

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)	药物产品进出口及批发商号 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
3.	Altuviio	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	科达有限公司 Four Star Companhia Lda.

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				prophylaxis to reduce the frequency of bleeding episodes, on-demand treatment & control of bleeding episodes and perioperative management of bleeding	
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
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

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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
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	科达有限公司 Four Star Companhia Lda.

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				children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season	
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.
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	康宁药业有限公司 The Glory Medicina Limitada

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				Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (HCM)	
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.	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.
16.	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
17.	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

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18.	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
19.	Comirnaty COVID-19 mRNA Vaccine (Omicron JN.1)	bretozameroan	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
20.	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
21.	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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22.	Dayvigo	lemborexant	片剂 Tablet	治疗失眠 To treat insomnia	康宁药业有限公司 The Glory Medicina Limitada
23.	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 FR α 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 FR α 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
24.	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.
25.	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.
26.	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.

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27.	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 Ltda.
28.	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
29.	Equfina	saquinamide	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
30.	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 Ltda.
31.	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患者	科达有限公司 Four Star Companhia Ltda.

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				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	
32.	Fabhalta	iptacopan	胶囊 Capsule	治疗阵发性夜间血红蛋白尿症 Treatment of paroxysmal nocturnal hemoglobinuria (PNH)	科达有限公司 Four Star Companhia Lda.
33.	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
34.	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
35.	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	科达有限公司 Four Star Companhia Lda.

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				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	
36.	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.
37.	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.
38.	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	科达有限公司 Four Star Companhia Lda.

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				who have neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas (PN)	
39.	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
40.	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.
41.	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
42.	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.

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43.	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.
44.	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.
45.	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.
46.	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数 $\geq 30 \text{ kg/m}^2$ (肥胖)或 $\geq 27 \text{ kg/m}^2$ 至 $< 30 \text{ kg/m}^2$ (过重)且至少患有	利华行有限公司 Agência Lei Va Hong Lda.

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				一种体重相关疾病，例如高血压、血脂异常、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 $\geq 30 \text{ kg/m}^2$ (obesity) or $\geq 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (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).	
47.	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

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48.	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 Ltda.
49.	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
50.	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 Ltda.

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51.	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.
52.	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.
53.	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.

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54.	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 hypercalcaemia in patients with parathyroid carcinoma and hypercalcaemia 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
55.	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.
56.	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.

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57.	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
58.	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($\geq 40\text{kg}$)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
59.	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

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60.	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.
61.	Qinlock	riporetinib	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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62.	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
63.	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 Ltda.

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64.	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.
65.	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
66.	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.

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67.	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.
68.	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.
69.	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.

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70.	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.
71.	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
72.	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
73.	Staquis	crisaborole	软膏 Ointment	治疗异位性皮炎 Treatment of atopic dermatitis	康宁药业有限公司 The Glory Medicina Limitada
74.	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.
75.	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

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76.	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.
77.	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
78.	Tazverik	tazemetostat	片剂 Tablet	治疗不符合完全切除条件的成人及 16 岁以上患者的转移性或局部晚期上皮样肉瘤；曾接受过至少两种全身性治疗且其肿瘤经检测为 EZH2 突变阳性的复发或难治性滤泡性淋巴瘤患者；治疗没有合适替代治疗的复发性或难治性滤泡性淋巴瘤患者 Treatment of adults and patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection; Treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation and who have received at least 2 prior systemic therapies; Treatment of adult patients with R/R FL who have no satisfactory alternative treatment options	科达有限公司 Four Star Companhia Lda.

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79.	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.
80.	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
81.	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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82.	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
83.	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.
84.	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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85.	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 阳性乳腺癌 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	利华行有限公司 Agência Lei Va Hong Lda.
86.	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
87.	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
88.	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	利华行有限公司 Agência Lei Va Hong Lda.

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				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	
89.	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.
90.	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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91.	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
92.	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.
93.	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.
94.	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.
95.	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.

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96.	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.
97.	Xdemvy	lotilaner	眼用溶液 ophthalmic solution	治疗蠕形螨睑缘炎 To treat demodex blepharitis	五洲 Firma Wuzhou
98.	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
99.	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
100.	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 (SCLC) 及既往铂类治疗进展后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.

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101.	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
102.	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

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103.	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
104.	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
105.	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
106.	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 Saude Magicure

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107.	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
108.	若欣林；盐酸托鲁地文拉法辛(安舒法辛)缓释片	toludesvenlafaxine (ansofaxine) hydrochloride	片剂 Tablet	治疗抑郁症 Treatment of depression	迈极康 Saude Magicure
109.	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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110.	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
111.	纽再乐；注射用甲磺酸奥马环素/甲磺酸奥马环素片	omadacycline	注射剂 Injection 片剂 Tablet	治疗社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.
112.	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	壹康 Uma-Saúde

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				lymphoma (r/r MCL) who have previously been treated with at least 2 lines of systemic therapy including bruton tyrosine kinase inhibitors (BTKis)	
113.	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
114.	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.
115.	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
116.	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	南光 Firma Nam Kwong

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				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	
117.	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

*按商品名称的字母/笔划排序

数据截至：5/2025

Commercial names are listed in alphabetical/strokes order

#最新获药物监督管理局批准上市的新药

Latest new drug approved for marketing by ISAF