已获药物监督管理局批准上市的新药清单
List of new drugs approved for marketing by Pharmaceutical Administration Bureau (ISAF)

项目	商品名称 Commercial Name	主成分 Active Ingredient(s)	剂型 Dosage Form	适应症 Indication(s)	药物产品出入口及批发商号 Firm for Import, Export and Wholesale of Pharmaceutical Products
1.	Abrysvo	RSV subgroup A PreF antigen, RSV subgroup B PreF antigen	注射剂 Injection	用于妊娠 24 至 36 周的孕妇通过母体免疫以预防刚出生至 6 个月的婴儿因呼吸道合胞病毒引起的下呼吸道疾病预防 60 岁及以上人群因呼吸道合胞病毒引起的下呼吸道疾病 Prevention of lower respiratory tract disease 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	康宁药业有限公司 The Glory Medicina Limitada
2.	Adzynma	rADAMTS13	注射剂 Injection	用于患有缺乏 ADAMTS13 蛋白酶的先天性血栓性血小板减少性紫斑症 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	注射剂 Injection	适用于 A 型血友病作为常规预防、需求性治疗及控制出血和手术全期的出血处理 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	科达有限公司 Four Star Companhia Lda.
4.	Anzupgo	delgocitinib	乳膏 Cream	对外用类固醇无效或不能使用外用类固醇治疗的中度至严重的慢性手部湿疹成人患者 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	注射剂 Injection	与颗粒细胞菌落刺激因子联合使用，将造血干细胞动员到外周血中，用于多发性骨髓瘤患者的血液单采和随后的自体移植 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	片剂 Tablet	用于每月偏头痛发作天数不少于 4 天的成人患者以预防偏头痛 Prophylaxis of migraine in adults who have at least 4 migraine days per month	康宁药业有限公司 The Glory Medicina Limitada
7.	Arexvy	RSVPreF3 antigen	注射剂 Injection	预防 60 岁及以上人群因呼吸道合胞病毒引起的下呼吸道疾病 Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older	利华行有限公司 Agência Lei Va Hong Lda.
8.	Augtyro	repotrectinib	胶囊 Capsule	治疗患有 ROS1 阳性的局部晚期或转移性非小细胞肺癌 Treatment of patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)	科达有限公司 Four Star Companhia Lda.
9.	Besremi	ropeginterferon alfa-2b	注射剂 Injection	治疗不具症状性脾肿大的真性红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	注射剂 Injection	预防正值或进入第一个呼吸道合胞病毒季节时出生的新生儿及婴儿和在第二个呼吸道合胞病毒好发季节仍易罹患严重呼吸道合胞病毒疾病的 24 个月或以下幼儿因感染呼吸道合胞病毒而导致的下呼吸道疾病 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	科达有限公司 Four Star Companhia Lda.
11.	Braftovi	encorafenib	胶囊 Capsule	与 binimetinib 联合使用，治疗带有 BRAF V600 突变且无法切除或转移性的黑色素瘤 与 cetuximab 联合使用，治疗带有 BRAF V600E 突变且曾接受全身性疗法的转移性结直肠癌 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	利华行有限公司 Agência Lei Va Hong Lda.

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12.	Brukinsa	zanubrutinib	胶囊 Capsule	治疗套细胞淋巴瘤、慢性淋巴细胞白血病/小淋巴细胞淋巴瘤及华氏巨球蛋白血症 To treat mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL) and Waldenström macroglobulinemia (WM)	康宁药业有限公司 The Glory Medicina Limitada
13.	Camzyos	mavacamten	胶囊 Capsule	治疗纽约心脏协会(NYHA)II-III 级症状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)	康宁药业有限公司 The Glory Medicina Limitada
14.	Cibinqo	abrocitinib	片剂 Tablet	治疗成人及 12 岁以上青少年的中度至重度湿疹(异位性皮肤炎) To treat adults and children 12 years of age and older with moderate-to-severe eczema (atopic dermatitis)	康宁药业有限公司 The Glory Medicina Limitada
15.	Cobenfy	xanomeline, trospium chloride	胶囊 Capsule	用于治疗成人精神分裂症 Treat adults with schizophrenia	科达有限公司 Four Star Companhia Lda.

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16.	Columvi	glofitamab	注射剂 Injection	用于治疗复发或难治性弥漫性大 B 细胞淋巴瘤，或经过两次或多次全身治疗后由滤泡性淋巴瘤引起的大 B 细胞淋巴瘤 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	利华行有限公司 Agência Lei Va Hong Lda.
17.	Comirnaty COVID-19 mRNA Vaccine	tozinameran	注射剂 Injection	预防新冠病毒感染 Prevention of COVID-19 infection	科达有限公司 Four Star Companhia Lda. 医臣药业 Pharmason Medicina
18.	Comirnaty COVID-19 mRNA Vaccine (Original/Omicron BA.4-5)	tozinameran, famtozinameran	注射剂 Injection	用于 12 岁及以上人群的新冠病毒加强免疫接种 Booster dose for immunization to prevent COVID-19 infection in individuals 12 years of age and older	科达有限公司 Four Star Companhia Lda. 医臣药业 Pharmason Medicina
19.	Comirnaty COVID-19 mRNA Vaccine (OMICRON XBB.1.5)	raxtozinameran	注射剂 Injection	用于 12 岁及以上人群的预防新冠病毒感染及加强免疫接种 Prevention of COVID-19 infection and booster dose for immunization to prevent COVID-19 infection in individuals 12 years of age and older	医臣药业 Pharmason Medicina

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20.	Comirnaty COVID-19 mRNA Vaccine (Omicron JN.1)	bretovameran	注射剂 Injection	用于 12 岁及以上人群预防由新型冠状病毒所引起的感染 Prevention of COVID-19 infection in individuals 12 years of age and older	医臣药业 Pharmason Medicina
21.	Comirnaty COVID-19 mRNA Vaccine (Omicron LP.8.1)	mRNA encoding LP.8.1	注射剂 Injection	用于 12 岁及以上人群预防由新型冠状病毒所引起的感染 Prevention of COVID-19 infection in individuals 12 years of age and older	医臣药业 Pharmason Medicina
22.	Crysvita	burosumab	注射剂 Injection	用于治疗 1 岁以上儿童及成人的性联遗传型低磷酸盐症 Treatment of X-linked Hypophosphatemia(XLH), in children and adolescents aged 1 to 17 years, and in adults	科达有限公司 Four Star Companhia Lda. 康宁药业有限公司 The Glory Medicina Limitada
23.	Danyelza	naxitamab	注射剂 Injection	与粒细胞-巨噬细胞集落刺激因子并用于治疗难治性/复发性高危神经母细胞瘤 Combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) for the treatment of relapsed or refractory high-risk neuroblastoma	利华行有限公司 Agência Lei Va Hong Lda. 德圣堂 Firma Tak Sing Tong

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24.	Datroway#	datopotamab deruxtecan	注射剂 Injection	单药用于既往接受过内分泌治疗及至少一种化疗的无法切除或转移性激素受体(HR)阳性、人表皮生长因子受体 2 阴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	科达有限公司 Four Star Companhia Lda.
25.	Dayvigo	lemborexant	片剂 Tablet	治疗失眠 To treat insomnia	康宁药业有限公司 The Glory Medicina Limitada
26.	Elahere	mirvetuximab soravtansine	注射剂 Injection	用于治疗既往接受过 1 至 3 种全身性治疗的 FRα阳性、铂类药物耐药的上皮性卵巢癌、输卵管癌或原发性腹膜癌 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	康宁药业有限公司 The Glory Medicina Limitada
27.	Elunate	fruquintinib	胶囊 Capsule	治疗曾接受抗血管内皮生长因子(VEGF)治疗、抗表皮生长因子受体(EGFR)治疗的转移性结肠癌 Treatment of metastatic colorectal cancer including those who have previously received anti-VEGF therapy and/or anti-EGFR therapy	科达有限公司 Four Star Companhia Lda.

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28.	Emblaveo	aztreonam, avibactam	注射剂 Injection	用于治疗药物选择有限或无替代治疗的成人复杂性腹腔内感染及医院获得性肺炎 For the treatment of adult patients with complicated intra-abdominal infections and hospital-acquired pneumonia who have limited or no alternative treatment options	康宁药业有限公司 The Glory Medicina Limitada
29.	Emgality	galcanezumab	注射剂 Injection	用于每月偏头痛发作天数不少于 4 天的成人患者以预防偏头痛 Prophylaxis of migraine in adults who have at least 4 migraine days per month	利华行有限公司 Agência Lei Va Hong Lda.
30.	Enhertu	trastuzumab deruxtecan	注射剂 Injection	治疗曾接受过两种或以上抗 HER2 疗程、具有无法切除或转移性 HER2 阳性乳癌 Treatment of unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens	科达有限公司 Four Star Companhia Lda.
31.	Enspryng	satralizumab	注射剂 Injection	治疗 AQP4-IgG 阳性的泛视神经脊髓炎 To treat neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4 (AQP4) antibody positive	利华行有限公司 Agência Lei Va Hong Lda.

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32.	Epkinly	epcoritamab	注射剂 Injection	治疗先前曾接受至少两线全身性治疗之复发性或难治性弥漫性大 B 细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	康宁药业有限公司 The Glory Medicina Limitada
33.	Equfina	safinamide	片剂 Tablet	与左旋多巴或其他药物并用治疗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	康宁药业有限公司 The Glory Medicina Limitada
34.	Evrysdi	risdiplam	溶液 Solution	用于 2 个月大或以上的患者，治疗临床诊断为 SMA 1 型、2 型、3 型或存有 1-4 个运动神经元存活-2 蛋白(SMN-2)的 5q 型脊髓性肌萎缩症 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	利华行有限公司 Agência Lei Va Hong Lda.

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35.	Evusheld	tixagevimab, cilgavimab	注射剂 Injection	用于成人及 12 岁或以上青少年作为新冠病毒暴露前的预防用药；治疗病情有进展至重症风险且不需辅助供氧的成人及 12 岁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	科达有限公司 Four Star Companhia Lda.
36.	Fabhalta	iptacopan	胶囊 Capsule	治疗阵发性夜间血红素尿症 Treatment of paroxysmal nocturnal hemoglobinuria (PNH)	科达有限公司 Four Star Companhia Lda.
37.	Fetcroja	cefiderocol	注射剂 Injection	治疗对药物有敏感性且治疗选择有限的细菌感染症 Treatment of bacterial infections that are susceptible and have limited treatment options	康宁药业有限公司 The Glory Medicina Limitada
38.	Hympavzi	marstacimab	注射剂 Injection	用于 A 型血友病或 B 型血友病的成人及 12 岁或以上青少年患者，作为常规预防以避免或减少出血事件的频率 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	康宁药业有限公司 The Glory Medicina Limitada

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39.	Imdelltra	tarlatamab	注射剂 Injection	用于既往接受过至少二线治疗(包括含铂类化疗药)期间或之后出现疾病进展的广泛期小细胞肺癌成人患者 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	利华行有限公司 Agência Lei Va Hong Lda.
40.	Imjudo	tremelimumab	注射剂 Injection	与 durvalumab 联合使用，治疗成人不可切除的肝细胞癌；与 durvalumab 及含铂类化疗药联合使用，治疗不携带表皮生长因子受体突变或间变性淋巴瘤激酶基因异常的转移性非小细胞肺癌 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	科达有限公司 Four Star Companhia Lda.

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41.	Itovebi	inavolisib	片剂 Tablet	与 palbociclib 及 fulvestrant 联合使用，用于内分泌治疗耐药、PIK3CA 突变、激素受体阳性及人表皮生长因子受体 2 阴性的局部晚期或转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	利华行有限公司 Agência Lei Va Hong Lda.
42.	Izervay	avacincaptad pegol	注射剂 Injection	治疗因年龄相关性黄斑变性继发的地图样萎缩 Treatment of geographic atrophy secondary to age-related macular degeneration	康宁药业有限公司 The Glory Medicina Limitada
43.	Jemperli	dostarlimab	注射剂 Injection	治疗接受含铂类化疗药治疗期间或之后产生疾病进展的错配修复缺陷/微卫星高度不稳定性的复发性或晚期子宫内膜癌 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	利华行有限公司 Agência Lei Va Hong Lda.

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44.	Kerendia	finerenone	片剂 Tablet	治疗患有第二型糖尿病相关的伴随有白蛋白尿的慢性肾病 Treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes	科达有限公司 Four Star Companhia Lda.
45.	Kisunla#	donanemab	注射剂 Injection	治疗经临床诊断为阿兹海默症引起的轻度认知障碍及轻度失智症(即阿兹海默症早期症状阶段)的成人患者，且这些患者需为载脂蛋白 E ε4 杂合子或非携带者，并经证实存在淀粉样蛋白病理变化 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 (ApoE ε4) heterozygotes or non-carriers with confirmed amyloid pathology	利华行有限公司 Agência Lei Va Hong Lda.
46.	Koselugo	selumetinib	胶囊 Capsule	治疗 3 岁或以上患有第 1 型神经纤维瘤病合并有症状且手术无法切除的丛状神经纤维瘤 To treat pediatric patients 3 years of age and older who have neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas (PN)	科达有限公司 Four Star Companhia Lda.

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47.	Lazcluze	lazertinib	片剂 Tablet	与 amivantamab 联合使用，用于具有表皮生长因子受体外显子 19 缺失或外显子 21(L858R)置换突变的局部晚期或转移性非小细胞肺癌成人患者的一线治疗 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	科达有限公司 Four Star Companhia Lda.
48.	Leqembi	lecanemab	注射剂 Injection	治疗处于轻度认知障碍或轻度痴呆阶段的阿尔茨海默病 Treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease	康宁药业有限公司 The Glory Medicina Limitada
49.	Leqvio	inclisiran	注射剂 Injection	治疗原发性高胆固醇血症（包括杂合子家族性和非家族性）及混合性血脂异常 Treatment of primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia	科达有限公司 Four Star Companhia Lda.
50.	Litfulo	ritlecitinib	胶囊 Capsule	治疗 12 岁以上青少年及成人的严重斑秃 Treatment of severe alopecia areata in adults and adolescents 12 years of age and older	康宁药业有限公司 The Glory Medicina Limitada

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51.	Livdelzi#	seladelpar	胶囊 Capsule	与 ursodeoxycholic acid 联合使用，用于对 ursodeoxycholic acid 单药治疗反应不足、或单药用于无法耐受 ursodeoxycholic acid 的原发性胆汁性胆管炎成人患者 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.	科达有限公司 Four Star Companhia Lda.
52.	Livtencity	maribavir	片剂 Tablet	适用于已接受造血干细胞移植或实体器官移植的成人患者，用于治疗对一种或多种先前疗法呈难治性(伴有或不伴有耐药性)的巨细胞病毒(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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53.	Lumakras	sotorasib	片剂 Tablet	治疗曾接受过至少一次含铂化疗或抗 PD-1 免疫疗法，且带有 KRAS G12C 突变之局部晚期或转移性非小细胞肺癌 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	利华行有限公司 Agência Lei Va Hong Lda.
54.	Lunsumio	mosunetuzumab	注射剂 Injection	治疗过往已接受二线或以上全身性疗法的复发型或难治型滤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	利华行有限公司 Agência Lei Va Hong Lda.
55.	Mektovi	binimetinib	片剂 Tablet	与 encorafenib 联合使用，治疗带有 BRAF V600 突变且无法切除或转移性的黑色素瘤 In combination with encorafenib is indicated for the treatment of unresectable or metastatic melanoma with a BRAF V600 mutation	利华行有限公司 Agência Lei Va Hong Lda.

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56.	Minjuvi	tafasitamab	注射剂 Injection	与 lenalidomide 联合使用，治疗不适合进行自体干细胞移植的复发性或难治性弥漫性大 B 细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)	科达有限公司 Four Star Companhia Lda.

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57.	Mounjaro	tirzepatide	注射剂 Injection	作为饮食及运动疗法以外的辅助治疗，单药或与其他糖尿病治疗药物联合使用以改善第二型糖尿病成人患者的血糖控制；用于体重控制，作为低热量饮食及增加体能活动的补充，用于成人且起始身体质量指數≥30 kg/m^2 (肥胖)或 ≥ 27 kg/m^2 至< 30 kg/m^2 (过重)且至少患有一种体重相关疾病，例如高血压、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).	利华行有限公司 Agência Lei Va Hong Lda.

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58.	Nefecon	budesonide	胶囊 Capsule	用于减少患有原发性 IgA 肾病且有疾病快速进展风险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
59.	Nilemdo	bempedoic acid	片剂 Tablet	配合饮食控制及最大耐受剂量的他汀类药物，用于杂合子家族性高胆固醇血症或需要额外降低 LDL-C 的动脉粥样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	利华行有限公司 Agência Lei Va Hong Lda.
60.	Nurtec	rimegepant	口服崩解片 Orally disintegrating tablet	治疗有先兆或无先兆之急性偏头痛的成人患者 Treatment of migraine with/without aura in adults 预防成人阵发性偏头痛 Preventive treatment of episodic migraine in adults	康宁药业有限公司 The Glory Medicina Limitada

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61.	Nustendi	bempedoic acid, ezetimibe	片剂 Tablet	配合饮食控制及最大耐受剂量的他汀类药物，用于杂合子家族性高胆固醇血症或需要额外降低 LDL-C 的动脉粥样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	利华行有限公司 Agência Lei Va Hong Lda.
62.	Ocrevus	ocrelizumab	注射剂 Injection	治疗患有复发型或早期原发进展型多发性硬化症 To treat relapsing or early primary progressive multiple sclerosis	利华行有限公司 Agência Lei Va Hong Lda.
63.	Ohtuvayre	ensifentrine	吸入悬浮液 Inhalation suspension	用于成人慢性阻塞性肺病的维持治疗 For the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients	利华行有限公司 Agência Lei Va Hong Lda.

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64.	Omjjara	momelotinib	片剂 Tablet	用于患有原发性骨髓纤维化、真性红细胞增多症后骨髓纤维化或血小板增多症后骨髓纤维化的中度至重度贫血成年患者，以治疗与疾病相关的脾肿大或症状，患者需既往未曾接受 JAK 抑制剂或既往曾接受 ruxolitinib 治疗 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	利华行有限公司 Agência Lei Va Hong Lda.
65.	Orkedia	evocalcet	片剂 Tablet	治疗维持性透析成人患者的继发性甲状旁腺功能亢进症；治疗甲状旁腺癌及因无法进行甲状旁腺切除或术后复发的原发性甲状旁腺功能亢进症引起的高钙血症 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	康宁药业有限公司 The Glory Medicina Limitada

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66.	Orpathys	savolitinib	片剂 Tablet	治疗已接受或不能耐受含铂化疗、具有间质-上皮转化因子(MET)外显子 14 跳变的转移性非小细胞肺癌 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	科达有限公司 Four Star Companhia Lda.
67.	Orserdu	elacestrant	片剂 Tablet	治疗雌激素受体阳性、人表皮生长因子受体 2 阴性、ESR1 突变的晚期或转移性乳腺癌 To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated, advanced or metastatic breast cancer	利华行有限公司 Agência Lei Va Hong Lda.
68.	Padcev	enfortumab vedotin	注射剂 Injection	治疗先前已接受含铂类化学疗法和 PD-1(或 PD-L1)抑制剂的局部晚期或转移性泌尿上皮癌 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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69.	Paxlovid	nirmatrelvir, ritonavir	片剂 Tablet	治疗轻度至中度及高机会伴有发展成严重新型冠状病毒感染风险的 12 岁(≥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	康宁药业有限公司 The Glory Medicina Limitada
70.	Pemazyre	pemigatinib	片剂 Tablet	用于曾接受过全身性治疗后疾病恶化、肿瘤具有 FGFR2 融合或重排的局部晚期或转移性胆管癌的成人患者 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
71.	Pluvicto	lutetium (^{177}Lu) vipivotide tetraxetan	注射剂 Injection	与雄激素剥夺疗法联合使用，用于治疗既往接受雄激素受体通路抑制及紫杉烷类化疗的前列腺特异性膜抗原阳性转移性去势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	科达有限公司 Four Star Companhia Lda.

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72.	Qfitlia	fitusiran	注射剂 Injection	用于 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 岁或以上青少年患者，作为常规预防以避免或减少出血事件的频率 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	科达有限公司 Four Star Companhia Lda.
73.	Qinlock	ripretinib	片剂 Tablet	治疗已接受包括 imatinib, sunitinib 和 regorafenib 等 3 种或以上激酶抑制剂治疗的晚期胃肠道间质瘤 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	科达有限公司 Four Star Companhia Lda.

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74.	Reblozyl	luspatercept	注射剂 Injection	治疗具有环状铁粒幼细胞的骨髓增生异常综合症，且不适合使用或对促红细胞生成素治疗反应不佳的输血依赖性贫血患者；治疗患有β-地中海贫血症的输血依赖性贫血患者 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	康宁药业有限公司 The Glory Medicina Limitada
75.	Retsevmo	selpercatinib	胶囊 Capsule	治疗既往未曾接受 RET 抑制剂的 RET 融合阳性的晚期非小细胞肺癌 治疗既往曾接受 sorafenib 及(或)lenvatinib 的 RET 融合阳性的晚期甲状腺癌 治疗 RET 突变型的晚期甲状腺髓质癌 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)	利华行有限公司 Agência Lei Va Hong Lda.

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76.	Rezurock	belumosudil	片剂 Tablet	用于 12 岁或以上 ·曾接受至少两线全身性治疗且失败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	科达有限公司 Four Star Companhia Lda.
77.	Ruxolitinib	ruxolitinib	乳膏 Cream	用于治疗 12 岁及以上青少年及成人的脸部白癜风 To treat vitiligo with facial involvement in adults and adolescents from 12 years	五洲 Firma Wuzhou
78.	Rybrevant	amivantamab	注射剂 Injection	治疗带有表皮生长因子受体外显子 20 插入突变型的晚期非小细胞肺癌成人患者，作为含铂类化学疗法治疗失败后之治疗 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	科达有限公司 Four Star Companhia Lda.
79.	Saphnelo	anifrolumab	注射剂 Injection	治疗已接受标准疗法的中、重度全身性红斑狼疮的成人患者 Treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy	科达有限公司 Four Star Companhia Lda.

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80.	Sarclisa	isatuximab	注射剂 Injection	治疗复发性或难治性多发性骨髓瘤 To treat relapsed/refractory multiple myeloma	科达有限公司 Four Star Companhia Lda.
81.	Scemblix	asciminib	片剂 Tablet	治疗先前已接受过至少 2 种酪氨酸激酶抑制剂治疗且处于慢性期的费城染色体阳性慢性髓性白血病(Ph+CML-CP)的成年患者；治疗携带 T315I 突变的 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	科达有限公司 Four Star Companhia Lda.
82.	Spevigo	spesolimab	注射剂 Injection	治疗全身型脓疱性干癣 Treatment of generalized pustular psoriasis (GPP)	利华行有限公司 Agência Lei Va Hong Lda.
83.	Sotyktu	deucravacitinib	片剂 Tablet	治疗中度至重度斑块状银屑病 To treat moderate-to-severe plaque psoriasis	康宁药业有限公司 The Glory Medicina Limitada
84.	Spikevax (Original/Omicron BA.4-5)	elasomeran, davesomeran	注射剂 Injection	用于 12 岁及以上人群的新冠病毒加强免疫接种 Booster dose for immunization to prevent COVID-19 infection in individuals 12 years of age and older	康宁药业有限公司 The Glory Medicina Limitada
85.	Staquis	crisaborole	软膏 Ointment	治疗异位性皮肤炎 Treatment of atopic dermatitis	康宁药业有限公司 The Glory Medicina Limitada

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86.	Sulanda	surufatinib	胶囊 Capsule	用于无法手术切除的局部晚期或转移性、进展期非功能性、分化良好(G1、G2)的胰腺和非胰腺来源的神经内分泌瘤 Treatment of unresectable locally advanced or metastatic, progressive non-functioning, well-differentiated (G1 or G2) pancreatic or extra-pancreatic neuroendocrine tumors	科达有限公司 Four Star Companhia Lda.
87.	Symproic	naldemedine tosylate	片剂 Tablet	治疗成人因鸦片类药物引起之便秘 To treat constipation caused by opioid medication	康宁药业有限公司 The Glory Medicina Limitada
88.	Tabrecta	capmatinib	片剂 Tablet	治疗带有 MET 外显子 14 跳读式突变的转移性非小细胞肺癌成人患者 Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to MET exon 14-skipping	科达有限公司 Four Star Companhia Lda.
89.	Takhzyro	lanadelumab	注射剂 Injection	预防 12 岁或以上遗传性血管性水肿患者的反复发作 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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90.	Talvey	talquetamab	注射剂 Injection	治疗既往接受过至少三种治疗(包括一种蛋白酶体抑制剂、一种免疫调节剂及一种抗 CD38 抗体)后出现疾病恶化的复发或难治性多发性骨髓瘤 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	科达有限公司 Four Star Companhia Lda.
91.	Tasfygo	tasurgratinib	片剂 Tablet	用于既往化疗后失败的，且经检测确认具有 FGFR2 融合/重排基因的，不可切除的胆道癌成人患者 Treatment of adult patients with unresectable biliary tract cancer harboring FGFR2 gene fusions or rearrangements that have progressed after prior chemotherapy	德圣堂 Tak Sing Tong

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92.	Tecvayli	teclistamab	注射剂 Injection	治疗既往接受过至少三种治疗(包括一种免疫调节剂、一种蛋白酶体抑制剂及一种抗 CD38 单株抗体)后出现疾病恶化的复发性或难治性多发性骨髓瘤 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	科达有限公司 Four Star Companhia Lda.
93.	Tepmetko	tepotinib	片剂 Tablet	治疗带有间质上皮转化因子外显子-14 跳读式突变的晚期或转移性之非小细胞肺癌 Treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations	康宁药业有限公司 The Glory Medicina Limitada
94.	Tezspire	tezepelumab	注射剂 Injection	常规维持治疗(如高剂量吸入性皮质类固醇及其他哮喘药物)仍无法充分控制病情的严重哮喘患者 Maintenance treatment of patients with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product	科达有限公司 Four Star Companhia Lda.

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95.	Tibsovo	ivosidenib	片剂 Tablet	与 azacitidine 联合使用，治疗无法接受标准诱导化疗，携带 IDH1 R132 突变的新诊断急性骨髓性白血病成人患者 用于既往已接受至少一种全身性治疗，携带 IDH1 R132 突变的局部晚期或转移性胆管癌成人患者 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	利华行有限公司 Agência Lei Va Hong Lda.
96.	Tivdak	tisotumab vedotin	注射剂 Injection	治疗在化疗期间或化疗后出现疾病恶化的复发性或转移性宫颈癌 Treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	康宁药业有限公司 The Glory Medicina Limitada

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97.	Trodelvy	sacituzumab govitecan	注射剂 Injection	治疗先前已接受两种或以上全身性治疗无效(其中至少一种用于治疗转移性疾病)之无法切除的局部晚期或转移性三阴性乳癌 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	科达有限公司 Four Star Companhia Lda.
98.	Truqap	capivasertib	片剂 Tablet	与 fulvestrant 联合使用，治疗激素受体阳性、人表皮生长因子受体阴性且至少带有一种 PIK3CA、AKT1 或 PTEN 基因变异的晚期或转移性乳腺癌 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	科达有限公司 Four Star Companhia Lda.

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99.	Tukysa	tucatinib	片剂 Tablet	与 trastuzumab 及 capecitabine 并用于曾接受至少两次针对 HER2 靶点的疗法的无法切除晚期或转移性 HER2 阳性乳癌 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	康宁药业有限公司 The Glory Medicina Limitada
100.	Tyrvaya	varenicline	鼻用喷雾剂 Nasal Spray	治疗干眼症的病征与症状 Treatment of the signs and symptoms of dry eye disease	五洲 Firma Wuzhou
101.	Ultomiris	ravulizumab	注射剂 Injection	治疗阵发性夜间血红素尿症、非典型溶血性尿毒症候群、全身型重症肌无力及视神经脊髓炎 Treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD)	康宁药业有限公司 The Glory Medicina Limitada

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102.	Vaborem	meropenem, vaborbactam	注射剂 Injection	治疗复杂性尿路感染，包括肾盂肾炎 治疗复杂性腹腔内感染 治疗院内型肺炎，包括呼吸器相关肺炎 治疗与上述任何感染相关或疑似与上述任何感染相关的菌血症 治疗对药物有敏感性且治疗选择有限的细菌感染症 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	利华行有限公司 Agência Lei Va Hong Lda.

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103.	Vabysmo	faricimab	注射剂 Injection	适用于治疗血管新生型(湿性)年龄相关性黄斑部退化病变的成年患者；适用于成人因糖尿病黄斑部水肿所引致的视觉障碍 To treat adults with neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME)	利华行有限公司 Agência Lei Va Hong Lda.
104.	Vanflyta	quizartinib	片剂 Tablet	与标准前导化疗(cytarabine 和 anthracycline)以及与标准巩固化疗 cytarabine 合并使用 ·用于新诊断 FLT3-ITD 阳性的急性髓细胞白血病成人患者 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	利华行有限公司 Agência Lei Va Hong Lda.
105.	Vanrafia	atrasentan	片剂 Tablet	用于降低患有原发性 IgAN 并有病情迅速恶化风险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	科达有限公司 Four Star Companhia Lda.
106.	Veklury	remdesivir	注射剂 Injection	治疗成人及 12 岁或以上(体重≥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	科达有限公司 Four Star Companhia Lda.

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107.	Velsipity	etrasimod	片剂 Tablet	治疗中度至严重活动性溃疡性结肠炎 To treat moderately-to-severely active ulcerative colitis	壹康 Uma-Saúde
108.	Veoza	fezolinetant	片剂 Tablet	治疗因更年期而引起的中度至严重的血管舒缩症状 Treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause	康宁药业有限公司 The Glory Medicina Limitada
109.	Verquvo	vericiguat	片剂 Tablet	治疗心脏射出分率下降且曾因为病情恶化而需接受静脉注射治疗的症状性心脏衰竭成人患者 Treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring IV therapy	科达有限公司 Four Star Companhia Lda.
110.	Voranigo	vorasidenib	片剂 Tablet	治疗 12 岁以上及成人患者手术后的 IDH1 或 IDH2 突变阳性的低度恶性星形细胞瘤或少突胶质细胞瘤 Treatment of adult and pediatric patients aged 12 years and older with low grade astrocytoma or oligodendroglioma with IDH1 or IDH2 mutation following surgery	利华行有限公司 Agência Lei Va Hong Lda.
111.	Vyalev	foslevodopa, foscarbidopa	注射剂 Injection	治疗晚期帕金森病成人患者的运动症状波动 Treatment of motor fluctuations in adults with advanced Parkinson’ s disease	康宁药业有限公司 The Glory Medicina Limitada
112.	Vyepti	eptinezumab	注射剂 Injection	用于成人预防偏头痛 For preventive treatment of migraine in adults	科达有限公司 Four Star Companhia Lda.

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113.	Vyloy	zolbetuximab	注射剂 Injection	联合氟尿嘧啶类及铂类药物用于 CLDN18.2 阳性、人表皮生长因子受体 2(HER2)阴性的局部晚期不可切除或转移性胃或胃食管交界处腺癌的患者 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	康宁药业有限公司 The Glory Medicina Limitada
114.	Wakix	pitolisant	片剂 Tablet	治疗猝睡症所导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	利华行有限公司 Agência Lei Va Hong Lda.
115.	Winrevair	sotatercept	注射剂 Injection	与其他肺动脉高压治疗方案联合使用，用于世界卫生组织功能程度分级第 II-III 级肺动脉高压的成人患者，以提高运动能力 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	利华行有限公司 Agência Lei Va Hong Lda.
116.	Xdemvy	lotilaner	眼用溶液 ophthalmic solution	治疗蠕形螨睑缘炎 To treat demodex blepharitis	五洲 Firma Wuzhou

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117.	Xospata	gilteritinib	片剂 Tablet	治疗具有 FLT3 突变的复发性或难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
118.	Xpovio	selinexor	片剂 Tablet	治疗复发或难治性多发性骨髓瘤 To treat relapsed refractory multiple myeloma (RRMM)	康宁药业有限公司 The Glory Medicina Limitada
119.	Zepzelca	lurbinectedin	注射剂 Injection	治疗曾接受含铂化疗仍疾病恶化的转移性小细胞肺癌 Treatment of metastatic small cell lung cancer (SCLC) that has progressed on or after prior platinum-containing therapy	科达有限公司 Four Star Companhia Lda.
120.	Zunveyl	benzgalantamine	片剂 Tablet	用于治疗成人轻度至中度阿尔茨海默型痴呆症状 Treatment of mild to moderate dementia of the Alzheimer's type in adults	康宁药业有限公司 The Glory Medicina Limitada
121.	贝美纳；盐酸恩沙替尼胶囊	ensartinib hydrochloride	胶囊 Capsule	治疗间变性淋巴瘤激酶阳性的局部晚期或转移性非小细胞肺癌 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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122.	艾弗沙；甲磺酸伏美替尼片	furmonertinib mesilate	片剂 Tablet	治疗具有抗表皮生长因子受体(EGFR)外显子 19 缺失(Ex19del)或外显子 21 (L858R)置换突变的局部晚期或转移性非小细胞肺癌成人患者 治疗既往经 EGFR 酪氨酸激酶抑制剂治疗时或治疗后出现疾病进展，并且经检测确认存在 EGFR T790M 突变阳性的局部晚期或转移性非小细胞肺癌成人患者 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	医诺 Firma Promise
123.	艾瑞恩；瑞维鲁胺片	rezvilutamide	片剂 Tablet	用于治疗高瘤负荷的转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	利华行有限公司 Agência Lei Va Hong Lda.

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124.	艾瑞康；羟乙磺酸达尔西利片	dalpiciclib isethionate	片剂 Tablet	用于治疗激素受体(HR)阳性、人表皮生长因子受体2(HER2)阴性局部晚期或转移性乳腺癌患者 Treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer	利华行有限公司 Agência Lei Va Hong Lda.
125.	艾维达；注射用瑞康曲妥珠单抗	trastuzumab rezetecan	注射剂 Injection	单药用于治疗存在 HER2(ERBB2)激活突变且既往接受过至少一种系统治疗的不可切除的局部晚期或转移性非小细胞肺癌成人患者 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	利华行有限公司 Agência Lei Va Hong Lda.
126.	安睿威；昂拉地韦片	onradivir	片剂 Tablet	用于成人单纯型甲型流感患者的治疗，不包括存在流感相关并发症高风险的患者 Treatment of 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

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127.	安瑞昔；泽贝妥单抗注射液	zuberitamab	注射剂 Injection	与标准 CHOP 化疗联合治疗 CD 20 阳性的非特指性弥漫大 B 细胞淋巴瘤 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
128.	百悦达；索托克拉片#	sonrotoclax	片剂 Tablet	既往接受过至少包含布鲁顿酪氨酸激酶抑制剂在内的一种系统治疗的慢性淋巴细胞白血病/成人患者 既往接受过至少两种系统性治疗(含布鲁顿酪氨酸激酶抑制剂)的复发或难治性套细胞淋巴瘤成人患者 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	康宁药业有限公司 The Glory Medicina Limitada

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129.	百赫安；注射用泽尼达妥单抗	zanidatamab	注射剂 Injection	用于既往接受过全身治疗的 HER2 高表达(IHC3+)的不可切除局部晚期或转移性胆道癌成人患者 For adult patients with unresectable locally advanced or metastatic HER2-overexpressing (IHC 3+) biliary tract cancer (BTC) who have received prior systemic therapy	康宁药业有限公司 The Glory Medicina Limitada
130.	百泽安；替雷利珠单抗注射液	tislelizumab	注射剂 Injection	治疗经典型霍奇金淋巴瘤、非小细胞肺癌、肝细胞癌、高度微卫星不稳定型实体瘤、食管鳞状细胞癌及鼻咽癌 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)	康宁药业有限公司 The Glory Medicina Limitada
131.	克瑞毕；泽美洛韦玛佐瑞韦单抗注射液	zamerovimab, mazorelvimab	注射剂 Injection	用于狂犬病病毒暴露者的被动免疫 Use in passive post-exposure prophylaxis of rabies	美俭 Firma Mekim
132.	怡诺轻；依苏帕格鲁肽α注射液	efsubaglutide alfa	注射剂 Injection	用于改善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	康宁药业有限公司 The Glory Medicina Limitada
133.	奕凯达；阿基仑赛注射液	axicabtagene ciloleucel	注射剂 Injection	治疗 B 细胞淋巴瘤 To treat B-cell Lymphoma	医臣药业 Pharmason Medicina

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134.	耐立克；雷巴替尼片	olverembatinib	片剂 Tablet	治疗对第一代及第二代酪氨酸激酶抑制剂耐药及/或不耐受的慢性髓细胞白血病慢性期 用于任何酪氨酸激酶抑制剂耐药，经诊断为伴有 T315I 突变的慢性髓细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	迈极康 Saúde Magicure

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135.	信必乐；托莱西单抗注射液	tafolecimab	注射剂 Injection	在控制饮食的基础上，与他汀类药物或与他汀类药物及其他降脂疗法联合使用，用于在接受中等剂量或中等剂量以上他汀类药物治疗，仍无法达到低密度脂蛋白胆固醇目标的原发性高胆固醇血症(包括杂合子型家族性和非家族性高胆固醇血症)及混合型血脂异常的成人患者，以降低低密度脂蛋白胆固醇、总胆固醇、载脂蛋白 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
136.	信必敏；替妥尤单抗 N01 注射液	teprotumumab	注射剂 Injection	治疗成人甲状腺眼病 Treatment of adults with thyroid eye disease	永康有限公司 Companhia de Great Life Limitada
137.	信玖凝；波哌达可基注射液	dalnacogene ponparvovec	注射剂 Injection	用于治疗中重度血友病 B 成年患者 Treatment of adult patients with moderate to severe hemophilia B	利华行有限公司 Agência Lei Va Hong Lda.

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138.	信美悦；匹康奇拜单抗注射液	picankibart	注射剂 Injection	用于适合系统性治疗的中重度斑块状银屑病成人患者 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
139.	信尔美；玛仕度肽注射液	mazdutide	注射剂 Injection	用于在控制饮食和增加体力活动基础上对成人患者的长期体重控制，初始体重指数（BMI）为：BMI≥28 kg/m^2（肥胖）；或 BMI≥24 kg/m^2（超重），并伴有至少一种体重相关的合并症（例如高血糖、高血压、血脂异常、脂肪肝、阻塞性睡眠呼吸暂停综合症等） 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
140.	若欣林；盐酸托鲁地文拉法辛缓释片	toludesvenlafaxine (ansofaxine) hydrochloride	片剂 Tablet	治疗抑郁症 Treatment of depression	迈极康 Saúde Magicure
141.	泰中定；阿泰特韦片/利托那韦片	atilotrelvir, ritonavir	片剂 Tablet	治疗轻、中度新型冠状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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142.	恩维达；恩沃利单抗注射液	envafolimab	注射剂 Injection	用于不可切除或转移性微卫星高度不稳定或错配修复基因缺陷型的晚期实体瘤 Treatment of patients with unresectable or metastatic microsatellite instability-high/ mismatch repair deficient (MSI-H/dMMR) advanced solid tumors	五洲 Firma Wuzhou
143.	纽再乐；注射用甲苯磺酸奥马环素/甲苯磺酸奥马环素片	omadacycline	注射剂 Injection 片剂 Tablet	治疗小区获得性细菌性肺炎及急性细菌性皮肤和皮肤结构感染 To treat community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infection (ABSSSI)	科达有限公司 Four Star Companhia Lda.

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144.	倍诺达；瑞基奥仑赛注射液	relmacabtagene autoleucel	注射剂 Injection	用于经过二线或以上系统性治疗后的复发或难治性大 B 细胞淋巴瘤；用于经过二线或以上系统性治疗的难治性或 24 个月内复发的滤泡性淋巴瘤 ;用于经过包括布鲁顿酪氨酸激酶抑制剂治疗在内的二线及以上系统性治疗的复发或难治性套细胞淋巴瘤 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
145.	华领片；多格列艾汀片	dorzagliatin	片剂 Tablet	用于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	康宁药业有限公司 The Glory Medicina Limitada
146.	源瑞达；纳基奥仑赛注射液	inaticabtagene autoleucel	注射剂 Injection	治疗成人复发或难治性 B 细胞急性淋巴细胞白血病 Treatment in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-cell ALL)	五洲 Firma Wuzhou

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147.	爱瑞卓；罗沙司他胶囊	roxadustat	胶囊 Capsule	用于慢性肾脏病引起的贫血，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	科达有限公司 Four Star Companhia Lda.
148.	瑞普多；瑞米布替尼片	remibrutinib	片剂 Tablet	用于 H1 抗组胺药控制不充分的慢性自发性荨麻疹成人患者 Treatment of adult patients with chronic spontaneous urticaria who remain symptomatic despite H1-antihistamine treatment	科达有限公司 Four Star Companhia Lda.
149.	达伯欣；伊匹木单抗 N01 注射液	ipilimumab N01	注射剂 Injection	联合 sintilimab，用于可手术切除的 IIB-III 期微卫星高度不稳定型或错配修复缺陷型的成人结肠癌患者的辅助治疗 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
150.	达伯特；氟泽雷塞片	fulzerasib	片剂 Tablet	用于至少接受过一种系统性治疗的鼠类肉瘤病毒癌基因 G12C 突变型的晚期非小细胞肺癌 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

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151.	达伯舒；信迪利单抗注射液	sintilimab	注射剂 Injection	治疗经典型霍奇金淋巴瘤、非小细胞肺癌、肝细胞癌、食管鳞癌及胃及胃食管交界处腺癌 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
152.	达伯乐；己二酸他雷替尼胶囊	taletrectinib adipate	胶囊 Capsule	用于酪氨酸受体激酶 ROS1 阳性的局部晚期或转移性非小细胞肺癌成人患者 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
153.	福可苏；伊基奥仑赛注射液	equecabtagene autoleucel	注射剂 Injection	治疗既往经过至少三线治疗后出现疾病恶化(至少使用过一种蛋白酶体抑制剂及免疫调节剂)的复发或难治性多发性骨髓瘤成人患者 Treatment of adult patients with relapsed or refractory multiple myeloma 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
154.	乐睿灵；来瑞特韦片	leritrelvir	片剂 Tablet	治疗轻中度新型冠状病毒感染 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

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155.	泽瑞尼；盐酸佐利替尼片	zorifertinib hydrochloride	片剂 Tablet	用于具有表皮生长因子受体外显子 19 缺失或外显子 21(L858R)置换突变 ,并伴中枢神经系统转移的局部晚期或转移性非小细胞肺癌成人患者 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	德圣堂 Tak Sing Tong
156.	双洛平；西格列他钠片	chiglitazar	片剂 Tablet	用于改善成人 2 型糖尿病患者的血糖控制 For improving glycemic control in adult patients with type 2 diabetes	仲联有限公司 Firma Polywell Limitada

*按商品名称的字母/笔划排序

数据截至：09/2026

Commercial names are listed in alphabetical/strokes order

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