突變型膽管癌 To treat IDH1-mutated AML、IDH1-mutated cholangiocarcinoma	Laboratoires Servier
126.	Tryngolza	olezarsen	注射劑 Injection	治療家族性高乳糜微粒血症綜合症 To treat familial chylomicronemia syndrome	Ionis Pharmaceuticals Inc.
127.	Tryptyr	acoltremon	眼用溶液 ophthalmic solution	治療乾眼症的徵象及症狀 To treat the signs and symptoms of dry eye disease	Alcon Inc.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
128.	Tryvio; Jeraygo	aprocitentan	片劑 Tablet	治療高血壓 To treat hypertension	Idorsia Pharmaceuticals US Inc.
129.	Tymlos; Eladynos	abaloparatide	注射劑 Injection	治療骨質疏鬆症 Treatment of osteoporosis	Radius Health Inc.
130.	Tziel	teplizumab	注射劑 Injection	延緩第 3 期 1 型糖尿病的發作 To delay the onset of stage 3 type 1 diabetes	Provention Bio Inc.
131.	Unloxcyt	cosibelimab	注射劑 Injection	治療皮膚鱗狀細胞癌 To treat cutaneous squamous cell carcinoma	Checkpoint Therapeutics, Inc.
132.	Vafseo	vadadustat	片劑 Tablet	治療慢性腎臟疾病導致之貧血 To treat anemia due to chronic kidney disease	Akebia Therapeutics, Inc.
133.	Vanflyta	quizartinib	片劑 Tablet	治療急性髓細胞白血病 Treatment for newly diagnosed acute myeloid leukemia	Daichi Sankyo, Inc.
134.	Vanrafia	atrasentan	片劑 Tablet	用於降低病情具快速進展風險且患有原發性免疫球蛋白 A 腎病成人的蛋白尿 To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression	Novartis Pharmaceuticals Corporation
135.	Veopoz	pozelimab	注射劑 Injection	治療 1 歲及以上患者的 CD55 缺乏蛋白丟失性腸病 (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	片劑 Tablet	治療更年期引起的中度至重度潮熱 To treat moderate to severe hot flashes caused by menopause	Ogeda SA ; Astellas Pharma Inc.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
137.	Vivjoa	oteseconazole	膠囊 Capsule	降低有復發性外陰陰道念珠菌病(RVVC)病史且無生殖潛力的女性的 RVVC 發病率 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	膠囊 Capsule	治療血小板低的成人中度或高危原發性或繼發性骨髓纖維化 To treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets	CTI BioPharma
139.	Voydeya	danicopan	片劑 Tablet	治療陣發性夜間血紅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	治療斑塊狀銀屑病 To treat plaque psoriasis	Dermavant Sciences
141.	Vyjuvek	beremagene geperpavec	混懸劑、凝膠 Suspension, Gel	治療患有營養不良性大皰性表皮松解症且伴有 VII 型膠原α1 鏈(COL7A1)基因突變的患者的傷口 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	注射劑 Injection	治療胃及胃食管交界處腺癌 To treat gastric or gastroesophageal junction adenocarcinoma	Astellas Pharma US, Inc.
143.	Vyvgart	efgartigimod alfa	注射劑 Injection	治療全身性重症肌無力 To treat generalized myasthenia gravis	Argenx BV

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
144.	Wainua; Wainzua	eplontersen	注射劑 Injection	治療遺傳性轉甲狀腺素蛋白介導的澱粉樣變性多發性神經病 To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis	AstraZeneca Pharmaceuticals LP
145.	Xacduro	sulbactam; durlobactam	注射劑 Injection	治療由鮑曼不動桿菌-醋酸鈣複合體敏感分離株引起的醫院獲得性細菌性肺炎和呼吸機相關細菌性肺炎 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	吸入製劑 Inhalation	輔助評估肺功能及肺部成像 To evaluate pulmonary function and imaging	Polarean Inc.
147.	Xenpozyme	olipudase alfa	注射劑 Injection	治療酸性鞘磷脂酶缺乏症 To treat acid sphingomyelinase deficiency	Sanofi S.A.
148.	Xolremdi	mavorixafor	膠囊 Capsule	治療 WHIM 綜合症 To treat WHIM syndrome	X4 Pharmaceuticals, Inc.
149.	Yorvipath	palopegteriparatide	注射劑 Injection	治療副甲狀腺功能低下症 To treat hypoparathyroidism	Ascendis Pharma Bone Diseases A/S
150.	Yselyt	linzagolix	片劑 Tablet	治療子宮肌瘤 To treat uterine fibroids	Theramex Ireland Limited
151.	Zavzpret	zavegepant	噴劑 Spray	治療偏頭痛 To treat migraine	Pfizer Inc.
152.	Zelsuvmi	berdazimer	凝膠 Gel	治療傳染性軟疣 To treat molluscum contagiosum	EPIH SPV, LLC

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
153.	Ziihera ; 百赫安 ; 注射用澤尼達妥單抗	zanidatamab	注射劑 Injection	用於既往接受過治療的 HER2 高表達的不可切除局部晚期或轉移性膽道癌患者 Treatment of adults with previously treated, unresectable locally advanced or metastatic HER2-positive biliary tract cancer	Jazz Pharmaceuticals Ireland Limited ; 百濟神州 (蘇州) 生物科技股份有限公司
154.	Zilbrysq	zilucoplan	注射劑 Injection	治療抗乙酰膽鹼受體抗體陽性的成人患者的全身性重症肌無力 To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive	UCB, Inc.
155.	Zokinvy	lonafarnib	膠囊 Capsule	治療哈欽森-吉爾福德早衰綜合症 Treatment of Hutchinson-Gilford progeria syndrome	Eiger Biopharmaceuticals
156.	Ztalmy	ganaxolone	混懸劑 Suspension	治療細胞周期蛋白依賴性激酶樣 5 缺乏症的癲癇發作 To treat seizures in cyclin-dependent kinase-like 5 deficiency disorder	Marinus Pharmaceuticals Inc.; Purdue Neuroscience Corp
157.	Zurzuvae	zuranolone	膠囊 Capsule	治療產後抑鬱症 To treat postpartum depression	Biogen Inc.
158.	Zynlonta	loncastuximab tesirine	注射劑 Injection	治療彌漫性大 B 細胞淋巴瘤 (DLBCL)及高級別 B 細胞淋巴瘤 (HGBL) To treat diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBCL)	ADC Therapeutics SA
159.	Zynyz	retifanlimab	注射劑 Injection	治療轉移性或復發性局部晚期默克爾細胞癌 To treat metastatic or recurrent locally advanced Merkel cell carcinoma	Incyte Corp ; MacroGenics Inc.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
160.	戈芮寧；注射用維拉 昔酶β	velaglucerase β	注射劑 Injection	用於 12 歲及以上青少年和成人 I 型和 III 型戈謝病患 者的長期酶替代治療 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
161.	地達西尼膠囊	dimdazenil	膠囊 Capsule	失眠的短期治療 Short-term treatment of insomnia	浙江京新藥業股份有限公司
162.	因他瑞；林普利塞片	linperlisib	片劑 Tablet	治療復發性或難治性濾泡性淋巴瘤成人患者 Treatment of adults with relapsed or refractory follicular lymphoma	上海瓊黎藥業有限公司
163.	艾比特；蘋果酸法米 替尼膠囊	famitinib malate	膠囊 Capsule	聯合注射用卡瑞利珠單抗用於既往接受含鉑化療治療 失敗但未接受過貝伐珠單抗治療的復發或轉移性宮頸 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	江蘇恒瑞醫藥股份有限公司
164.	艾心安；注射用瑞凱 西單抗	recaticimab	注射劑 Injection	在控制飲食的基礎上，與他汀類藥物、或者與他汀類 藥物及其它降脂療法聯合用藥，用於接受中等或以上 劑量他汀類藥物治療仍無法達到低密度脂蛋白膽固醇 (LDL-C)目標的原發性高膽固醇血症和混合型血脂異常 的成人患者；單藥用於非家族性高膽固醇血症和混合 型血脂異常的成人患者，以降低低密度脂蛋白膽固醇 (LDL-C)、總膽固醇(TC)、載脂蛋白 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,	廣東恒瑞醫藥有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
				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.	艾速達；硫酸艾瑪昔替尼片	ivarmacitinib sulfate	片劑 Tablet	用於對一種或多種 TNF 抑制劑療效不佳或不耐受的活動性強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	江蘇恒瑞醫藥股份有限公司
166.	艾瑞凱；戈來雷塞片	glecirasib	片劑 Tablet	用於至少接受過一種系統性治療的 KRAS G12C 突變型的晚期非小細胞肺癌(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	上海艾力斯醫藥科技股份有限公司
167.	汝佳寧；鹽酸來羅西利片	lerociclib hydrochloride	片劑 Tablet	用於激素受體陽性、人表皮生長因子受體 2 陰性局部晚期或轉移性乳腺癌成人患者；與芳香化酶抑制劑聯合使用作為初始內分泌治療；與氟維司群聯合用於既往接受內分泌治療後疾病進展的患者 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.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
168.	伊速達；瑪舒拉沙韋片	suraxavir marboxil	片劑 Tablet	用於既往健康的 12 歲及以上青少年和成人單純性甲型和乙型流感患者的治療，不包括存在流感相關併發症高風險的患者 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.	江西科睿藥業有限公司
169.	伏羅尼布片	vorolanib	片劑 Tablet	與依維莫司聯合，用於既往接受過酪氨酸激酶抑制劑治療失敗的晚期腎細胞癌患者 In combination with everolimus, for patients with advanced renal cell carcinoma who have failed prior treatment with a tyrosine kinase inhibitor	貝達藥業股份有限公司
170.	先諾欣； 先諾特韋片/利托那韋片	ritonavir;simnotrelvir	片劑 Tablet	治療新冠病毒感染 Treatment of COVID-19 infection	先聲藥業有限公司
171.	安久衛； 安奈拉唑鈉腸溶片	anaprazole sodium	片劑 Tablet	治療十二指腸潰瘍 Treatment of duodenal ulcer	軒竹生物科技股份有限公司
172.	安洛晴；枸橼酸依奉阿克膠囊	envonalkib	膠囊 Capsule	治療未經過間變性淋巴瘤激酶抑制劑治療的 ALK 陽性的局部晚期或轉移性非小細胞肺癌 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	正大天晴藥業集團股份有限公司
173.	安佑平；菲諾利單抗注射液	finotonlimab	注射劑 Injection	與含鉑化療聯合用於復發性和/或轉移性頭頸部鱗狀細胞癌 Treatment of recurrent and/or metastatic head and neck squamous cell carcinoma in combination with platinum-based chemotherapy	神州細胞工程有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
174.	安方寧；格索雷塞片	garsorasib	片劑 Tablet	用於治療已接受過至少一種全身治療的成人 KRAS G12C 突變的局部晚期或轉移性非小細胞肺癌 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	上海正大天晴醫藥科技開發有限公司
175.	安達靜；夫那奇珠單抗注射液	vunakizumab	注射劑 Injection	治療適合系統治療或光療的中度至重度斑塊狀銀屑病成人患者 Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	蘇州盛迪亞生物醫藥有限公司
176.	安睿威；昂拉地韋片	onradivir	片劑 Tablet	用於成人單純性甲型流感患者的治療 Treatment of adult patients with simple influenza A	廣東眾生睿創生物科技有限公司
177.	沙艾特；注射用埃普奈明	aponermin	注射劑 Injection	治療接受過至少 2 種系統性治療方案的復發或難治性多發性骨髓瘤成人患者 Treatment of adult patients with relapsed or refractory multiple myeloma after two or more systemic therapies	武漢海特生物製藥股份有限公司
178.	阿茲夫定片	azvudine	片劑 Tablet	治療新冠病毒感染 Treatment of COVID-19 infection	河南真實生物科技有限公司
179.	阿得貝利單抗注射液	adebrelimab	注射劑 Injection	治療小細胞肺癌 Treatment of small cell lung cancer	江蘇恒瑞醫藥股份有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
180.	貝塔寧；枸橼酸倍維巴肽注射液	bevifibatide citrate	注射劑 Injection	用於進行經皮冠狀動脈介入術（包括進行冠狀動脈內支架置入術）的急性冠脈綜合症患者，以降低急性閉塞、支架內血栓、無復流和慢血流發生的風險 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	百奧泰生物製藥股份有限公司
181.	伯瑞替尼腸溶膠囊	bozitinib	膠囊 Capsule	治療具有間質-上皮轉化因子（MET）外顯子 14 跳變的局部晚期或轉移性非小細胞肺癌患者 To treat patients with MET exon 14 skipping non-small cell lung cancer (NSCLC)	北京浦潤奧生物科技有限責任公司
182.	君適達；昂戈瑞西單抗注射液	ongerlicimab	注射劑 Injection	在控制飲食的基礎上，與他汀類藥物、或者與他汀類藥物和依折麥布聯合用藥，用於在接受中等劑量或中等劑量以上他汀類藥物治療，仍無法達到低密度脂蛋白膽固醇（LDL-C）目標的原發性高膽固醇血症（非家族性）和混合型血脂異常的成人患者 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	上海君實生物醫藥科技股份有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
183.	依達方； 依沃西單抗注射液	ivonescimab	注射劑 Injection	聯合培美曲塞和卡鉑，用於經表皮生長因子受體酪氨酸激酶抑制劑治療後進展的 EGFR 基因突變陽性的局部晚期或轉移性非鱗狀非小細胞肺癌 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	康方賽諾醫藥有限公司
184.	東英賀；艾考磷布韋片	encofosbuvir	片劑 Tablet	與磷酸萘坦司韋膠囊聯用，治療初治或經干擾素治療的基因 1、2、3、6 型成人慢性丙型肝炎病毒感染，可合併或不合併代償性肝硬化 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	宜昌東陽光長江藥業股份有限公司
185.	東衛卓；磷酸萘坦司韋膠囊	netanasvir phosphate	膠囊 Capsule	用於與艾考磷布韋片聯用，治療初治或經干擾素治療的基因 1、2、3、6 型成人慢性丙型肝炎病毒感染，可合併或不合併代償性肝硬化 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	廣東東陽光藥業股份有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
186.	佳泰萊；蘆康沙妥珠單抗注射液	sacituzumab tirumotecan	注射劑 Injection	用於既往至少接受過 2 種系統治療（其中至少 1 種治療針對晚期或轉移性階段）的不可切除的局部晚期或轉移性三陰性乳腺癌成人患者 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	四川科倫博泰生物醫藥股份有限公司
187.	金立希；賽立奇單抗注射液	xeligekimab	注射劑 Injection	治療適合系統治療或光療的中度至重度斑塊狀銀屑病成人患者 Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	重慶智翔金泰生物製藥股份有限公司
188.	思美寧； 苯磺酸克利加巴林膠囊	crisugabalin besilate	膠囊 Capsule	治療糖尿病性周圍神經病理性疼痛 To treat peripheral neuropathic pain	海思科醫藥集團股份有限公司
189.	思舒靜；安瑞克芬注射液	anrikefon	注射劑 Injection	用於治療腹部手術後的輕至中度疼痛 Treatment of mild to moderate pain following abdominal surgery	海思科醫藥集團股份有限公司
190.	派舒寧；塞納帕利膠囊	senaparib	膠囊 Capsule	用於晚期上皮性卵巢癌、輸卵管癌或原發性腹膜癌成人患者在一線含鉑化療達到完全緩解或部分緩解後的維持治療 Maintenance treatment of adult patients with 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	上海英派藥業有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
191.	科泰萊；塔戈利單抗注射液	tagitanlimab	注射劑 Injection	用於既往接受過二線及以上化療失敗的復發或轉移性鼻咽癌患者的治療 Treatment of patients with recurrent or metastatic nasopharyngeal cancer (NPC) who have previously failed second-line or higher chemotherapy	四川科倫博泰生物醫藥股份有限公司
192.	科露平；妥拉美替尼膠囊	tunlametinib	膠囊 Capsule	Treatment of advanced melanoma carrying neuroblastoma ras viral oncogene homolog (NRAS) mutations who have previously undergone PD-1/PD-L1 treatment 治療曾接受抗 PD-1/PD-L1 治療的 NRAS 突變的晚期黑色素瘤患者	上海科州藥物研發有限公司
193.	津立生；納盧梭拜單抗注射液	narlumosbart	注射劑 Injection	治療不可手術切除或手術切除可能導致嚴重功能障礙的骨巨細胞瘤成人患者 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
194.	信立汀；苯甲酸福格列汀片	fotagliptin benzoate	片劑 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	深圳信立泰藥業股份有限公司
195.	信立安；戊二酸利那拉生酯膠囊	linaprazan glurate	膠囊 Capsule	用於反流性食管炎 Treatment of gastroesophageal reflux disease	上海生諾醫藥科技有限公司
196.	信玖凝；波脈達可基注射液	dalnacogene ponparvovec	注射劑 Injection	治療中重度 B 型血友病成年患者 Treatment of adult patients with moderate to severe hemophilia B	上海信致醫藥科技有限公司
197.	信爾美；瑪仕度肽注射液 [#]	mazdutide	注射劑 Injection	用於在控制飲食和增加體力活動基礎上對成人患者的長期體重控制，初始體重指數（BMI）為：BMI≥28	信達生物製藥（蘇州）有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
				kg/m ² (肥胖); 或 BMI≥24 kg/m ² (超重) · 並伴有至少一種體重相關的合併症 (例如高血糖、高血壓、血脂異常、脂肪肝、阻塞性睡眠呼吸暫停綜合症等) As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial Body Mass Index (BMI) of BMI≥28 kg/m ² (obesity) or BMI≥24 kg/m ² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hyperglycemia, hypertension, dyslipidemia, fatty liver, or obstructive sleep apnea syndrome and etc.)	
198.	重組人源 抗狂犬病毒單抗	ormutivimab	注射劑 Injection	治療狂犬病病毒感染 Treatment of rabies virus infection	華北製藥集團新藥研究開發有 限責任公司
199.	佩金；拓培非格司亭 注射液	telpegfilgrastim	注射劑 Injection	降低非髓性惡性腫瘤患者在接受容易引起發熱性中性粒細胞減少症的骨髓抑制性抗癌藥物治療時以發熱性中性粒細胞減少症為表現的感染發生率 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.	廈門特寶生物工程股份有限公 司
200.	倍長平；考格列汀片	cofroglipatin	片劑 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	海思科醫藥集團股份有限公司
201.	倍穩； 鹽酸凱普拉生片	keverprazan hydrochloride	片劑 Tablet	治療十二指腸潰瘍、反流性食管炎 Treatment of duodenal ulcer, reflux esophagitis	江蘇柯菲平醫藥股份有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
202.	海納安；氈恩紫魯胺軟膠囊	deuzenlutamide	膠囊 Capsule	用於接受醋酸阿比特龍及化療後出現疾病進展，且既往未接受新型雄激素受體抑制劑的轉移性去勢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	海創藥業股份有限公司
203.	海益坦；谷美替尼片	glumetinib	片劑 Tablet	用於具有間質-上皮轉化因子外顯子 14 跳變的局部晚期或轉移性非小細胞肺癌 Treatment of patients with locally advanced or metastatic non-small cell lung cancer with MET exon 14 skipping mutation METex14	上海海和藥物研究開發股份有限公司
204.	高瑞哲；戈利昔替尼膠囊	golidocitinib	膠囊 Capsule	既往至少接受過一線系統性治療的復發或難治的外周 T 細胞淋巴瘤 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（江蘇）醫藥股份有限公司
205.	軒悅寧；吡洛西利片	bireociclib	片劑 Tablet	用於激素受體陽性、人表皮生長因子受體 2 陰性的晚期或轉移性乳腺癌成人患者；與氟維司群聯合用於既往接受內分泌治療後出現疾病進展的患者；單藥用於既往轉移性階段接受過兩種及以上內分泌治療和一種化療後出現疾病進展的患者 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	軒竹生物科技股份有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
				have progressed after receiving two or more endocrine therapies and one chemotherapy in the metastatic stage	
206.	盛捷維；磷酸森格列汀片	cetagliptin phosphate	片劑 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	盛世泰科生物醫藥技術（蘇州）股份有限公司
207.	啓欣可；伊魯阿克片	iruplinalkib	片劑 Tablet	既往接受過克唑替尼治療後疾病進展或對克唑替尼不耐受的間變性淋巴瘤激酶（ALK）陽性的局部晚期或轉移性非小細胞肺癌（NSCLC）患者的治療 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	齊魯製藥有限公司
208.	培莫沙肽注射液	pegmolesatide	注射劑 Injection	治療慢性腎病引起的貧血 Treatment of anemia due to chronic kidney disease	江蘇豪森藥業集團有限公司
209.	康悅達；普奇拜單抗注射液	stapokibart	注射劑 Injection	治療中度至重度異位性皮膚炎 Treatment of moderate to severe atopic dermatitis	成都康諾行生物醫藥科技有限公司
210.	惠優靜；脯氨酸加格列淨片	henagliflozin	片劑 Tablet	單藥治療或與鹽酸二甲雙胍聯合使用改善成人 2 型糖尿病患者的血糖控制 Monotherapy or as add-on therapy to metformin to improve glycemic control	惠升生物製藥股份

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
211.	達伯樂；己二酸他雷替尼膠囊	taletrectinib	膠囊 Capsule	用於經 ROS1-TKI 治療後進展的 ROS1 陽性局部晚期或轉移性非小細胞肺癌（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	葆元生物醫藥科技（杭州）有限公司
212.	舒沃哲；舒沃替尼片	sunvozertinib	片劑 Tablet	治療帶有表皮生長因子受體外顯子 20 插入突變型的局部晚期或轉移性非小細胞肺癌的成人患者 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（江蘇）醫藥股份有限公司
213.	複邦德；艾諾米替片	ainuovirine; lamivudine; tenofovir disoproxil fumarate	片劑 Tablet	治療未接受過治療的 HIV-1 感染成人患者 Treatment of treatment-naïve adults with HIV-1 infection	江蘇艾迪藥業股份有限公司
214.	復妥寧；枸橼酸伏維西利膠囊	fovinaciclib citrate	膠囊 Capsule	聯合氟維司群，適用於既往接受內分泌治療後出現疾病進展的激素受體陽性、人表皮生長因子 2 陰性的復發或轉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	錦州奧鴻藥業有限責任公司
215.	普佑恒；普特利單抗注射液	pucotenlimab	注射劑 Injection	治療 MSI-H 或 dMMR 實體瘤；黑色素瘤 Treatment of MSI-H or dMMR solid tumors; melanoma	樂普生物科技股份有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
216.	華堂寧； 多格列艾汀片	dorzagliatin	片劑 Tablet	治療 2 型糖尿病 Treatment of Type 2 diabetes	華領醫藥技術（上海）有限公司
217.	開坦尼； 卡度尼利單抗注射液	cadonilimab	注射劑 Injection	治療宮頸癌 To treat cervical cancer	康方藥業有限公司
218.	景助達； 恩替司他片	entinostat	片劑 Tablet	聯合芳香化酶抑制劑用於治療激素受體陽性、人類表皮生長因子受體-2 陰性，經內分泌治療復發或進展的局部晚期或轉移性乳腺癌 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	泰州億騰景昂藥業股份有限公司
219.	奧壹新；利厄替尼片	limertinib	片劑 Tablet	用於既往經表皮生長因子酪氨酸激酶抑制劑治療時或治療後出現疾病進展，並且經檢測確認存在 EGFR T790M 突變陽性的局部晚期或轉移性非小細胞肺癌 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	江蘇奧賽康藥業有限公司
220.	奧特康唑膠囊	oteseconazole	膠囊 Capsule	治療重度外陰陰道假絲酵母菌病（VVC） To treat vulvovaginal candidiasis (VVC)	eVENUS Pharmaceutical Laboratories Inc.

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
221.	愛達羅；依若奇單抗注射液	ebdarokimab	注射劑 Injection	治療成人中度至重度斑塊狀銀屑病 Treatment of moderate-to-severe plaque psoriasis in adult	中山康方生物醫藥有限公司
222.	新舒沐；甲磺酸普雷福韋片	pradefovir mesylate	片劑 Tablet	治療成人慢性乙型肝炎 Treatment of adult patients with chronic hepatitis B infection	西安葛藍新通製藥有限公司
223.	新替妥；斯泰度塔單抗注射液	siltartoxatug	注射劑 Injection	用於破傷風緊急預防 Emergency prevention of post-traumatic tetanus	珠海泰諾麥博製藥股份有限公司
224.	善澤平；普盧格列汀片	prusogliptin	片劑 Tablet	用於改善成人 2 型糖尿病患者的血糖控制 To improve glycemic control in patients with type 2 diabetes mellitus	石藥集團歐意藥業有限公司
225.	瑞必達； 甲磺酸瑞齊替尼膠囊	rezivertinib	膠囊 Capsule	用於既往經表皮生長因子受體酪氨酸激酶抑制劑治療時或治療後出現疾病進展，並且經檢測確認存在 EGFR T790M 突變陽性的局部晚期或轉移性非小細胞肺癌 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	上海倍而達藥業有限公司
226.	瑞坦寧；注射用磷羅拉匹坦帕洛諾司瓊	fosrclonazepam palonosetron	注射劑 Injection	用於預防成人高度致吐性化療引起的急性和遲發性噁心及嘔吐 prevention of acute and delayed nausea and vomiting caused by highly emetogenic chemotherapy (HEC) in adults	福建盛迪醫藥有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
227.	瑞格列汀二甲雙胍片	retagliptin; metformin	片劑 Tablet	用於改善成人 2 型糖尿病患者的血糖控制 To improve glycemic control in patients with type 2 diabetes mellitus	山東盛迪醫藥有限公司
228.	瑞維魯胺片	rezvolutamide	片劑 Tablet	治療高腫瘤負荷的轉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	江蘇恒瑞醫藥股份有限公司
229.	聖瑞沙；甲磺酸瑞厄替尼片	rilertinib mesylate	片劑 Tablet	用於既往經表皮生長因子受體酪氨酸激酶抑制劑治療時或治療後出現疾病進展，並且經檢測確認存在 EGFR T790M 突變陽性的局部晚期或轉移性非小細胞肺癌 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	南京聖和藥業股份有限公司
230.	聖諾迪；奧磷布韋片	alfosbuvir	片劑 Tablet	治療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)	南京聖和藥業股份有限公司
231.	漢斯狀；斯魯利單抗注射液	serplulimab	注射劑 Injection	治療鱗狀非小細胞肺癌、轉移性非鱗狀非小細胞肺癌、晚期實體瘤 Treatment of squamous non-small cell lung cancer; metastatic non-squamous non-small cell lung cancer; advanced solid tumors	上海復宏漢霖生物技術股份有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
232.	邁粒生；注射用阿格司亭α	albipagrastim alfa	注射劑 Injection	用於成年非髓性惡性腫瘤患者在接受容易引起發熱性中性粒細胞減少症的骨髓抑制性抗癌藥物治療時，降低以發熱性中性粒細胞減少症為表現的感染發生率 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	江蘇泰康生物醫藥有限公司
233.	睿鉑生；艾米邁托賽注射液	amimestrocel	注射劑 Injection	用於治療 14 歲以上消化道受累為主的激素治療失敗的急性移植抗宿主病 Treatment of patients over 14 years old with acute graft-versus-host disease with predominant gastrointestinal involvement who have failed hormone therapy	鉑生卓越生物科技（北京）有限公司
234.	澤普平；鹽酸吉卡昔替尼片	gecacitinib hydrochloride	片劑 Tablet	用於中危或高危骨髓纖維化包括原發性骨髓纖維化、真性紅細胞增多症繼發性骨髓纖維化及原發性血小板增多症繼發性骨髓纖維化的成人患者 Treatment of intermediate- and high-risk myelofibrosis, including primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF), and post-essential thrombocythemia myelofibrosis (PET-MF)	蘇州澤璟生物製藥股份有限公司
235.	澤瑞尼；鹽酸佐利替尼片	zorifertinib hydrochloride	片劑 Tablet	用於具有表皮生長因子受體（EGFR）19 號外顯子缺失或外顯子 21（L858R）置換突變，並伴有中樞神經系統（CNS）轉移的局部晚期或轉移性非小細胞肺癌	江蘇晨泰醫藥科技有限公司

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥企 Pharmaceutical company
				(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	
236.	賽美納；甲磺酸貝福替尼膠囊	befotertinib	膠囊 Capsule	治療 EGFR T790M 突變陽性的轉移性非小細胞肺癌 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
237.	賽愷澤；澤沃基奧侖賽注射液	zevorcabtagene autoleucel	注射劑 Injection	治療復發性或難治性多發性骨髓瘤 To Treat relapsed/refractory multiple myeloma (RRMM)	科濟生物醫藥（上海）有限公司
238.	鹽酸凱普拉生注射液；鹽酸凱普拉生片	carenaprazan hydrochloride	片劑；注射劑 Tablet, Injection	治療十二指腸潰瘍、反流性食道炎 Treatment of duodenal ulcer, reflux esophagitis	江蘇柯菲平醫藥股份有限公司

*按商品名稱的字母/筆劃排序

資料截至：6/2025

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