

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.	Adquey	difamilast	油膏 Ointment	治療輕至中度異位性皮膚炎 To treat mild to moderate atopic dermatitis	Acrotech Biopharma
3.	Adstiladrin	nadofaragene firadenovec	混懸劑 Suspension	用於治療對卡介苗無反應的高風險非肌肉侵犯性膀胱癌 伴有或無乳突狀瘤的原位癌的成年患者 Treatment of adult patients with high-risk Bacillus Calmette Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors	Ferring Pharmaceuticals
4.	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
5.	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.
6.	Alyftrek	Vanzacaftor; tezacaftor; deutivacaftor	片劑 Tablet	治療囊性纖維化 To treat cystic fibrosis	Vertex Pharmaceuticals Incorporated
7.	Agamree	vamorolone	溶液劑 Solution	治療裘馨氏肌肉失養症 To treat Duchenne muscular dystrophy	Santhera Pharmaceuticals
8.	Ambelvist	gadoquatane	注射劑 Injection	與 MRI 結合使用，用於檢測和顯像具有異常血管生成的病灶	Bayer HealthCare Pharmaceuticals, Inc.

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				To detect and visualize lesions with abnormal vascularity, in conjunction with MRI	
9.	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	Alnylam Pharms Inc.
10.	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
11.	Anktiva	nogapendekin alfa	注射劑 Injection	治療膀胱癌 To treat bladder cancer	Altor BioScience, LLC
12.	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.
13.	Aqvesme	mitapivat	片劑 Tablet	用於成人 α -或 β -地中海貧血的貧血治療 Treatment of anemia in adults with alpha- or beta-thalassemia	Agios Pharmaceuticals, Inc.
14.	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.
15.	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 leukemia	Autolus GmbH
16.	Avlayah	tividenofusp alfa	注射劑 Injection	用於治療在出現症狀前或已出現症狀且體重至少為 5 公斤的兒科患者中發生的亨特綜合症（粘多糖病 II 型）的神經表現	Denali Therapeutics Inc.

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				Treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment	
17.	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
18.	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
19.	Baxfendy	baxdrostat	膠囊 Capsule	與其他降壓藥合併治療、用於降低對藥物控制不足的成人高血壓 Treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other agents	Corcept Therapeutics Incorporated
20.	Beqvez	fidanacogene elaparvec	注射劑 Injection	治療 B 型血友病 Treatment of hemophilia B	Pfizer Inc.
21.	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.
22.	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.

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23.	Blujepa	gepotidacin	片劑 Tablet	治療非複雜性尿路感染 To treat uncomplicated urinary tract infections	GlaxoSmithKline
24.	Boey	trenibotulinumtoxinE	注射劑 Injection	用於暫時改善成年患者在皺眉時眉間出現的中度至重度皺紋 (眉間紋) · 尤其適用於對心理健康造成嚴重影響的患者 For the temporary improvement in the appearance of moderate to severe lines between the eyebrows seen at maximum frown (glabellar lines), when these have an important psychological impact in adult patients	AbbVie Limited
25.	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.
26.	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)
27.	Brinsupri	brensocatib	片劑 Tablet	治療非纖維囊腫型支氣管擴張 To treat non-cystic fibrosis bronchiectasis	Insmad Incorporated
28.	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.
29.	Bysanti	milsaperidone	片劑 Tablet	用於治療精神分裂症 · 以及治療與雙極性障礙第一型相關的躁症或混合發作 To treat schizophrenia and to treat manic or mixed episodes associated with bipolar I disorder	Vanda Pharmaceuticals, Inc.
30.	Cardamyst	etripamil	吸入製劑 Inhalation	治療陣發性室上性心搏過速 To treat episodes of paroxysmal supraventricular tachycardia	Milestone Pharmaceuticals Inc.

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31.	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.
32.	Casgevy	exagamglogene autotemcel	注射劑 Injection	用於治療β-地中海貧血及鐮刀型紅血球疾病 Treatment of beta thalassemia and sickle cell disease	Vertex Pharmaceuticals (Ireland) Limited
33.	Cenrifki	tolebrutinib	片劑 Tablet	用於治療成人繼發進展型多發性硬化症 Treatment of adult patients with secondary progressive multiple sclerosis (SPMS)	Sanofi Winthrop Industrie
34.	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.
35.	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.
36.	Cypsedo	cipepofol	注射劑 Injection	用於成人手術中的全身麻醉誘導 For induction of general anesthesia in adults undergoing surgery	Haisco-USA Pharmaceuticals, Inc.
37.	Dawnzera	donidalorsen	注射劑 Injection	用於預防遺傳性血管性水腫的發作 To prevent attacks of hereditary angioedema	Ionis Pharmaceuticals Inc.
38.	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	Revance Therapeutics Inc.

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				To treat moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity	
39.	Daybue	trofinetide	溶液劑 Solution	治療雷特綜合症 To treat Rett syndrome	Acadia Pharmaceuticals Inc.
40.	Decnupaz	pivekimab sunirine	注射劑 Injection	治療成人母細胞性漿細胞樣樹突狀細胞腫瘤 Treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN)	AbbVie Inc.
41.	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.
42.	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
43.	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
44.	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
45.	Ekterly	sebetralstat	片劑 Tablet	治療遺傳性血管性水腫急性發作 To treat acute attacks of hereditary angioedema	KalVista Pharmaceuticals, Inc.

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46.	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.
47.	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.
48.	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
49.	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.
50.	Enflonsia ; 安福暢 ; 克萊羅韋單抗注射液	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
51.	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.
52.	Enzeshu ; 恩澤舒 ; 注射用蘇維西塔單抗	suvemcitug (sevacizumab)	注射劑 Injection	聯合紫杉醇、多柔比星脂質體或拓撲替康用於鉑耐藥後接受過不超過 1 種系統治療的成人復發性卵巢癌、輸卵管癌或原發性腹膜癌	江蘇先聲生物製藥有限公司

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				Treating recurrent ovarian cancer, fallopian tube cancer, or primary peritoneal cancer in combination with paclitaxel, liposomal doxorubicin, or topotecan in adults who have received at least one systemic therapy after platinum resistance	
53.	Etcamah	camizestrant	片劑 Tablet	與 CDK 4/6 抑制劑聯合使用，用於治療檢測到 ESR1 突變，並且在接受一線內分泌治療聯合 CDK4/6 抑制劑治療期間未出現疾病進展的雌激素受體陽性、HER2 陰性的局部晚期或轉移性乳腺癌成年患者 In combination with a CDK4/6 inhibitor, for the treatment of adult patients with ER-positive, HER2-negative, locally advanced or metastatic breast cancer upon detection of ESR1-mutation and without disease progression during first-line endocrine therapy in combination with a CDK4/6 inhibitor	AstraZeneca AB
54.	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
55.	Exdensur	depemokimab	注射劑 Injection	作為附加的維持治療，用於治療以嗜酸性粒細胞表型為特徵的重度哮喘 To treat severe asthma characterized by an eosinophilic phenotype as an add-on maintenance therapy	GSK
56.	Exxua	gepirone	片劑 Tablet	治療憂鬱症 To treat major depressive disorder	Mission Pharmacal Company
57.	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

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58.	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. ; Traverse Therapeutics Inc. ; Bristol Myers Squibb
59.	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
60.	Foundayo	orforglipron	片劑 Tablet	用於肥胖成人，或伴隨至少一種體重相關共病的超重成人，減少多餘體重並長期維持減重效果，須併用低熱量飲食及增加身體活動。 To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition, in combination with a reduced-calorie diet and increased physical activity	Eli Lilly and Company
61.	Frehemgo [#]	denecimig	注射劑 Injection	預防血友病 A 患者的出血事件 Prophylaxis of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency)	Novo Nordisk A/S
62.	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
63.	Gomekli	mirdametininib	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.

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64.	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
65.	Hemgenix	etranacogene dezaparvovec	注射劑 Injection	治療 B 型血友病 Treatment of hemophilia B	CSL Behring LLC
66.	Hernexeos	zongertinib	片劑 Tablet	用於治療具有 HER2 酪氨酸激酶結構域激活突變且已接受過全身治療的不可切除或轉移性非鱗狀非小細胞肺癌成人患者 To treat adults with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy	Boehringer Ingelheim Pharmaceuticals, Inc.
67.	Hyrnuo	sevabertinib	片劑 Tablet	治療腫瘤具有 HER2 酪氨酸激酶結構域活化突變，且已接受過全身性治療的局部晚期或轉移性非鱗狀非小細胞肺癌患者 To treat locally advanced or metastatic non-squamous non-small cell lung cancer with tumors that have activating HER2 tyrosine kinase domain activating mutations in patients who received a systemic therapy	Bayer HealthCare Pharmaceuticals, Inc.
68.	Icotyde	icotrokinra	片劑 Tablet	用於治療 12 歲及以上、體重至少 40 公斤且適合接受全身治療或光療的中度至重度斑塊型銀屑病成人及青少年患者	Janssen Biotech, Inc.

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				To treat moderate-to-severe plaque psoriasis in patients 12 years and older who weigh at least 40 kg and who are candidates for systemic therapy or phototherapy	
69.	Idvynso	doravirine, islatravir	片劑 Tablet	用於治療成人 HIV-1 感染 To treat HIV-1 infection	Merck
70.	Imaavy ; 安力威 ; 尼卡利單抗注射液	nipocalimab	注射劑 Injection	治療全身性重症肌無力 To treat generalized myasthenia gravis	Janssen Biotech, Inc.
71.	Inpefa	sotagliflozin	片劑 Tablet	治療心臟衰竭 To treat heart failure	Lexicon Pharms Inc.
72.	Inluriyo ; 擇叙 ; 甲苯磺酸依侖司群片	imlunestrant	片劑 Tablet	用於治療經至少一線內分泌治療後出現疾病進展的雌激素受體陽性 (ER+)、人類表皮生長因子受體 2 陰性 (HER2-)、雌激素受體 1 (ESR1) 突變的晚期或轉移性乳癌 To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, estrogen receptor-1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	Eli Lilly Nederland B.V.
73.	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
74.	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.
75.	Isembyld [#]	apitegromab	注射劑 Injection	用於正在接受 SMN2 靶向藥物治療的 2 歲及以上兒童和成人脊髓性肌萎縮症患者 To treat spinal muscular atrophy in adults and pediatric patients 2 years of age and older who are currently receiving an SMN2-targeted treatment	Scholar Rock, Inc.

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76.	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
77.	Jascayd ; 博優維 ; 那米司特片	nerandomilast	片劑 Tablet	治療特發性肺纖維化 To treat idiopathic pulmonary fibrosis	Boehringer Ingelheim Pharmaceuticals, Inc.
78.	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
79.	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
80.	Jideytro	zidesamtinib	片劑 Tablet	用於治療既往接受 ROS1 激酶抑制劑治療後的局部晚期或轉移性 ROS1 陽性非小細胞肺癌成人患者 To treat adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer after receiving a ROS1 kinase inhibitor	Nuvalent, Inc.
81.	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
82.	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
83.	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

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
84.	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
85.	Klygefa [#]	gefurulimab	注射劑 Injection	用於治療抗乙酰膽鹼受體抗體陽性的成人全身型重症肌無力患者 Treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive	Alexion Europe
86.	Komzifti	ziftomenib	膠囊 Capsule	治療具有核磷蛋白 1 突變的復發或難治性急性髓系白血病成人患者 To treat adults with relapsed or refractory acute myeloid leukemia with nucleophosmin 1 mutation	Kura Oncology, Inc.
87.	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
88.	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.
89.	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.
90.	Kygevvi	doxocitine; doxribtimine	粉劑 Powder	治療胸苷激酶 2 缺乏症 To treat thymidine kinase 2 deficiency	UCB
91.	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

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
92.	Lamzedo	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
93.	Leqselvi	deuruxolitinib	片劑 Tablet	治療嚴重斑禿 To treat severe alopecia areata	Sun Pharmaceutical Industries, Inc.
94.	Lerochol	lerodalcibep	注射劑 Injection	降低成人高膽固醇血症患者的低密度脂蛋白膽固醇，作為飲食和運動的輔助治療 To reduce low-density lipoprotein cholesterol in adults with hypercholesterolemia, as an adjunct to diet and exercise	LIB Therapeutics
95.	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.
96.	Lifyorli	relacorilant	膠囊 Capsule	與白蛋白紫杉醇聯合使用，用於治療既往接受過一至三種全身性治療（其中一種至少包含 bevacizumab）的成人鉑耐藥性上皮性卵巢癌、輸卵管癌或原發性腹膜癌患者 In combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab	Corcept Therapeutics Incorporated
97.	Lipfendra	enlicitide decanoate	片劑 Tablet	用於降低低密度脂蛋白膽固醇 To reduce low-density lipoprotein cholesterol	Merck Sharp & Dohme LLC
98.	Lisraya [#]	brepocitinib	片劑 Tablet	治療成人皮肌炎 To treat dermatomyositis in adults	Priovant Therapeutics, Inc.
99.	Loargys	pegzilarginase	注射劑	治療 2 歲及以上患者的高精氨酸血症	Immedica Pharma AB

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
			Injection	To treat people from 2 years of age with hyperargininemia	Unimedica AB
100.	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
101.	Lumisight	pegulicanine	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.
102.	Lumvoa	veligrotag	注射劑 Injection	用於治療甲狀腺眼病 To treat thyroid eye disease	Viridian Therapeutics Inc.
103.	Lupkynis	voclosporin	膠囊 Capsule	治療狼瘡性腎炎 To treat lupus nephritis	Aurinia Pharmaceuticals Inc.
104.	Lynavoy	linerixibat	片劑 Tablet	治療原發性膽汁性膽管炎相關的膽汁淤積性瘙癢 To treat cholestatic pruritus associated with primary biliary cholangitis (PBC)	GlaxoSmithKline
105.	Lynkuet	elinzanetant	膠囊 Capsule	治療更年期引起的中度至重度血管舒縮症狀 Treatment of moderate to severe vasomotor symptoms due to menopause.	Bayer HealthCare Pharmaceuticals Inc.
106.	Lynozyl	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
107.	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

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
108.	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
109.	Mimrylo [#]	rusfertide	注射劑 Injection	治療成人真性紅血球增多症引發的紅血球增生 Treatment of erythrocytosis in adults with polycythemia vera (PV)	Takeda Pharmaceuticals America, Inc.
110.	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
111.	Modeyso	dordaviprone	膠囊 Capsule	治療 H3 K27M 突變且既往接受過治療後病情出現進展的彌漫性中線神經膠質瘤 To treat diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy	Jazz Pharmaceuticals, Inc.
112.	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.
113.	Myqorzo ; 星舒平 ; 阿夫凱泰片	aficamten	片劑 Tablet	治療症狀性梗阻性肥厚型心肌病 To treat symptomatic obstructive hypertrophic cardiomyopathy	Cytokinetics
114.	Nemluvio	nemolizumab	注射劑 Injection	治療結節性癢疹 To treat prurigo nodularis	Galderma Laboratories, L.P.
115.	Nereus	tradipitant	膠囊 Capsule	預防成人暈動病 For the prevention of motion sickness in adults	Vanda Pharmaceuticals Inc.
116.	NexoBrid	anacaulase	凝膠 Gel	去除成人深度部分或全層熱燒傷的焦痂	Mediowound, Ltd

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 remove eschar in adults with deep partial thickness or full thickness thermal burns	
117.	Nezgylal	leriglitazone	混懸劑 Suspension	用於治療 2 至 12 歲、腦部病灶鈔增強陰性的男性腦型腎上腺腦白質營養不良患者 Treatment of cerebral adrenoleukodystrophy (cALD) in males with adrenoleukodystrophy (ALD) aged 2 to 12 years with non-gadolinium (Gd) enhancing lesions (i.e. Gd negative)	Minoryx Therapeutics S.L.
118.	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.
119.	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
120.	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.
121.	Nuzolvence	zoliflodacin	顆粒劑 Granules	治療由淋病奈瑟球菌引起的單純性泌尿生殖道淋病 To treat uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae	Entasis Therapeutics
122.	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.
123.	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
124.	Omlonti	omidenepeg	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
125.	OmvoH	mirikizumab	注射劑 Injection	治療潰瘍性結腸炎 To treat ulcerative colitis	Eli Lilly
126.	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
127.	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
128.	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
129.	Palsonify	paltusotine	片劑 Tablet	用於對手術治療反應不足及/或無法接受手術的成人肢端肥大症患者 To treat acromegaly in adults who had an inadequate response to surgery and/or for whom surgery is not an option	Crinetics Pharmaceuticals, Inc.
130.	Pasatru [#]	garetosmab	注射劑 Injection	用於減少進行性骨化性纖維發育不良成人患者新異位骨化病變的形成及經臨床評估的急性發作 To reduce new heterotopic ossification (HO) and clinician-assessed disease flare-ups in adults with fibrodysplasia ossificans progressive (FOP)	Regeneron Pharmaceuticals, Inc.
131.	Piasmy	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
132.	Pixclara [#]	floretyrosine F 18	注射劑 Injection	配合正電子發射斷層掃描，與其他診斷評估結合用於鑒別復發性或進展性膠質瘤與治療相關變化	Telix Pharmaceuticals US, 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
				To use with positron emission tomography to differentiate recurrent or progressive glioma from treatment-related change in conjunction with other diagnostic evaluations	
133.	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.
134.	Povofortay [#]	povorcitinib	片劑 Tablet	用於對抗 TNF 治療反應不足、不耐受或存在禁忌症的活動性中度至重度化膿性汗腺炎成人患者 Treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults who have responded inadequately to, or who are intolerant or contraindicated to an anti-TNF therapy	Incyte Biosciences Distribution B.V.
135.	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.
136.	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.
137.	Quviviq	daridorexant	片劑 Tablet	治療失眠 To treat insomnia	Actelion Ltd ; Idorsia Ltd
138.	Orzeyful	oveporexton	片劑 Tablet	治療第一型嗜睡症 To treat narcolepsy type 1	Takeda Pharmaceuticals America, Inc.
139.	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	Akeso Biopharma Co., Ltd.

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
				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	
140.	Rapiblyk	landiolol	注射劑 Injection	治療室上性心搏過速 To treat supraventricular tachycardia	AOP Orphan Pharmaceuticals GmbH
141.	Rasonque [#]	daraxonrasib	片劑 Tablet	治療既往接受過至少一種系統性治療，或不適合接受多藥聯合系統性治療的轉移性胰腺導管腺癌成人患者 Treatment of adult patients with metastatic pancreatic adenocarcinoma (PDAC) who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy	Revolution Medicines, Inc.
142.	Redemplo；瑞達普； 普樂司蘭鈉注射液	plozasiran	注射劑 Injection	用於降低家族性乳糜微粒血症綜合徵成人患者的甘油三酯 To reduce triglycerides in adults with familial chylomicronemia syndrome	Arrowhead Pharmaceuticals, Inc.
143.	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
144.	Revtorpyk	gedatolisib	注射劑 Injection	與氟維司群聯合使用，用於在接受至少一輪荷爾蒙治療後，在轉移期出現病況惡化的、具有荷爾蒙受體陽性、人類表皮生長因子受體 2 陰性之局部晚期或轉移性乳癌患者，且未檢測到 PIK3CA 基因突變的患者	Celcuity 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
				In combination with fulvestrant, to treat hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-), locally advanced or metastatic breast cancer without a PIK3CA mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting	
145.	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.
146.	Reyvow	lasmiditan	片劑 Tablet	治療偏頭痛 Treatment of migraine	Eli Lilly
147.	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
148.	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.
149.	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.
150.	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.
151.	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	Novo Nordisk Inc; Pyramid Laboratories

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 lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function	
152.	Roctavian	valoctocogene roxaparvovec	注射劑 Injection	治療 A 型血友病 Treatment of Hemophilia A	BioMarin Pharmaceutical Inc.
153.	Rolvedon	eflapeggrastim	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
154.	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腱鞘巨細胞瘤 To treat symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity	Deciphera Pharmaceuticals, LLC
155.	Rystiggo	rozanolixizumab	注射劑 Injection	治療全身性重症肌無力 Treatment of generalized myasthenia gravis	UCB Pharmaceuticals
156.	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
157.	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.
158.	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

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
159.	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.
160.	Simtriyo	centanafadine	膠囊 Capsule	治療注意力不足過動症 To treat attention-deficit hyperactivity disorder (ADHD)	Otsuka Pharmaceutical Co., Ltd.
161.	Sofdra	sofpironium	凝膠 Gel	治療原發性腋窩多汗症 To treat primary axillary hyperhidrosis	Botanix SB Inc.
162.	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.
163.	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.
164.	Skyclarys	omaveloxolone	膠囊 Capsule	治療弗裏德裏希共濟失調 To treat Friedrich's ataxia	Reata Pharmaceuticals Inc.
165.	Tauklarify [#]	florquinitau F 18	注射劑 Injection	用於對正在接受阿爾茨海默病評估的認知功能受損成人 患者進行腦部正電子發射斷層掃描，以識別存在 tau 蛋 白神經纖維纏結病理的患者 To be used for positron emission tomography (PET) of the brain in adults with cognitive impairment who are being evaluated for Alzheimer disease to identify patients with tau neurofibrillary tangle (NFT) pathology	Cerveau Technologies, 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
166.	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.)
167.	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
168.	Trutakna	atacept	注射劑 Injection	用於減少患有原發性免疫球蛋白 A 腎病變並有病情迅速惡化風險的蛋白尿 To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression	Vera Therapeutics, Inc.
169.	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.
170.	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.
171.	Tryvio; Jeraygo	aprocitentan	片劑 Tablet	治療高血壓 To treat hypertension	Idorsia Pharmaceuticals US Inc.
172.	Tymlos; Eladynos	abaloparatide	注射劑 Injection	治療骨質疏鬆症 Treatment of osteoporosis	Radius Health Inc.
173.	Tzield	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.
174.	Unloxcyt	cosibelimab	注射劑 Injection	治療皮膚鱗狀細胞癌 To treat cutaneous squamous cell carcinoma	Checkpoint 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
175.	Utebzi	tebipenem pivoxil	片劑 Tablet	適用於口服治療選擇有限或無其他口服治療選擇的成人患者，以治療由多種敏感微生物引起的複雜性尿路感染（包括腎盂腎炎） To treat complicated urinary tract infections, including pyelonephritis, caused by several susceptible microorganisms in adults who have limited or no alternative oral treatment options	GlaxoSmithKline
176.	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.
177.	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.
178.	Veppanu	vepdegestrant	片劑 Tablet	用於治療雌激素受體陽性、人類表皮生長因子受體 2 陰性、ESR1 突變的晚期或轉移性乳癌 To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated advanced or metastatic breast cancer	Arvinas Operations, Inc.
179.	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
180.	Vizz	aceclidine	眼用溶液 Ophthalmic solution	治療老花眼 To treat presbyopia	LENZ Therapeutics, Inc.
181.	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	CTI BioPharma

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 intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets	
182.	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
183.	Voyxact ; 伊再可 ; 貝利單抗注射液	sibeprenlimab	注射劑 Injection	用於降低原發性免疫球蛋白 A 腎病變患者的蛋白尿 To reduce proteinuria in primary immunoglobulin A nephropathy	Otsuka Pharmaceutical Company, Ltd.
184.	Vtama	tapinarof	乳膏 Cream	治療斑塊狀銀屑病 To treat plaque psoriasis	Dermavant Sciences
185.	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
186.	Vyvgart	efgartigimod alfa	注射劑 Injection	治療全身性重症肌無力 To treat generalized myasthenia gravis	Argenx BV
187.	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
188.	Waskyra	etuvetidigene autotemcel	注射劑 Injection	用於治療 Wiskott-Aldrich 綜合症 Treatment of Wiskott-Aldrich Syndrome (WAS)	Fondazione Telethon ETS
189.	Wayrilz	rilzabrutinib	片劑 Tablet	用於治療對免疫球蛋白、抗 D 療法或皮質類固醇治療反應不足的成人免疫性血小板減少症	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
				To treat persistent or chronic immune thrombocytopenia that has not sufficiently responded to immunoglobulins, anti-D therapy or corticosteroids	
190.	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.
191.	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.
192.	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.
193.	Xocova ; Zokovea	ensitrelvir	片劑 Tablet	用於 12 歲及以上青少年和成人在接觸 COVID-19 患者後進行 COVID-19 暴露後預防 For post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19	Shionogi Inc.
194.	Xolremdi	mavorixafor	膠囊 Capsule	治療 WHIM 綜合症 To treat WHIM syndrome	X4 Pharmaceuticals, Inc.
195.	Yartemlea	narsoplimab	注射劑 Injection	治療成人及 2 歲及以上患者的造血幹細胞移植相關血栓性微血管病 Treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy	Omeros Corporation
196.	Yorvipath	Palo-pegteriparatide	注射劑 Injection	治療副甲狀腺功能低下症 To treat hypoparathyroidism	Ascendis Pharma Bone Diseases A/S
197.	Yselty	linzagolix	片劑 Tablet	治療子宮肌瘤 To treat uterine fibroids	Theramex Ireland Limited

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
198.	Yuviwel	navepegritide	注射劑 Injection	用於增加 2 歲及以上、骨骺尚未閉合之軟骨發育不全兒童患者的線性生長 To increase linear growth in pediatric patients 2 years and older with achondroplasia with open epiphyses	Ascendis Pharma
199.	Zanvastro [#]	zilganersen	注射劑 Injection	治療兒童及成人患者的亞歷山大病 To treat Alexander disease in pediatric and adult patients	Ionis Pharmaceuticals, Inc.
200.	Zavzpret	zavegepant	噴劑 Spray	治療偏頭痛 To treat migraine	Pfizer Inc.
201.	Zaynich	cefepime; zidebactam	注射劑 Injection	用於治療成人複雜性尿路感染，包括腎盂腎炎 Treatment of adult patients with complicated urinary tract infections (cUTI) including pyelonephritis	ACS Dobfar S.p.A.; Wockhardt Suisse USA LLC
202.	Zegfrovy ; 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
203.	Zelsuvmi	berdazimer	凝膠 Gel	治療傳染性軟疣 To treat molluscum contagiosum	EPIH SPV, LLC
204.	Zenbexus [#]	iberdomide	膠囊 Capsule	與雷妥尤單抗、透明質酸酶及地塞米松聯合使用，治療既往接受過至少一種治療（包括蛋白酶體抑制劑和免疫調節劑）的多發性骨髓瘤成人患者 To be used in combination with daratumumab and hyaluronidase and dexamethasone for adults with multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent	Bristol-Myers Squibb 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
205.	Zeydovio [#]	glepaglutide	注射劑 Injection	治療成人短腸綜合症 Treatment of adults with Short Bowel Syndrome (SBS)	Zealand Pharma A/S
206.	Zilbrysq	zilucoplan	注射劑 Injection	治療抗乙醯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.
207.	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
208.	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
209.	Zurzuvae	zuranolone	膠囊 Capsule	治療產後抑鬱症 To treat postpartum depression	Biogen Inc.
210.	Zycubo	copper histidinate	注射劑 Injection	治療兒童患者的孟克斯病 Treatment of Menkes disease in pediatric patients	Sentynl Therapeutics, Inc.
211.	Zynlonta	loncastuximab tesirine	注射劑 Injection	治療瀰漫性大 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
212.	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.
213.	戈芮寧；注射用維拉替酶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
214.	卡達沙；甲磺酸氬申艾替尼片 [#]	asandeutertinib mesylate	片劑 Tablet	用於具有表皮生長因子受體外顯子 19 缺失或外顯子 21 置換突變，並伴有中樞神經系統轉移的局部晚期或轉移性非小細胞肺癌成人患者的一線治療 First-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring EGFR exon 19 deletion (19DEL) or exon 21 L858R substitution mutations and CNS metastases	浙江同源康醫藥股份有限公司
215.	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
216.	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
217.	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
218.	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	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
				On the basis of dietary control, in combination with statins or other lipid lowering therapy for the treatment of adult patients with primary hypercholesterolemia and mixed dyslipidemia, who fail to achieve low-density lipoprotein cholesterol (LDL-C) goals after receiving moderate or higher doses of statins treatment; Monotherapy for adult patients with non-familial hypercholesterolemia and mixed dyslipidemia to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), and apolipoprotein B (ApoB) levels	
219.	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
220.	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
221.	艾瑞環；澤美妥司他片	zeprumetostat	片劑 Tablet	用於既往接受過至少一種系統性治療的復發或難治外周 T 細胞淋巴瘤成人患者 Treatment for adult patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL) who have received at least one prior line of systemic therapy	江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
222.	艾澤利；瑞拉芙普α注射液	retlirafusp alfa	注射劑 Injection	聯合氟尿嘧啶類和鉑類藥物用於 PD-L1 陽性 (CPS≥1) 的局部晚期不可切除、復發或轉移性胃及食管結合部腺癌的一線治療 In combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of PD-L1-positive (CPS ≥1) locally advanced unresectable, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma	蘇州盛迪亞生物醫藥有限公司
223.	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.
224.	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
225.	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	貝達藥業股份有限公司

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
				In combination with everolimus, for patients with advanced renal cell carcinoma who have failed prior treatment with a tyrosine kinase inhibitor	
226.	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
227.	先頤達；埃諾格魯肽注射液	ecnoglutide	注射劑 Injection	用於成人 2 型糖尿病患者的血糖控制 For glycemic control in adult patients with type 2 diabetes	杭州先為達生物科技股份有限公司
228.	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
229.	安比銳；苯甲酸安達艾替尼膠囊	andamertinib benzoate	膠囊 Capsule	用於既往經含鉑化療治療時或治療後出現疾病進展，或不耐受含鉑化療，並且經檢測確認存在表皮生長因子受體 20 號外顯子插入突變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, who have progressed on or after platinum-based chemotherapy or are intolerant to platinum-based chemotherapy	鞍石藥業(寧波)有限責任公司
230.	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

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
231.	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
232.	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
233.	安煦；羅伐昔替尼片	rovadicitinib	片劑 Tablet	用於中危-2 或高危的原發性骨髓纖維化 (PMF)、真性紅細胞增多症後骨髓纖維化 (PPV-MF) 或原發性血小板增多症後骨髓纖維化 (PET-MF) 成人患者的一線治療，治療疾病相關脾腫大或疾病相關症狀 For the first-line treatment of adult patients with intermediate-2 or high-risk primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF), or post-essential thrombocythemia myelofibrosis (PET-MF), for the treatment of disease-related splenomegaly or disease-related symptoms	正大天晴藥業集團股份有限公司
234.	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
235.	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	武漢海特生物製藥股份有限公司

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
				Treatment of adult patients with relapsed or refractory multiple myeloma after two or more systemic therapies	
236.	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
237.	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
238.	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
239.	貝特琳；注射用鹽酸伊吡諾司他	ifupinostat hydrochloride	注射劑 Injection	用於既往接受過至少兩線系統性治療的復發或難治性瀰漫性大 B 細胞淋巴瘤成人患者 Treatment for relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) in patients who have received at least two prior systemic therapies	廣州必貝特醫藥股份有限公司
240.	貝捷邁；鹽酸匹米替尼膠囊	pimicotinib	膠囊 Capsule	用於治療手術切除可能會導致功能受限或出現較嚴重併發症的症狀性腱鞘巨細胞瘤（TGCT）成年患者	默克雪蘭諾（北京）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
				For the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) where surgical resection is likely to result in functional limitation or severe morbidity/ complications	
241.	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
242.	利生妥；利沙托克拉片	lisaftoclax	片劑 Tablet	用於既往經過至少包含布魯頓酪氨酸激酶 (BTK) 抑制劑在內的一種系統治療的成人慢性淋巴細胞白血病 (CLL) /小淋巴細胞淋巴瘤 (SLL) 患者 Treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) in patients who have previously received at least one prior systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor	蘇州亞盛藥業有限公司
243.	君適達；昂戈瑞西單抗注射液	ongeracicimab	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	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
				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	
244.	宜諾欣；佐來曲替尼片	zurletrectinib	片劑 Tablet	用於符合下列條件的成人和 12 歲以上青少年實體瘤患者：攜帶神經營養酪氨酸受體激酶（NTRK）融合基因且不包括已知獲得性耐藥突變，患有局部晚期、轉移性疾病或手術切除可能導致嚴重併發症的患者，以及無滿意替代治療或既往治療失敗的患者 For the treatment of adult and adolescent patients aged 12 years and older with solid tumors who have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, who have locally advanced or metastatic disease or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or who have progressed following prior treatment	北京諾誠健華醫藥科技有限公司
245.	宜澤康；注射用倫康依隆妥單抗	izalontamab brengitecan	注射劑 Injection	用於治療既往經至少二線系統化療和 PD-1/PD-L1 抑制劑治療失敗的復發/轉移性鼻咽癌的成人患者 Treatment of patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) who have previously failed at least two lines of systemic chemotherapy and PD-1/PD-L1 inhibitor therapy	成都百利多特生物藥業有限責任公司

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
246.	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
247.	依適寧；鹽酸蘭諾可 泮片	lanoracopan hydrochloride	片劑 Tablet	用於治療既往未接受過補體抑制劑治療的陣發性睡眠性血紅蛋白尿症（PNH）成人患者 To treat adult patients with paroxysmal nocturnal hemoglobinuria (PNH) who have not previously received complement inhibitor therapy.	武漢朗來科技發展有限公司
248.	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
249.	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	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
				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	
250.	東澤安；奧洛格列淨 膠囊	Olorigliflozin	膠囊 Capsule	用於改善成人 2 型糖尿病患者的血糖控制 For improving glycemic control in adult patients with type 2 diabetes mellitus	宜昌東陽光長江藥業股份有限公司
251.	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
252.	昂偉達；鹽酸司美那 非片	simenafil hydrochloride	片劑 Tablet	治療勃起功能障礙 Treatment of erectile dysfunction	蘇州旺山旺水生物醫藥股份有限公司
253.	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
254.	金速希；斯樂韋米單 抗注射液	silevimig	注射劑 Injection	用於成人狂犬病病毒暴露者的被動免疫 For passive immunization in adults following rabies virus (RABV) exposure	重慶智翔金泰生物製藥股份有限公司

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
255.	金蓓欣；注射用伏欣奇拜單抗	firsekibart	注射劑 Injection	用於對非甾體類抗炎藥和/或秋水仙鹼禁忌、不耐受或缺乏療效的，以及不適合反覆使用類固醇激素的成人痛風性關節炎急性發作 For patients with acute episodes of gout arthritis in adults who are contraindicated, intolerant, or lack curative effects with nonsteroidal anti-inflammatory drugs and/or colchicine, and who are not suitable for repeated use of steroids	長春金賽藥業有限責任公司
256.	孟平；法贊雷生片	fazamorexant	片劑 Tablet	用於治療以入睡困難和/或睡眠維持困難為特徵的成人失眠患者 To treat adult patients with insomnia characterized by difficulty falling asleep and/or difficulty staying asleep	江蘇海岸藥業有限公司
257.	奇佑康；古莫奇單抗注射液	gumokimab	注射劑 Injection	用於治療適合接受系統治療或光療的中度至重度斑塊狀銀屑病成人患者 For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy	中山康方生物醫藥有限公司
258.	首要澤；康特替尼顆粒	conteltinib	顆粒劑 Granules	用於未經過間變性淋巴瘤激酶（ALK）抑制劑治療的ALK陽性的局部晚期或轉移性非小細胞肺癌（NSCLC）患者的治療 For the treatment of ALK-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) in patients who have not previously received treatment with an ALK inhibitor	首藥控股（北京）股份有限公司
259.	美佑恒；注射用維貝柯妥塔單抗	becotatug vedotin	注射劑 Injection	治療既往經至少二線系統化療和PD-1/PD-L1抑制劑治療失敗的復發/轉移性鼻咽癌的成人患者	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
				To treat adult patients with recurrent/metastatic nasopharyngeal carcinoma who have progressed after at least two prior lines of systemic chemotherapy and PD-1/PD-L1 inhibitor therapy	
260.	英沐樂；庫萊韋拜單 抗注射液 [#]	clulevibart	注射劑 Injection	用於即將進入或出生在第一個呼吸道合胞病毒流行季的胎齡≥35 周的新生兒和嬰兒預防 RSV 引起的下呼吸道感染，不包括患有慢性肺疾病（包含支氣管肺發育異常）或伴有有臨床意義的先天性呼吸道異常的兒童 Prevention of respiratory syncytial virus (RSV)-associated lower respiratory tract infection (LRTI) in neonates and infants born at a gestational age of at least 35 weeks who are entering or were born during their first RSV season. The indication excludes children with chronic lung disease, including bronchopulmonary dysplasia, or clinically significant congenital airway abnormalities.	瑞陽（山東）生物製藥有限公司
261.	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
262.	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
263.	派達康；維培那肽注射液	visepegenatide	注射劑 Injection	用於成人 2 型糖尿病患者的血糖控制 For glycemic control in adult patients with type 2 diabetes	派格生物醫藥（杭州）股份有限公司
264.	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	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
				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	
265.	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
266.	科露平；妥拉美替尼膠囊	tunlametinib	膠囊 Capsule	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 Treatment of advanced melanoma carrying neuroblastoma ras viral oncogene homolog (NRAS) mutations who have previously undergone PD-1/PD-L1 treatment	上海科州藥物研發有限公司
267.	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
268.	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
269.	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
270.	信妥安；蘋果酸司妥吉侖片	sitokiren	片劑 Tablet	治療原發性高血壓 For the treatment of primary hypertension	上海上藥信誼藥廠有限公司

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
271.	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
272.	恒凱萊；雷尼基奧侖 賽注射液	ranicabtagene autoleucel	注射劑 Injection	治療經過二線或以上系統性治療後成人復發或難治性大 B 細胞淋巴瘤，包括彌漫性大 B 細胞淋巴瘤非特指型、 濾泡性淋巴瘤轉化的彌漫性大 B 細胞淋巴瘤、伴 MYC 和 BCL2 重排的高級別 B 細胞淋巴瘤、高級別 B 細胞淋 巴瘤非特指型 Treatment of adult patients with relapsed or refractory large B-cell lymphoma (r/r LBCL) who have received two or more lines of systemic therapy. This includes diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS); diffuse large B-cell lymphoma transformed from follicular lymphoma; high-grade B-cell lymphoma with MYC and BCL2 rearrangements and high- grade B-cell lymphoma, not otherwise specified (HGBL, NOS).	上海恒潤達生生物科技股份有 限公司
273.	恆優達；富馬酸立康 可泮膠囊 [#]	licancopan fumarate	膠囊 Capsule	用於治療既往未接受過補體抑制劑治療的陣發性睡眠性 血紅蛋白尿症成人患者 Treatment of adults patients with paroxysmal nocturnal hemoglobinuria (PNH) who have not previously received complement inhibitor therapy	成都盛迪醫藥有限公司
274.	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	廈門特寶生物工程股份有限公 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
				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	
275.	毫安通；琥珀酸安維吡啶片	anivecrine succinate	片劑 Tablet	用於輕、中度阿爾茨海默病症狀的治療 Treatment of mild to moderate Alzheimer's disease	通化金馬藥業集團股份有限公司
276.	倍長平；考格列汀片	coflogliptin	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
277.	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
278.	恩尼妥；安尼妥單抗注射液	anbenitamab	注射劑 Injection	聯合化療適用於治療既往至少接受過一種含曲妥珠單抗治療方案的局部晚期或轉移性 HER2 陽性成人胃或胃食管結合部腺癌患者 In combination with chemotherapy for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have previously received at least one trastuzumab-containing treatment regimen	上海津曼特生物科技有限公司
279.	邦瑞順；貝澤昔替尼片	bezacitinib	片劑 Tablet	用於中危-2 或高危的原發性骨髓纖維化、真性紅細胞增多症繼發的骨髓纖維化或原發性血小板增多症繼發的骨髓纖維化成年患者的一線治療，治療疾病相關脾腫大或改善疾病相關症狀	杭州邦順製藥股份有限公司

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
				For the first-line treatment of adult patients with intermediate-2 or high-risk primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF), or post-essential thrombocythemia myelofibrosis (PET-MF), for the treatment of disease-related splenomegaly or disease-related symptoms	
280.	海納安；氈恩紮魯胺軟膠囊	deutenzalutamide	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
281.	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
282.	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

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
283.	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 have progressed after receiving two or more endocrine therapies and one chemotherapy in the metastatic stage	軒竹生物科技股份有限公司
284.	軒菲寧；地羅阿克片	dirozalkib	片劑 Tablet	用於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 patients with ALK-positive, locally advanced, or metastatic non-small cell lung cancer (NSCLC) who have not previously received ALK inhibitor therapy	軒竹生物科技股份有限公司
285.	泰妥妥；鹽酸妥諾達非片	tunodafil hydrochloride	片劑 Tablet	治療勃起功能障礙 Treatment of erectile dysfunction	揚子江藥業集團有限公司
286.	益賽那；安弗利奇塔單抗注射液 [#]	anflekritug	注射劑 Injection	用於對非甾體類抗炎藥和/或秋水仙鹼禁忌、不耐受或缺乏療效的，以及不適合反覆使用類固醇激素的成人痛風性關節炎急性發作 Treatment of acute attacks of gouty arthritis in adults who have contraindications to, are intolerant of, or have inadequate response to NSAIDs and/or colchicine, and who are not suitable for repeated corticosteroid use	三生國健藥業（上海）股份有限公司
287.	益賽拓；安沐奇塔單抗注射液	amdokitug	注射劑 Injection	用於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	三生國健藥業（上海）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
				For the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	
288.	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
289.	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
290.	莫米司特片	mufemilast	片劑 Tablet	用於治療符合接受光療或系統治療指徵的中度至重度斑塊狀銀屑病的成人患者 For the treatment of adult patients with moderate to severe plaque psoriasis who are eligible for phototherapy or systemic therapy	贛州和美藥業股份有限公司
291.	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
292.	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
293.	康美納；酒石酸泰瑞西利膠囊	tibremciclib tartrate	膠囊 Capsule	聯合氟維司群，適用於既往接受內分泌治療後進展的激素受體（HR）陽性、人表皮生長因子受體 2（HER2）陰性的局部晚期或轉移性成年乳腺癌患者 In combination with fulvestrant for adult patients with HR+/HER2- locally advanced or metastatic breast cancer who have progressed following prior endocrine therapy	貝達藥業股份有限公司

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
294.	捷恩泰；替恩戈替尼片	tinengotinib	片劑 Tablet	用於既往接受過系統性治療和 FGFR 抑制劑治療，且具有成纖維細胞生長因子受體 2 融合或重排的晚期、轉移性或不可手術切除的膽管癌成人患者的治療 Treatment of adult patients with advanced, metastatic, or unresectable cholangiocarcinoma harboring fibroblast growth factor receptor (FGFR) 2 fusions or rearrangements who have previously received systemic therapy and FGFR inhibitor treatment	藥捷安康(南京)科技股份有限公司
295.	博佳凝；注射用波米泰酶α	bemiltenase alfa	注射劑 Injection	用於凝血因子 VIII 或 IX 的抑制物>5 個 Bethesda 單位 (BU) 的先天性血友病 A 或 B 成人患者的出血治療 For the treatment of bleeding in adult patients with congenital hemophilia A or B who have factor VIII or IX inhibitors > 5 Bethesda units (BU)	江蘇貝捷泰生物科技有限公司
296.	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
297.	復邦德；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
298.	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

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
299.	普亦克；培來加南噴霧劑	peceleganan	噴霧劑 Spray	用於治療由表皮葡萄球菌、溶血葡萄球菌、鮑曼不動桿菌導致的 I 度或淺 II 度燒燙傷繼發創面感染 Treatment of secondary wound infections caused by Staphylococcus epidermidis, Staphylococcus haemolyticus, and Acinetobacter baumannii in first-degree or superficial second-degree burns	普萊醫藥（江蘇）股份有限公司
300.	普利得凱；普基奧侖賽注射液	puzolcabtagene autoleucel	注射劑 Injection	治療 CD19 陽性的難治或復發性急性 B 淋巴細胞白血病患者 To treat patients with CD19-positive refractory or relapsed acute B-cell lymphoblastic leukemia	重慶精準生物技術有限公司
301.	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
302.	華亦淨；瑞西奇拜單抗注射液	recibokibart	注射劑 Injection	治療成人(體重≥40kg)泛發性膿疱型銀屑病發作 Treatment of acute flares of generalized pustular psoriasis (GPP) in adults weighing 40 kg or more	上海華奧泰生物藥業股份有限公司
303.	華索靈；塞多明基注射液	donaperminogene	注射劑 Injection	用於治療不適合血運重建手術或手術效果不佳的嚴重下肢缺血（下肢動脈硬化閉塞症、血栓閉塞性脈管炎和糖尿病下肢缺血等）導致的肢體潰瘍 Indicated for the treatment of limb ulcers due to severe lower limb ischemia (including lower extremity arteriosclerosis obliterans, thromboangiitis obliterans, and diabetic lower limb ischemia, etc.) in patients who are not candidates for revascularization surgery or in whom revascularization has been unsuccessful	北京諾思蘭德生物技術股份有限公司
304.	華優諾；立貝韋塔單抗注射液	libevitug	注射劑 Injection	用於治療伴有或不伴有代償期肝硬化的慢性丁型肝炎病毒（HDV）感染成年患者	華輝安健（北京）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
				For the treatment of adult patients with chronic hepatitis delta virus (HDV) infection, with or without compensated cirrhosis	
305.	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
306.	琥珀酸思普可泮片	ciprocopan succinate	片劑 Tablet	治療既往未接受過補體抑制劑治療的陣發性睡眠性血紅蛋白尿症（PNH）成人患者 Treatment of adult patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) who are complement-inhibitor-naïve	四川海思科製藥有限公司
307.	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
308.	奧美克松；阿更葡萄糖 鈉注射液	amogammadex sodium	注射劑 Injection	用於拮抗羅庫溴銨誘導的神經肌肉阻滯 Reversal of neuromuscular blockade induced by rocuronium bromide	杭州奧默醫藥股份有限公司
309.	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
310.	奧格特韋鈉膠囊	olgotrelvir	膠囊	用於治療輕中型新型冠狀病毒感染的成年患者	浙江艾森藥業有限公司

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
			Capsule	Treatment of adult patients with mild to moderate COVID-19 infection	
311.	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.
312.	舒泰萊；注射用博度曲妥珠單抗	trastuzumab botidotin	注射劑 Injection	用於既往接受過一種或一種以上抗 HER2 藥物治療的不可切除或轉移性 HER2 陽性成人乳腺癌患者 For the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have previously received one or more anti-HER2 therapies	四川科倫博泰生物醫藥股份有限公司
313.	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
314.	愛領達；酒石酸凡瑞格拉替尼片 [#]	fanregratinib tartrate	片劑 Tablet	用於既往接受過系統性治療，且具有成纖維細胞生長因子受體 2 融合或重排的晚期、轉移性或不可手術切除的肝內膽管癌成人患者的治療 Treatment of adult patients with advanced, metastatic or unresectable intrahepatic cholangiocarcinoma (ICC) with fibroblast growth factor receptor (FGFR) 2 fusion/rearrangement who have previously received systemic therapy	和記黃埔醫藥（上海）有限公司
315.	新多妥；芮特韋拜單抗注射液 [#]	retavibart	注射劑 Injection	用於即將進入或出生在第一個呼吸道合胞病毒流行季的新生兒和嬰兒預防 RSV 所致的下呼吸道感染 Prevention of RSV-associated lower respiratory tract infection (LRTI) in neonates and infants who are entering or are born during their first RSV season	珠海泰諾麥博製藥股份有限公司

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
316.	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
317.	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
318.	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
319.	維可妥；緯利妥米單抗注射液 [#]	velinotamig	注射劑 Injection	用於既往至少接受過三線治療（包括一種蛋白酶體抑制劑、一種免疫調節劑和一種抗 CD38 單株抗體）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 (RRMM) who have previously received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody	重慶智翔金泰生物製藥股份有限公司
320.	維邁妥；安瑞曲替尼膠囊	eratrectinib	膠囊 Capsule	用於符合下列條件的成人和≥12 歲的青少年實體瘤患者：經充分驗證的檢測方法診斷為攜帶神經營養酪氨酸受體激酶（NTRK）融合基因且不包括已知獲得性耐藥突變；患有局部晚期、轉移性疾病或手術切除可能導致嚴重併發症的患者；以及無滿意替代治療或既往治療失敗的患者	江蘇威凱爾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
				For adult and adolescent (≥12 years of age) patients with solid tumors who meet the following criteria: diagnosed by a validated test as carrying a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without known acquired resistance mutations; have locally advanced or metastatic disease or where surgical resection is likely to result in severe complications; and have no satisfactory alternative treatments or whose prior treatments have failed.	
321.	愷力美；舒瑞基奧侖賽注射液	satricabtagene autoleucel	注射劑 Injection	用於治療 CLDN18.2 陽性、人類表皮生長因子受體 2 (HER2) 陰性，至少二線治療失敗的晚期胃/食管胃結合部腺癌 Treatment for patients with Claudin18.2-positive, HER2-negative advanced gastric/gastroesophageal junction adenocarcinoma (G/GEJA) in patients who have failed at least two prior lines of therapy	愷興生命科技(上海)有限公司
322.	瑞瑪比嗪注射液	relmapirazin	注射劑 Injection	與特定的經皮腎小球濾過率測量設備配合使用，評估患者的腎小球濾過率 Use in conjunction with specific transcutaneous glomerular filtration rate measurement equipment to assess the patient's glomerular filtration rate	杭州中美華東製藥有限公司
323.	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	上海倍而達藥業有限公司

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
				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	
324.	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
325.	瑞恒盈；舒地胰島素注射液	insulin sudelidec	注射劑 Injection	治療成人 2 型糖尿病 To treat type 2 diabetes mellitus	江蘇恒瑞醫藥股份有限公司
326.	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
327.	瑞鳴；魯茲諾雷鈉片	ruzinurad	片劑 Tablet	用於痛風伴高尿酸血症患者 For use in patients with gout accompanied by hyperuricemia	江蘇恒瑞醫藥股份有限公司
328.	聖瑞沙；甲磺酸瑞厄替尼片	rilotinib 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
329.	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）	南京聖和藥業股份有限公司

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
				To treat chronic HCV infection in adults (genotypes 1, 2, 3, 6)	
330.	瑪帕西沙韋膠囊	pixavir marboxil	膠囊 Capsule	用於 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 For the treatment of uncomplicated influenza A and B in adolescents and adults aged 12 years and older	健康元藥業集團股份有限公司
331.	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
332.	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
333.	邁瑞東；馬來酸美凡厄替尼片	mifanertinib maleate	片劑 Tablet	用於表皮生長因子受體(EGFR)21 號外顯子 L858R 置換突變的局部晚期或轉移性非小細胞肺癌(NSCLC)成人患者的一線治療	杭州中美華東製藥有限公司

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
				For first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 21 L858R substitution mutation	
334.	睿鉑生；艾米邁托賽注射液	amimetrocel	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	鉑生卓越生物科技（北京）有限公司
335.	境斐；注射用菲澤妥單抗 [#]	felzartamab	注射劑 Injection	聯合來那度胺和地塞米松用於既往至少接受過一線治療的多發性骨髓瘤成年患者 Treatment of multiple myeloma (MM) in combination with lenalidomide and dexamethasone in adults who have received at least one prior line of therapy	天境生物藥業（杭州）股份有限公司
336.	鐳 ^{99m} Tc]佩昔瑞特加肽注射液	Technetium (^{99m} Tc) Rectegatide Pecixetan	注射劑 Injection	用於可疑肺癌患者區域淋巴結轉移的輔助檢查 As an adjunct for the assessment of regional lymph node metastasis in patients with suspected lung cancer	佛山瑞迪奧醫藥有限公司
337.	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	蘇州澤環生物製藥股份有限公司

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
				Treatment of intermediate- and high-risk myelofibrosis, including primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF), and post-essential thrombocythemia myelofibrosis (PET-MF)	
338.	濟樂美；硫酸索西美雷塞片	sosimerasib sulfate	片劑 Tablet	用於至少接受過一種系統性治療的鼠類肉瘤病毒癌基因 (KRAS) G12C 突變型的晚期非小細胞肺癌 (NSCLC) 成人患者 For the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harboring the KRAS G12C mutation who have received at least one prior systemic therapy	浙江杭煜製藥有限公司
339.	賽坦欣；庫莫西利膠囊	culmerciclib	膠囊 Capsule	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激素受體陽性、人表皮生長因子受體 2 陰性的局部晚期或轉移性乳腺癌成人患者 In combination with fulvestrant for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in adult patients who have disease progression following prior endocrine therapy	正大天晴藥業集團股份有限公司
340.	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
341.	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

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
342.	麗倍坦；萊康奇塔單抗注射液 [#]	lecankitug	注射劑 Injection	用於適合接受系統治療或光療的中重度斑塊狀銀屑病的成人患者 Treatment of adult patients with moderate-to-severe plaque psoriasis who are suitable for systemic therapy or phototherapy	珠海市麗珠單抗生物技術有限公司
343.	麓可達；洛布替尼片	rocbrutinib	片劑 Tablet	用於既往接受過至少兩種系統性治療（含布魯頓氏酪氨酸激酶[BTK]抑制劑）的復發或難治性套細胞淋巴瘤（MCL）成人患者 For adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have previously received at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.	廣州麓鵬製藥有限公司
344.	鹽酸去甲烏藥碱注射液	higenamine hydrochloride	注射劑 Injection	用於核素心肌灌注顯像以評估心肌缺血 Indicated for radionuclide myocardial perfusion imaging to evaluate myocardial ischemia	珠海潤都製藥股份有限公司
345.	鹽酸伊司特韋片	iscartrelvir hydrochloride	片劑 Tablet	用於治療成人輕型、中型新型冠狀病毒感染 Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults	西湖製藥（杭州）有限公司
346.	鹽酸凱普拉生注射液；鹽酸凱普拉生片	carenoprazan 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

Commercial names are listed in alphabetical/strokes order

資料截至：09/2026

[#]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