已獲藥物監督管理局批准上市的新藥清單
List of new drugs approved for marketing by Pharmaceutical Administration Bureau (ISAF)

項目	商品名稱 Commercial Name	主成分 Active Ingredient(s)	劑型 Dosage Form	適應症 Indication(s)	藥物產品出入口及批發商號 Firm for Import, Export and Wholesale of Pharmaceutical Products
1.	Abrysvo△	RSV subgroup A PreF antigen, RSV subgroup B PreF antigen	注射劑 Injection	用於妊娠 24 至 36 週的孕婦通過母體免疫以預防剛出生至 6 個月的嬰兒因呼吸道合胞病毒引起的下呼吸道疾病 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 caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunization during pregnancy between 24 and 36 weeks of gestation Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older	康寧葯業有限公司 The Glory Medicina Limitada
2.	Adzynma	rADAMTS13	注射劑 Injection	用於患有缺乏 ADAMTS13 蛋白酶的先天性血栓性血小板減少性紫斑症 Treatment of ADAMTS13 deficiency in patients with congenital thrombotic thrombocytopenic purpura (cTTP)	全昌行有限公司 Firma Chun Cheong - Produtos Farmacêuticos, Limitada

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3.	Altuviiio△	efanesoctocog alfa	注射劑 Injection	適用於 A 型血友病作為常規預防、需求性治療及控制出血和手術全期的出血處理 Use in patient with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes, on-demand treatment & control of bleeding episodes and perioperative management of bleeding	科達有限公司 Four Star Companhia Lda.
4.	Anzupgo	delgocitinib	乳膏 Cream	對外用類固醇無效或不能使用外用類固醇治療的中度至嚴重的慢性手部濕疹成人患者 To treat moderate to severe chronic hand eczema (CHE) in adults who cannot use corticosteroids applied to the skin or in whom such corticosteroids do not work well enough	五洲 Firma Wuzhou
5.	Aphexda△	motixafortide	注射劑 Injection	與顆粒細胞菌落刺激因子聯合使用，將造血幹細胞動員到外周血中，用於多發性骨髓瘤患者的血液單採和隨後的自體移植 In combination with granulocyte colony-stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma	五洲 Firma Wuzhou

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6.	Aquipta△	atogepant	片劑 Tablet	用於每月偏頭痛發作天數不少於 4 天的成人患者以預防偏頭痛 Prophylaxis of migraine in adults who have at least 4 migraine days per month	康寧葯業有限公司 The Glory Medicina Limitada
7.	Arexvy△	RSVPreF3 antigen	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 caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older	利華行有限公司 Agência Lei Va Hong Lda.
8.	Augtyro	repotrectinib	膠囊 Capsule	治療患有 ROS1 陽性的局部晚期或轉移性非小細胞肺癌 Treatment of patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)	科達有限公司 Four Star Companhia Lda.
9.	Besremi	ropeginterferon alfa-2b	注射劑 Injection	治療不具症狀性脾腫大的真性紅血球增多症的成人患者 To treat polycythemia vera in adults who do not have symptoms of an enlarged spleen	全昌行有限公司 Firma Chun Cheong - Produtos Farmacêuticos, Limitada 五洲 Firma Wuzhou

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10.	Beyfortus	nirsevimab	注射劑 Injection	預防正值或進入第一個呼吸道合胞病毒季節時出生的新生兒及嬰兒和在第二個呼吸道合胞病毒好發季節仍易罹患嚴重呼吸道合胞病毒疾病的 24 個月或以下幼兒因感染呼吸道合胞病毒而導致的下呼吸道疾病 Prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season	科達有限公司 Four Star Companhia Lda.
11.	Braftovi	encorafenib	膠囊 Capsule	與 binimetinib 聯合使用，治療帶有 BRAF V600 突變且無法切除或轉移性的黑色素瘤 與 cetuximab 聯合使用，治療帶有 BRAF V600E 突變且曾接受全身性療法的轉移性結直腸癌 In combination with binimetinib for the treatment of unresectable or metastatic melanoma with a BRAF V600 mutation In combination with cetuximab, for the treatment of metastatic colorectal cancer with a BRAF V600E mutation, who have received prior systemic therapy	利華行有限公司 Agência Lei Va Hong Lda.

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12.	Brukinsa	zanubrutinib	膠囊 Capsule	治療套細胞淋巴瘤、慢性淋巴細胞白血病/小淋巴細胞淋巴瘤及華氏巨球蛋白血症 To treat mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL) and Waldenström macroglobulinemia (WM)	康寧葯業有限公司 The Glory Medicina Limitada
13.	Camzyos	mavacamten	膠囊 Capsule	治療紐約心臟協會(NYHA)II-III 級症狀性梗阻性肥厚型心肌病 Treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (HCM)	康寧葯業有限公司 The Glory Medicina Limitada
14.	Cibinqo	abrocitinib	片劑 Tablet	治療成人及 12 歲以上青少年的中度至重度濕疹(異位性皮膚炎) To treat adults and children 12 years of age and older with moderate-to-severe eczema (atopic dermatitis)	康寧葯業有限公司 The Glory Medicina Limitada
15.	Cobenfy	xanomeline, trospium chloride	膠囊 Capsule	用於治療成人精神分裂症 Treat adults with schizophrenia	科達有限公司 Four Star Companhia Lda.

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16.	Columvi	glofitamab	注射劑 Injection	用於治療復發或難治性瀰漫性大 B 細胞淋巴瘤，或經過兩次或多次全身治療後由濾泡性淋巴瘤引起的大 B 細胞淋巴瘤 To treat relapsed or refractory diffuse large B-cell lymphoma, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy	利華行有限公司 Agência Lei Va Hong Lda.
17.	Comirnaty COVID-19 mRNA Vaccine△	tozinameran	注射劑 Injection	預防新冠病毒感染 Prevention of COVID-19 infection	科達有限公司 Four Star Companhia Lda. 醫臣藥業 Pharmason Medicina
18.	Comirnaty COVID-19 mRNA Vaccine (Original/Omicron BA.4-5)△	tozinameran, famtozinameran	注射劑 Injection	用於 12 歲及以上人群的新冠病毒加強免疫接種 Booster dose for immunization to prevent COVID-19 infection in individuals 12 years of age and older	科達有限公司 Four Star Companhia Lda. 醫臣藥業 Pharmason Medicina
19.	Comirnaty COVID-19 mRNA Vaccine (Omicron XBB.1.5)△	raxtozinameran	注射劑 Injection	用於 12 歲及以上人群的預防新冠病毒感染及加強免疫接種 Prevention of COVID-19 infection and booster dose for immunization to prevent COVID-19 infection in individuals 12 years of age and older	醫臣藥業 Pharmason Medicina

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20.	Comirnaty COVID-19 mRNA Vaccine (Omicron JN.1)[△]	bretovameran	注射劑 Injection	用於 12 歲及以上人群預防由新型冠狀病毒所引起的感染 Prevention of COVID-19 infection in individuals 12 years of age and older	醫臣藥業 Pharmason Medicina
21.	Comirnaty COVID-19 mRNA Vaccine (Omicron LP.8.1)[△]	mRNA encoding LP.8.1	注射劑 Injection	用於 12 歲及以上人群預防由新型冠狀病毒所引起的感染 Prevention of COVID-19 infection in individuals 12 years of age and older	醫臣藥業 Pharmason Medicina
22.	Crysvita	burosumab	注射劑 Injection	用於治療 1 歲以上兒童及成人的性聯遺傳型低磷酸鹽症 Treatment of X-linked Hypophosphatemia(XLH), in children and adolescents aged 1 to 17 years, and in adults	科達有限公司 Four Star Companhia Lda. 康寧葯業有限公司 The Glory Medicina Limitada
23.	Danyelza	naxitamab	注射劑 Injection	與粒細胞-巨噬細胞集落刺激因子併用於治療難治性/復發性高危神經母細胞瘤 Combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) for the treatment of relapsed or refractory high-risk neuroblastoma	利華行有限公司 Agência Lei Va Hong Lda. 德聖堂 Firma Tak Sing Tong

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24.	Datroway	datopotamab deruxtecan	注射劑 Injection	單藥用於既往接受過內分泌治療及至少一種化療的無法切除或轉移性激素受體(HR)陽性、人表皮生長因子受體 2 陰性的乳腺癌成人患者 As monotherapy for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine therapy and at least one line of chemotherapy in the advanced setting	科達有限公司 Four Star Companhia Lda.
25.	Dayvigo	lemborexant	片劑 Tablet	治療失眠 To treat insomnia	康寧葯業有限公司 The Glory Medicina Limitada
26.	Elahere	mirvetuximab soravtansine	注射劑 Injection	用於治療既往接受過 1 至 3 種全身性治療的 FRα陽性、鉑類藥物耐藥的上皮性卵巢癌、輸卵管癌或原發性腹膜癌 Treatment of patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens	康寧葯業有限公司 The Glory Medicina Limitada
27.	Elunate	fruquintinib	膠囊 Capsule	治療曾接受抗血管內皮生長因子(VEGF)治療、抗表皮生長因子受體(EGFR)治療的轉移性結腸癌 Treatment of metastatic colorectal cancer including those who have previously received anti-VEGF therapy and/or anti-EGFR therapy	科達有限公司 Four Star Companhia Lda.

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28.	Elrexfio#	elranatamab	注射劑 Injection	單藥治療既往接受過至少三種治療(包括一種免疫調節劑、一種蛋白酶體抑制劑及一種抗 CD38 抗體)後出現疾病惡化的復發或難治性多發性骨髓瘤成人患者 Monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy	康寧葯業有限公司 The Glory Medicina Limitada
29.	Emblaveo	aztreonam, avibactam	注射劑 Injection	用於治療藥物選擇有限或無替代治療的成人複雜性腹腔內感染及醫院獲得性肺炎 For the treatment of adult patients with complicated intra-abdominal infections and hospital-acquired pneumonia who have limited or no alternative treatment options	康寧葯業有限公司 The Glory Medicina Limitada
30.	Emgality	galcanezumab	注射劑 Injection	用於每月偏頭痛發作天數不少於 4 天的成人患者以預防偏頭痛 Prophylaxis of migraine in adults who have at least 4 migraine days per month	利華行有限公司 Agência Lei Va Hong Lda.

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31.	Enhertu	trastuzumab deruxtecan	注射劑 Injection	治療曾接受過兩種或以上抗 HER2 療程、具有無法切除或轉移性 HER2 陽性乳癌 Treatment of unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens	科達有限公司 Four Star Companhia Lda.
32.	Enspryng	satralizumab	注射劑 Injection	治療 AQP4-IgG 陽性的泛視神經脊髓炎 To treat neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4 (AQP4) antibody positive	利華行有限公司 Agência Lei Va Hong Lda.
33.	Epkinly	epcoritamab	注射劑 Injection	治療先前曾接受至少兩線全身性治療之復發性或難治性瀰漫性大 B 細胞淋巴瘤的成人患者 Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy	康寧葯業有限公司 The Glory Medicina Limitada
34.	Equfina	safinamide	片劑 Tablet	與左旋多巴或其他藥物併用治療中至晚期的帕金森氏症 As adjunctive treatment to levodopa or other medicines in patients with mid- to late-stage Parkinson's disease	康寧葯業有限公司 The Glory Medicina Limitada

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35.	Evrysdi	risdiplam	溶液 Solution	用於 2 個月大或以上的患者，治療臨床診斷為 SMA 1 型、2 型、3 型或存有 1-4 個運動神經元存活-2 蛋白(SMN-2)的 5q 型脊髓性肌萎縮症 Treatment of 5q spinal muscular atrophy (SMA) in patients 2 months of age and older, with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies	利華行有限公司 Agência Lei Va Hong Lda.
36.	Evusheld△	tixagevimab, cilgavimab	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；治療病情有進展至重症風險且不需輔助供氧的成人及 12 歲或以上的新冠病毒感染者 To prevent COVID-19 in adults and adolescents from 12 years of age; To treat COVID-19 infection in adults and adolescents from 12 years of age who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	科達有限公司 Four Star Companhia Lda.
37.	Fabhalta	iptacopan	膠囊 Capsule	治療陣發性夜間血紅素尿症 Treatment of paroxysmal nocturnal hemoglobinuria (PNH)	科達有限公司 Four Star Companhia Lda.
38.	Fetcroja	cefiderocol	注射劑 Injection	治療對藥物有敏感性且治療選擇有限的細菌感染症 Treatment of bacterial infections that are susceptible and have limited treatment options	康寧葯業有限公司 The Glory Medicina Limitada

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39.	Hympavzi	marstacimab	注射劑 Injection	用於 A 型血友病或 B 型血友病的成人及 12 歲或以上青少年患者，作為常規預防以避免或減少出血事件的頻率 For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A or hemophilia B	康寧葯業有限公司 The Glory Medicina Limitada
40.	Imdelltra	tarlatamab	注射劑 Injection	用於既往接受過至少二線治療(包括含鉑類化療藥)期間或之後出現疾病進展的廣泛期小細胞肺癌成人患者 Treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after at least two prior lines of therapy including platinum-based chemotherapy	利華行有限公司 Agência Lei Va Hong Lda.

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41.	Imjudo	tremelimumab	注射劑 Injection	與 durvalumab 聯合使用，治療成人不可切除的肝細胞癌；與 durvalumab 及含鉑類化療藥聯合使用，治療不攜帶表皮生長因子受體突變或間變性淋巴瘤激酶基因異常的轉移性非小細胞肺癌 In combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC); In combination with durvalumab and platinum-based chemotherapy for the treatment of metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations	科達有限公司 Four Star Companhia Lda.
42.	Itovebi	inavolisib	片劑 Tablet	與 palbociclib 及 fulvestrant 聯合使用，用於內分泌治療耐藥、PIK3CA 突變、激素受體陽性及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 palbociclib and fulvestrant for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer	利華行有限公司 Agência Lei Va Hong Lda.

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43.	Izervay△	avacincaptad pegol	注射劑 Injection	治療因年齡相關性黃斑變性繼發的地圖樣萎縮 Treatment of geographic atrophy secondary to age-related macular degeneration	康寧葯業有限公司 The Glory Medicina Limitada
44.	Jemperli△	dostarlimab	注射劑 Injection	治療接受含鉑類化療藥治療期間或之後產生疾病進展的錯配修復缺陷/微衛星高度不穩定性的復發性或晚期子宮內膜癌 Treatment of patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen	利華行有限公司 Agência Lei Va Hong Lda.
45.	Kerendia	finerenone	片劑 Tablet	治療患有第二型糖尿病相關的伴隨有白蛋白尿的慢性腎病 Treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes	科達有限公司 Four Star Companhia Lda.

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46.	Kisunla	donanemab	注射劑 Injection	治療經臨床診斷為阿茲海默症引起的輕度認知障礙及輕度失智症(即阿茲海默症早期症狀階段)的成人患者，且這些患者需為載脂蛋白 Eε4 雜合子或非攜帶者，並經證實存在澱粉樣蛋白病理變化 Treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer’ s disease (Early symptomatic Alzheimer’ s disease) who are apolipoprotein E ε4 (ApoEε4) heterozygotes or non-carriers with confirmed amyloid pathology	利華行有限公司 Agência Lei Va Hong Lda.
47.	Koselugo	selumetinib	膠囊 Capsule	治療 3 歲或以上患有第 1 型神經纖維瘤病合併有症狀且手術無法切除的叢狀神經纖維瘤 To treat pediatric patients 3 years of age and older who have neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas (PN)	科達有限公司 Four Star Companhia Lda.

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48.	Lazcluze	lazertinib	片劑 Tablet	與 amivantamab 聯合使用，用於具有表皮生長因子受體外顯子 19 缺失或外顯子 21(L858R)置換突變的局部晚期或轉移性非小細胞肺癌成人患者的一線治療 In combination with amivantamab for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations	科達有限公司 Four Star Companhia Lda.
49.	Leqembi	lecanemab	注射劑 Injection	治療處於輕度認知障礙或輕度痴呆階段的阿爾茨海默病 Treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease	康寧葯業有限公司 The Glory Medicina Limitada
50.	Leqvio	inclisiran	注射劑 Injection	治療原發性高膽固醇血症（包括雜合子家族性和非家族性）及混合性血脂異常 Treatment of primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia	科達有限公司 Four Star Companhia Lda.
51.	Litfulo	ritlecitinib	膠囊 Capsule	治療 12 歲以上青少年及成人的嚴重斑禿 Treatment of severe alopecia areata in adults and adolescents 12 years of age and older	康寧葯業有限公司 The Glory Medicina Limitada

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52.	Livdelzi△	seladelpar	膠囊 Capsule	與 ursodeoxycholic acid 聯合使用，用於對 ursodeoxycholic acid 單藥治療反應不足、或單藥用於無法耐受 ursodeoxycholic acid 的原發性膽汁性膽管炎成人患者 Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.	科達有限公司 Four Star Companhia Lda.
53.	Livtencity	maribavir	片劑 Tablet	適用於已接受造血幹細胞移植或實體器官移植的成人患者，用於治療對一種或多種先前療法呈難治性(伴有或不伴有耐藥性)的巨細胞病毒(CMV)感染及/或疾病 Treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies in adult patients who have undergone a hematopoietic stem cell transplant or solid organ transplant	全昌行有限公司 Firma Chun Cheong - Produtos Farmacêuticos, Limitada

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54.	Lumakras△	sotorasib	片劑 Tablet	治療曾接受過至少一次含鉑化療或抗 PD-1 免疫療法，且帶有 KRAS G12C 突變之局部晚期或轉移性非小細胞肺癌 Treatment of patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), who have experienced progression after prior treatment with platinum-based chemotherapy and/or anti-PD-1 immunotherapy	利華行有限公司 Agência Lei Va Hong Lda.
55.	Lunsumio	mosunetuzumab	注射劑 Injection	治療過往已接受二線或以上全身性療法的復發型或難治型濾泡性淋巴瘤的成人患者 Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies	利華行有限公司 Agência Lei Va Hong Lda.
56.	Mektovi	binimetinib	片劑 Tablet	與 encorafenib 聯合使用，治療帶有 BRAF V600 突變且無法切除或轉移性的黑色素瘤 In combination with encorafenib is indicated for the treatment of unresectable or metastatic melanoma with a BRAF V600 mutation	利華行有限公司 Agência Lei Va Hong Lda.

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57.	Minjuvi	tafasitamab	注射劑 Injection	與 lenalidomide 聯合使用，治療不適合進行自體幹細胞移植的復發性或難治性瀰漫性大 B 細胞淋巴瘤的成年患者 In combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT)	科達有限公司 Four Star Companhia Lda.

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58.	Mounjaro	tirzepatide	注射劑 Injection	作為飲食及運動療法以外的輔助治療，單藥或與其他糖尿病治療藥物聯合使用以改善第二型糖尿病成人患者的血糖控制；用於體重控制，作為低熱量飲食及增加體能活動的補充，用於成人且起始身體質量指數≥30 kg/m^2 (肥胖)或 ≥ 27 kg/m^2 至< 30 kg/m^2 (過重)且至少患有一種體重相關疾病，例如高血壓、血脂異常、阻塞性睡眠呼吸中止、心血管疾病、糖尿病前期或第二型糖尿病 As monotherapy or in addition to other diabetes medications for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise. For weight management, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial Body Mass Index (BMI) of ≥ 30 kg/m^2 (obesity) or ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, obstructive sleep apnea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus)	利華行有限公司 Agência Lei Va Hong Lda.

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59.	Nefecon	budesonide	膠囊 Capsule	用於減少患有原發性 IgA 腎病且有疾病快速進展風險的成年病人的蛋白尿 To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) who are at high risk of disease progression	康福 Firma Welfare
60.	Nilemdo△	bempedoic acid	片劑 Tablet	配合飲食控制及最大耐受劑量的他汀類藥物，用於雜合子家族性高膽固醇血症或需要額外降低 LDL-C 的動脈粥樣硬化性心血管疾病的成人患者 As adjuncts to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C	利華行有限公司 Agência Lei Va Hong Lda.
61.	Nurtec	rimegepant	口服崩解片 Orally disintegrating tablet	治療有先兆或無先兆之急性偏頭痛的成人患者 Treatment of migraine with/without aura in adults 預防成人陣發性偏頭痛 Preventive treatment of episodic migraine in adults	康寧葯業有限公司 The Glory Medicina Limitada

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62.	Nustendi△	bempedoic acid, ezetimibe	片劑 Tablet	配合飲食控制及最大耐受劑量的他汀類藥物，用於雜合子家族性高膽固醇血症或需要額外降低 LDL-C 的動脈粥樣硬化性心血管疾病的成人患者 As adjuncts to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C	利華行有限公司 Agência Lei Va Hong Lda.
63.	Ocrevus	ocrelizumab	注射劑 Injection	治療患有復發型或早期原發進展型多發性硬化症 To treat relapsing or early primary progressive multiple sclerosis	利華行有限公司 Agência Lei Va Hong Lda.
64.	Ohtuvayre△	ensifentrine	吸入懸浮液 Inhalation suspension	用於成人慢性阻塞性肺病的維持治療 For the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients	利華行有限公司 Agência Lei Va Hong Lda.

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65.	Omjjara△	momelotinib	片劑 Tablet	用於患有原發性骨髓纖維化、真性紅細胞增多症後骨髓纖維化或血小板增多症後骨髓纖維化的中度至重度貧血成年患者，以治療與疾病相關的脾腫大或症狀，患者需既往未曾接受 JAK 抑制劑或既往曾接受 ruxolitinib 治療 Treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anemia who have primary myelofibrosis (PMF), post polycythemia vera myelofibrosis (post PV MF) or post essential thrombocythemia myelofibrosis (post ET MF) and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib	利華行有限公司 Agência Lei Va Hong Lda.
66.	Orkedia	evocalcet	片劑 Tablet	治療維持性透析成人患者的繼發性甲狀旁腺功能亢進症；治療甲狀旁腺癌及因無法進行甲狀旁腺切除或術後復發的原發性甲狀旁腺功能亢進症引起的高鈣血症 Treatment of secondary hyperparathyroidism in patients on maintenance dialysis; Treatment of hypercalcemia in patients with parathyroid carcinoma and hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or patients with recurrent primary hyperparathyroidism after parathyroidectomy	康寧葯業有限公司 The Glory Medicina Limitada

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67.	Orpathys	savolitinib	片劑 Tablet	治療已接受或不能耐受含鉑化療、具有間質-上皮轉化因子(MET)外顯子 14 跳變的轉移性非小細胞肺癌 Treatment of metastatic NSCLC with MET exon 14-skipping alterations in patients who have progressed after or who are unable to tolerate platinum-based chemotherapy	科達有限公司 Four Star Companhia Lda.
68.	Orserdu△	elacestrant	片劑 Tablet	治療雌激素受體陽性、人表皮生長因子受體 2 陰性、ESR1 突變的晚期或轉移性乳腺癌 To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated, advanced or metastatic breast cancer	利華行有限公司 Agência Lei Va Hong Lda.
69.	Padcev	enfortumab vedotin	注射劑 Injection	治療先前已接受含鉑類化學療法和 PD-1(或 PD-L1)抑制劑的局部晚期或轉移性泌尿上皮癌 Treatment of locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor 1 or programmed death ligand 1 inhibitor	全昌行有限公司 Firma Chun Cheong - Produtos Farmacêuticos, Limitada

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70.	Paxlovid	nirmatrelvir, ritonavir	片劑 Tablet	治療輕度至中度及高機會伴有發展成嚴重新型冠狀病毒感染風險的 12 歲(≥40kg)或以上的患者 Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19	康寧葯業有限公司 The Glory Medicina Limitada
71.	Pemazyre	pemigatinib	片劑 Tablet	用於曾接受過全身性治療後疾病惡化、腫瘤具有 FGFR2 融合或重排的局部晚期或轉移性膽管癌的成人患者 Treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement	永康有限公司 Companhia de Great Life Limitada
72.	Pluvicto	lutetium (^{177}Lu) vipivotide tetraxetan	注射劑 Injection	與雄激素剝奪療法聯合使用，用於治療既往接受雄激素受體通路抑制及紫杉烷類化療的前列腺特異性膜抗原陽性轉移性去勢抵抗性前列腺癌的成人患者 In combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition for the treatment of adult patients with progressive prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane-based chemotherapy	科達有限公司 Four Star Companhia Lda.

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73.	Qfitlia	fitusiran	注射劑 Injection	用於 A 型血友病(先天性第八凝血因子缺乏症)或 B 型血友病(先天性第九凝血因子缺乏症)的成人及 12 歲或以上青少年患者，作為常規預防以避免或減少出血事件的頻率 For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B	科達有限公司 Four Star Companhia Lda.
74.	Qinlock	ripretinib	片劑 Tablet	治療已接受包括 imatinib, sunitinib 和 regorafenib 等 3 種或以上激酶抑制劑治療的晚期胃腸道間質瘤 Treatment of patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib, sunitinib and regorafenib	科達有限公司 Four Star Companhia Lda.

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75.	Reblozyl	luspatercept	注射劑 Injection	治療具有環狀鐵粒幼細胞的骨髓增生異常綜合症，且不適合使用或對促紅細胞生成素治療反應不佳的輸血依賴性貧血患者；治療患有β-地中海貧血症的輸血依賴性貧血患者 To treat myelodysplastic syndromes with ring sideroblasts (MDS-RS) who need regular red blood cell (RBC) transfusions and have not responded well to or cannot receive erythropoiesis stimulating agent (ESA); To treat β -thalassemia who need regular RBC transfusions	康寧葯業有限公司 The Glory Medicina Limitada
76.	Retsevmo	selpercatinib	膠囊 Capsule	治療既往未曾接受 RET 抑制劑的 RET 融合陽性的晚期非小細胞肺癌 治療既往曾接受 sorafenib 及(或)lenvatinib 的 RET 融合陽性的晚期甲狀腺癌 治療 RET 突變型的晚期甲狀腺髓質癌 Treatment of advanced RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor Treatment of advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory Treatment of advanced RET-mutant medullary thyroid cancer (MTC)	利華行有限公司 Agência Lei Va Hong Lda.

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77.	Rezurock	belumosudil	片劑 Tablet	用於 12 歲或以上，曾接受至少兩線全身性治療且失敗的慢性移植物抗宿主病患者 Treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy	科達有限公司 Four Star Companhia Lda.
78.	Ruxolitinib	ruxolitinib	乳膏 Cream	用於治療 12 歲及以上青少年及成人的臉部白癜風 To treat vitiligo with facial involvement in adults and adolescents from 12 years	五洲 Firma Wuzhou
79.	Rybrevant	amivantamab	注射劑 Injection	治療帶有表皮生長因子受體外顯子 20 插入突變型的晚期非小細胞肺癌成人患者，作為含鉑類化學療法治療失敗後之治療 Treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy	科達有限公司 Four Star Companhia Lda.
80.	Saphnelo△	anifrolumab	注射劑 Injection	治療已接受標準療法的中、重度全身性紅斑狼瘡的成人患者 Treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy	科達有限公司 Four Star Companhia Lda.

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81.	Sarclisa	isatuximab	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	科達有限公司 Four Star Companhia Lda.
82.	Scemblix	asciminib	片劑 Tablet	治療先前已接受過至少 2 種酪氨酸激酶抑制劑治療且處於慢性期的費城染色體陽性慢性髓性白血病(Ph+CML-CP)的成年患者；治療攜帶 T315I 突變的 Ph+CML-CP 的成年患者 To treat adults patients with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs); To treat adults patients with Ph+ CML in CP with the T315I mutation	科達有限公司 Four Star Companhia Lda.
83.	Spevigo	spesolimab	注射劑 Injection	治療全身型膿皰性乾癬 Treatment of generalized pustular psoriasis (GPP)	利華行有限公司 Agência Lei Va Hong Lda.
84.	Sotyktu	deucravacitinib	片劑 Tablet	治療中度至重度斑塊狀銀屑病 To treat moderate-to-severe plaque psoriasis	康寧葯業有限公司 The Glory Medicina Limitada
85.	Spikevax△ (Original/Omicron BA.4-5)	elasomeran, davesomeran	注射劑 Injection	用於 12 歲及以上人群的新冠病毒加強免疫接種 Booster dose for immunization to prevent COVID-19 infection in individuals 12 years of age and older	康寧葯業有限公司 The Glory Medicina Limitada
86.	Staquis	crisaborole	軟膏 Ointment	治療異位性皮膚炎 Treatment of atopic dermatitis	康寧葯業有限公司 The Glory Medicina Limitada

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87.	Sulanda	surufatinib	膠囊 Capsule	用於無法手術切除的局部晚期或轉移性、進展期非功能性、分化良好(G1、G2)的胰腺和非胰腺來源的神經內分泌瘤 Treatment of unresectable locally advanced or metastatic, progressive non-functioning, well-differentiated (G1 or G2) pancreatic or extra-pancreatic neuroendocrine tumors	科達有限公司 Four Star Companhia Lda.
88.	Syfovre#△	pegcetacoplan	注射劑 Injection	治療因年齡相關性黃斑變性繼發的地圖樣萎縮 Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	利華行有限公司 Agência Lei Va Hong Lda.
89.	Symproic	naldemedine tosylate	片劑 Tablet	治療成人因鴉片類藥物引起之便秘 To treat constipation caused by opioid medication	康寧葯業有限公司 The Glory Medicina Limitada
90.	Tabrecta	capmatinib	片劑 Tablet	治療帶有 MET 外顯子 14 跳讀式突變的轉移性非小細胞肺癌成人患者 Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to MET exon 14-skipping	科達有限公司 Four Star Companhia Lda.
91.	Takhzyro	lanadelumab	注射劑 Injection	預防 12 歲或以上遺傳性血管性水腫患者的反覆發作 Prevention of recurrent attacks of hereditary angioedema in patients aged 12 years and older	全昌行有限公司 Firma Chun Cheong - Produtos Farmacêuticos, Limitada

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92.	Talvey	talquetamab	注射劑 Injection	治療既往接受過至少三種治療(包括一種蛋白酶體抑制劑、一種免疫調節劑及一種抗 CD38 抗體)後出現疾病惡化的復發或難治性多發性骨髓瘤 Treatment of patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy	科達有限公司 Four Star Companhia Lda.
93.	Tasfygo	tasurgratinib	片劑 Tablet	用於既往化療後失敗的，且經檢測確認具有 FGFR2 融合/重排基因的，不可切除的膽道癌成人患者 Treatment of adult patients with unresectable biliary tract cancer harboring FGFR2 gene fusions or rearrangements that have progressed after prior chemotherapy	德聖堂 Tak Sing Tong

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94.	Tecvayli	teclistamab	注射劑 Injection	治療既往接受過至少三種治療(包括一種免疫調節劑、一種蛋白酶體抑制劑及一種抗 CD38 單株抗體)後出現疾病惡化的復發性或難治性多發性骨髓瘤 Treatment of patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy	科達有限公司 Four Star Companhia Lda.
95.	Tepmetko	tepotinib	片劑 Tablet	治療帶有間質上皮轉化因子外顯子-14 跳讀式突變的晚期或轉移性之非小細胞肺癌 Treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations	康寧葯業有限公司 The Glory Medicina Limitada
96.	Tezspire	tezepelumab	注射劑 Injection	常規維持治療(如高劑量吸入性皮質類固醇及其他哮喘藥物)仍無法充分控制病情的嚴重哮喘患者 Maintenance treatment of patients with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product	科達有限公司 Four Star Companhia Lda.

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97.	Tibsovo	ivosidenib	片劑 Tablet	與 azacitidine 聯合使用，治療無法接受標準誘導化療，攜帶 IDH1 R132 突變的新診斷急性骨髓性白血病成人患者 用於既往已接受至少一種全身性治療，攜帶 IDH1 R132 突變的局部晚期或轉移性膽管癌成人患者 In combination with azacitidine for the treatment of newly diagnosed acute myeloid leukemia in adult patients with an IDH1 R132 mutation who are unable to receive standard induction chemotherapy Treatment of adult patients with IDH1 R132-mutated locally advanced or metastatic cholangiocarcinoma who have received at least one prior systemic therapy	利華行有限公司 Agência Lei Va Hong Lda.
98.	Tivdak	tisotumab vedotin	注射劑 Injection	治療在化療期間或化療後出現疾病惡化的復發性或轉移性宮頸癌 Treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	康寧葯業有限公司 The Glory Medicina Limitada

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99.	Trodelvy	sacituzumab govitecan	注射劑 Injection	治療先前已接受兩種或以上全身性治療無效(其中至少一種用於治療轉移性疾病)之無法切除的局部晚期或轉移性三陰性乳癌 Treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received at least two prior systemic therapies, including at least one prior therapy for locally advanced or metastatic disease	科達有限公司 Four Star Companhia Lda.
100.	Truqap	capivasertib	片劑 Tablet	與 fulvestrant 聯合使用，治療激素受體陽性、人表皮生長因子受體陰性且至少帶有一種 PIK3CA、AKT1 或 PTEN 基因變異的晚期或轉移性乳腺癌 In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations	科達有限公司 Four Star Companhia Lda.

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101.	Tukysa△	tucatinib	片劑 Tablet	與 trastuzumab 及 capecitabine 併用於曾接受至少兩次針對 HER2 靶點的療法的無法切除晚期或轉移性 HER2 陽性乳癌 In combination with trastuzumab and capecitabine for the treatment of patients with HER2-positive locally advanced or metastatic breast cancer who have received at least 2 prior anti-HER2 treatment regimens	康寧葯業有限公司 The Glory Medicina Limitada
102.	Tyrvaya	varenicline	鼻用噴霧劑 Nasal Spray	治療乾眼症的病徵與症狀 Treatment of the signs and symptoms of dry eye disease	五洲 Firma Wuzhou
103.	Ultomiris	ravulizumab	注射劑 Injection	治療陣發性夜間血紅素尿症、非典型溶血性尿毒症候群、全身型重症肌無力及視神經脊髓炎 Treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD)	康寧葯業有限公司 The Glory Medicina Limitada

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104.	Vaborem△	meropenem, vaborbactam	注射劑 Injection	治療複雜性尿路感染，包括腎盂腎炎 治療複雜性腹腔內感染 治療院內型肺炎，包括呼吸器相關肺炎 治療與上述任何感染相關或疑似與上述任何感染相關的菌血症 治療對藥物有敏感性且治療選擇有限的細菌感染症 Treatment of complicated urinary tract infection (cUTI), including pyelonephritis. Treatment of complicated intra-abdominal infections (cIAI). Treatment of hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP). Treatment of patients with bacteremia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Treatment of bacterial infections that are susceptible and have limited treatment options	利華行有限公司 Agência Lei Va Hong Lda.

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105.	Vabysmo	faricimab	注射劑 Injection	適用於治療血管新生型(濕性)年齡相關性黃斑部退化病變的成年患者；適用於成人因糖尿病黃斑部水腫所引致的視覺障礙 To treat adults with neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME)	利華行有限公司 Agência Lei Va Hong Lda.
106.	Vanflyta	quizartinib	片劑 Tablet	與標準前導化療(cytarabine 和 anthracycline)以及與標準鞏固化療 cytarabine 合併使用，用於新診斷 FLT3-ITD 陽性的急性髓細胞白血病成人患者 In combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3-ITD positive	利華行有限公司 Agência Lei Va Hong Lda.
107.	Vanrafia△	atrasentan	片劑 Tablet	用於降低患有原發性 IgAN 並有病情迅速惡化風險的成人患者的蛋白尿水平 To reduce proteinuria in adult patients with primary immunoglobulin A nephropathy (IgAN) at risk for rapid disease progression	科達有限公司 Four Star Companhia Lda.
108.	Veklury△	remdesivir	注射劑 Injection	治療成人及 12 歲或以上(體重≥40kg)的新冠病毒感染 To treat adults and children 12 years of age and older and weighing at least 40 kg with COVID-19 infection	科達有限公司 Four Star Companhia Lda.

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109.	Velsipity	etrasimod	片劑 Tablet	治療中度至嚴重活動性潰瘍性結腸炎 To treat moderately-to-severely active ulcerative colitis	壹康 Uma-Saúde
110.	Veoza△	fezolinetant	片劑 Tablet	治療因更年期而引起的中度至嚴重的血管舒縮症狀 Treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause	康寧葯業有限公司 The Glory Medicina Limitada
111.	Verquvo	vericiguat	片劑 Tablet	治療心臟射出分率下降且曾因為病情惡化而需接受靜脈注射治療的症狀性心臟衰竭成人患者 Treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring IV therapy	科達有限公司 Four Star Companhia Lda.
112.	Voranigo△	vorasidenib	片劑 Tablet	治療 12 歲以上及成人患者手術後的 IDH1 或 IDH2 突變陽性的低度惡性星形細胞瘤或少突膠質細胞瘤 Treatment of adult and pediatric patients aged 12 years and older with low grade astrocytoma or oligodendroglioma with IDH1 or IDH2 mutation following surgery	利華行有限公司 Agência Lei Va Hong Lda.
113.	Vyalev△	foslevodopa, foscarbidopa	注射劑 Injection	治療晚期帕金森病成人患者的運動症狀波動 Treatment of motor fluctuations in adults with advanced Parkinson's disease	康寧葯業有限公司 The Glory Medicina Limitada
114.	Vyepti△	eptinezumab	注射劑 Injection	用於成人預防偏頭痛 For preventive treatment of migraine in adults	科達有限公司 Four Star Companhia Lda.

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115.	Vyloy	zolbetuximab	注射劑 Injection	聯合氟尿嘧啶類及鉑類藥物用於 CLDN18.2 陽性、人表皮生長因子受體 2(HER2)陰性的局部晚期不可切除或轉移性胃或胃食管交界處腺癌的患者 In combination with fluoropyrimidine- and platinum-containing chemotherapy for treating locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma in patients whose tumors are HER2-negative and CLDN18.2 positive	康寧葯業有限公司 The Glory Medicina Limitada
116.	Wakix	pitolisant	片劑 Tablet	治療猝睡症所導致的白天嗜睡或猝倒 To treat excessive daytime sleepiness (EDS) or sudden onset of weak or paralyzed muscles (cataplexy) due to narcolepsy	利華行有限公司 Agência Lei Va Hong Lda.
117.	Winrevair	sotatercept	注射劑 Injection	與其他肺動脈高壓治療方案聯合使用，用於世界衛生組織功能程度分級第 II-III 級肺動脈高壓的成人患者，以提高運動能力 In combination with other pulmonary arterial hypertension (PAH) therapies, for the treatment of PAH in adult patients with WHO Functional Class (FC) II to III, to improve exercise capacity	利華行有限公司 Agência Lei Va Hong Lda.
118.	Xdemvy	lotilaner	眼用溶液 ophthalmic solution	治療蠕形蟎瞼緣炎 To treat demodex blepharitis	五洲 Firma Wuzhou

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119.	Xospata	gilteritinib	片劑 Tablet	治療具有 FLT3 突變的復發性或難治性急性骨髓性白血病的成人患者 Treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation	全昌行有限公司 Firma Chun Cheong - Produtos Farmacêuticos, Limitada
120.	Xpovio	selinexor	片劑 Tablet	治療復發或難治性多發性骨髓瘤 To treat relapsed refractory multiple myeloma (RRMM)	康寧葯業有限公司 The Glory Medicina Limitada
121.	Zepzelca	lurbinectedin	注射劑 Injection	治療曾接受含鉑化療仍疾病惡化的轉移性小細胞肺癌 Treatment of metastatic small cell lung cancer (SCLC) that has progressed on or after prior platinum-containing therapy	科達有限公司 Four Star Companhia Lda.
122.	Zunveyl[△]	benzgalantamine	片劑 Tablet	用於治療成人輕度至中度阿爾茨海默型癡呆症狀 Treatment of mild to moderate dementia of the Alzheimer's type in adults	康寧葯業有限公司 The Glory Medicina Limitada
123.	貝美納；鹽酸恩沙替尼膠囊	ensartinib hydrochloride	膠囊 Capsule	治療間變性淋巴瘤激酶陽性的局部晚期或轉移性非小細胞肺癌 Treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC)	五洲 Firma Wuzhou

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124.	艾弗沙；甲磺酸伏美替尼片	furmonertinib mesilate	片劑 Tablet	治療具有抗表皮生長因子受體(EGFR)外顯子 19 缺失(Ex19del)或外顯子 21 (L858R)置換突變的局部晚期或轉移性非小細胞肺癌成人患者 治療既往經 EGFR 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 19 deletion (Ex19del) or exon 21 (L858R) substitution mutations Treatment of adult patients with locally advanced or metastatic NSCLC who experienced disease progression during or after prior treatment with EGFR tyrosine kinase inhibitors and who were tested positive for the EGFR T790M mutation	醫諾 Firma Promise
125.	艾瑞恩；瑞維魯胺片	rezvilutamide	片劑 Tablet	用於治療高瘤負荷的轉移性激素敏感性前列腺癌(mHSPC)患者 Treatment of patients with high tumor burden metastatic hormone-sensitive prostate cancer (mHSPC	利華行有限公司 Agência Lei Va Hong Lda.

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126.	艾瑞康；羥乙磺酸達爾西利片	dalpiciclib isethionate	片劑 Tablet	用於治療激素受體(HR)陽性、人表皮生長因子受體2(HER2)陰性局部晚期或轉移性乳腺癌患者 Treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer	利華行有限公司 Agência Lei Va Hong Lda.
127.	艾維達；注射用瑞康曲妥珠單抗	trastuzumab rezetecan	注射劑 Injection	單藥用於治療存在 HER2(ERBB2)激活突變且既往接受過至少一種系統治療的不可切除的局部晚期或轉移性非小細胞肺癌成人患者 Treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer harboring activating HER2 (ERBB2) mutations who have received at least one prior systemic therapy	利華行有限公司 Agência Lei Va Hong Lda.
128.	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、復發或轉移性胃及胃食管結合部腺癌的一線治療 In combination with fluorouracil and platinum-based drugs as a first-line treatment for locally advanced, unresectable, recurrent, or metastatic gastric cancer and gastroesophageal junction adenocarcinoma (GC/GEJA) with a PD-L1 positive CPS ≥ 1	科達有限公司 Four Star Companhia Lda.

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129.	安久衛；安奈拉唑鈉腸溶片#	anaprazole	片劑 Tablet	治療十二指腸潰瘍 Treatment of duodenal ulcers	永年醫藥國際 Médica Mundial Vitalidade
130.	安睿威；昂拉地韋片	onradivir	片劑 Tablet	用於成人單純型甲型流感患者的治療，不包括存在流感相關併發症高風險的患者 Treatment of adult patients with uncomplicated influenza A, not specifically indicated for high-risk groups	美康行 Agência Mei Hong 永康有限公司 Companhia de Great Life Limitada
131.	安瑞昔；澤貝妥單抗注射液	zuberitamab	注射劑 Injection	與標準 CHOP 化療聯合治療 CD 20 陽性的非特指性彌漫大 B 細胞淋巴瘤 In combination with standard CHOP chemotherapy for the treatment of CD20-positive diffuse large B-cell lymphoma , not otherwise specified (DLBCL, NOS)	五洲 Firma Wuzhou

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132.	百悅達；索托克拉片	sonrotoclax	片劑 Tablet	既往接受過至少包含布魯頓酪氨酸激酶抑制劑在內的一種系統治療的慢性淋巴細胞白血病/成人患者 既往接受過至少兩種系統性治療(含布魯頓酪氨酸激酶抑制劑)的復發或難治性套細胞淋巴瘤成人患者 Treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior systemic therapy, including a Bruton’ s tyrosine kinase (BTK) inhibitor Treatment of adult patients relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior systemic therapies, including a BTK inhibitor	康寧葯業有限公司 The Glory Medicina Limitada
133.	百赫安；注射用澤尼達妥單抗	zanidatamab	注射劑 Injection	用於既往接受過全身治療的 HER2 高表達(IHC3+)的不可切除局部晚期或轉移性膽道癌成人患者 For adult patients with unresectable locally advanced or metastatic HER2-overexpressing (IHC 3+) biliary tract cancer (BTC) who have received prior systemic therapy	康寧葯業有限公司 The Glory Medicina Limitada

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134.	百澤安；替雷利珠單抗注射液	tislelizumab	注射劑 Injection	治療經典型霍奇金淋巴瘤、非小細胞肺癌、肝細胞癌、高度微衛星不穩定型實體瘤、食管鱗狀細胞癌及鼻咽癌 To treat classical Hodgkin lymphoma (cHL), non-small cell lung cancer, hepatocellular carcinoma (HCC), microsatellite instability-high solid cancer (MSI-H), esophageal squamous cell carcinoma (ESCC) and nasopharyngeal cancer (NPC)	康寧葯業有限公司 The Glory Medicina Limitada
135.	克瑞畢；澤美洛韋瑪佐瑞韋單抗注射液	zamerovimab, mazorelvimab	注射劑 Injection	用於狂犬病病毒暴露者的被動免疫 Use in passive post-exposure prophylaxis of rabies	美儉 Firma Mekim
136.	怡諾輕；依蘇帕格魯肽α注射液	efsubaglutide alfa	注射劑 Injection	用於第二型糖尿病成人患者的血糖控制 For glycemic control in adults with type 2 diabetes mellitus	康寧葯業有限公司 The Glory Medicina Limitada
137.	奕凱達；阿基侖賽注射液	axicabtagene ciloleucel	注射劑 Injection	治療 B 細胞淋巴瘤 To treat B-cell Lymphoma	醫臣藥業 Pharmason Medicina

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138.	耐立克；雷巴替尼片	olverembatinib	片劑 Tablet	治療對第一代及第二代酪氨酸激酶抑制劑耐藥及/或不耐受的慢性髓細胞白血病慢性期 用於任何酪氨酸激酶抑制劑耐藥，經診斷為伴有 T315I 突變的慢性髓細胞白血病慢性期或加速期 Treatment of patients with chronic myeloid leukemia resistant to and/or intolerant of first- and second-generation tyrosine kinase inhibitors (TKI) Treatment of patients with TKI-resistant chronic-phase chronic myeloid leukemia (CP-CML) or accelerated-phase CML (AP-CML) harboring the T315I mutation	邁極康 Saúde Magicure

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139.	信必樂；托萊西單抗注射液	tafolecimab	注射劑 Injection	在控制飲食的基礎上，與他汀類藥物或與他汀類藥物及其他降脂療法聯合使用，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目標的原發性高膽固醇血症(包括雜合子型家族性和非家族性高膽固醇血症)及混合型血脂異常的成人患者，以降低低密度脂蛋白膽固醇、總膽固醇、載脂蛋白 B 水平 As adjunct to diet, in combination with statins or statins and other lipid-lowering therapies, for the treatment of adult patients with primary hypercholesterolemia (including heterozygous familial and non-familial hypercholesterolemia) and mixed dyslipidemia, who have failed to achieve LDL-C goals by using moderate or higher doses of statin to reduce LDL-C, TC and ApoB levels	永康有限公司 Companhia de Great Life Limitada
140.	信必敏；替妥尤單抗 N01 注射液	teprotumumab N01	注射劑 Injection	治療成人甲狀腺眼病 Treatment of adults with thyroid eye disease	永康有限公司 Companhia de Great Life Limitada
141.	信玖凝；波哌達可基注射液	dalnacogene ponparvovec	注射劑 Injection	用於治療中重度血友病 B 成年患者 Treatment of adult patients with moderate to severe hemophilia B	利華行有限公司 Agência Lei Va Hong Lda.

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142.	信美悅；匹康奇拜單抗注射液	picankibart	注射劑 Injection	用於適合系統性治療的中重度斑塊狀銀屑病成人患者 Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy	永康有限公司 Companhia de Great Life Limitada
143.	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 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.)	永康有限公司 Companhia de Great Life Limitada
144.	若欣林；鹽酸托魯地文拉法辛緩釋片	toludesvenlafaxine hydrochloride	片劑 Tablet	治療抑鬱症 Treatment of depression	邁極康 Saúde Magicure
145.	泰中定；阿泰特韋片/利托那韋片	atilotrelvir, ritonavir	片劑 Tablet	治療輕、中度新型冠狀病毒感染的成人患者 Treatment of adult patients with mild and moderate COVID-19 infection	清新有限公司 Cheng San Limitada

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146.	軒悅寧；吡洛西利片#	bireociclib	片劑 Tablet	與芳香化酶抑制劑聯合用於女性乳腺癌患者的初始內分泌治療的激素受體(HR)陽性及人表皮生長因子受體2(HER2)陰性的局部晚期或轉移性乳腺癌 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(HR)陽性及人表皮生長因子受體 2(HER2)陰性的局部晚期或轉移性乳腺癌 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激素受體陽性及人表皮生長因子受體 2 陰性的晚期或轉移性乳腺癌患者 In combination with aromatase inhibitors as the initial endocrine therapy for patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) locally advanced or metastatic breast cancer In combination with fulvestrant for the treatment of patients with HR+/HER2- advanced or metastatic breast cancer whose disease has progressed after prior endocrine therapy As a monotherapy for HR+/HER2- advanced or metastatic breast cancer patients who have progressed after receiving two or more lines of endocrine therapies and one chemotherapy in the metastatic stage.	永年醫藥國際 Médica Mundial Vitalidade

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147.	恩維達；恩沃利單抗注射液	envafolimab	注射劑 Injection	用於不可切除或轉移性微衛星高度不穩定或錯配修復基因缺陷型的晚期實體瘤 Treatment of patients with unresectable or metastatic microsatellite instability-high/ mismatch repair deficient (MSI-H/dMMR) advanced solid tumors	五洲 Firma Wuzhou
148.	紐再樂；注射用甲苯磺酸奧馬環素/甲苯磺酸奧馬環素片	omadacycline	注射劑 Injection 片劑 Tablet	治療社區獲得性細菌性肺炎及急性細菌性皮膚和皮膚結構感染 To treat community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infection (ABSSSI)	科達有限公司 Four Star Companhia Lda.

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149.	倍諾達；瑞基奧侖賽注射液	relmacabtagene autoleucel	注射劑 Injection	用於經過二線或以上系統性治療後的復發或難治性大 B 細胞淋巴瘤；用於經過二線或以上系統性治療的難治性或 24 個月內復發的濾泡性淋巴瘤；用於經過包括布魯頓酪氨酸激酶抑制劑治療在內的二線及以上系統性治療的復發或難治性套細胞淋巴瘤 Treatment of relapsed or refractory large B-cell lymphoma (r/r LBCL) after two or more lines of systemic therapy. Treatment of follicular lymphoma that is refractory or that relapses with 24 months of second-line or above systemic treatment. Treatment of relapsed or refractory mantle cell lymphoma (r/r MCL) who have previously been treated with at least 2 lines of systemic therapy including bruton tyrosine kinase inhibitors (BTKis)	壹康 Uma-Saúde
150.	華領片；多格列艾汀片	dorzagliatin	片劑 Tablet	用於改善成人第二型糖尿病患者的血糖控制 For improving glycemic control in adult patients with type 2 diabetes	康寧葯業有限公司 The Glory Medicina Limitada

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151.	壹立康；瑪帕西沙韋膠囊#	pixavir marboxil	膠囊 Capsule	用於既往健康的 12 歲及以上青少年和成人單純型甲型及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 uncomplicated influenza A and B in previously healthy adults and adolescents aged ≥ 12 years, excluding patients at high risk of influenza-related complications	博康醫療有限公司 Bond Medical Companhia Lda.
152.	源瑞達；納基奧侖賽注射液	inaticabtagene autoleucel	注射劑 Injection	治療成人復發或難治性 B 細胞急性淋巴細胞白血病 Treatment in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-cell ALL)	五洲 Firma Wuzhou
153.	愛瑞卓；羅沙司他膠囊	roxadustat	膠囊 Capsule	用於慢性腎臟病引起的貧血，包括透析及非透析患者 Treatment of anemia of chronic kidney disease in both non-dialysis-dependent and dialysis-dependent patients	科達有限公司 Four Star Companhia Lda.
154.	瑞普多；瑞米布替尼片	remibrutinib	片劑 Tablet	用於 H1 抗組胺藥控制不充分的慢性自發性蕁麻疹成人患者 Treatment of adult patients with chronic spontaneous urticaria who remain symptomatic despite H1-antihistamine treatment	科達有限公司 Four Star Companhia Lda.

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155.	達伯欣；伊匹木單抗 N01 注射液	ipilimumab N01	注射劑 Injection	聯合 sintilimab，用於可手術切除的 IIB-III 期微衛星高度不穩定型或錯配修復缺陷型的成人結腸癌患者的輔助治療 In combination with sintilimab, for the adjuvant treatment of resectable stage IIB-III microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) colon cancer in adult patients	永康有限公司 Companhia de Great Life Limitada
156.	達伯特；氟澤雷塞片	fulzerasib	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 G12C 突變型的晚期非小細胞肺癌 To treat patients with advanced non-small cell lung cancer (NSCLC) carrying the Kirsten rat sarcoma viral oncogene (KRAS) G12C mutation who have received at least one systemic treatment	永康有限公司 Companhia de Great Life Limitada
157.	達伯舒；信迪利單抗注射液	sintilimab	注射劑 Injection	治療經典型霍奇金淋巴瘤、非小細胞肺癌、肝細胞癌、食管鱗癌及胃及胃食管交界處腺癌 To treat classical Hodgkin lymphoma (cHL), non-small cell lung cancer, hepatocellular carcinoma (HCC), esophageal cancer (EC) and adenocarcinoma of esophagogastric junction (EGJA)	永康有限公司 Companhia de Great Life Limitada
158.	達伯樂；己二酸他雷替尼膠囊	taletrectinib adipate	膠囊 Capsule	用於酪氨酸受體激酶 ROS1 陽性的局部晚期或轉移性非小細胞肺癌成人患者 Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer	永康有限公司 Companhia de Great Life Limitada

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159.	福可蘇；伊基奧侖賽注射液	equecabtagene autoleucel	注射劑 Injection	治療既往經過至少三綫治療後出現疾病惡化(至少使用過一種蛋白酶體抑制劑及免疫調節劑)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 who have progressed after at least three lines of prior therapies containing at least one proteasome inhibitor and immunomodulatory agent	南光 Firma Nam Kwong
160.	樂睿靈；來瑞特韋片	leritrelvir	片劑 Tablet	治療輕中度新型冠狀病毒感染 Treatment of mild-to-moderate COVID-19 infection	美康行 Agência Mei Hong 永康有限公司 Companhia de Great Life Limitada
161.	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外顯子 19 缺失或外顯子 21(L858R)置換突變，並伴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 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	德聖堂 Tak Sing Tong
162.	雙洛平；西格列他鈉片	chiglitazar	片劑 Tablet	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	仲聯有限公司 Firma Polywell Limitada

*按商品名稱的字母/筆劃排序

Commercial names are listed in alphabetical/strokes order

資料截至：11/2026

#最新獲藥物監督管理局批准上市的新藥

Latest new drug approved for marketing by ISAF

▵尚未在中國內地批准上市的新藥

New drugs not yet approved for marketing in Mainland China