

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.	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.
2.	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
3.	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)	康寧藥業有限公司 The Glory Medicina Limitada

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4.	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)	康寧藥業有限公司 The Glory Medicina Limitada
5.	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)	康寧藥業有限公司 The Glory Medicina Limitada
6.	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
7.	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

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8.	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
9.	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.
10.	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.
11.	Dayvigo	lemborexant	片劑 Tablet	治療失眠 To treat insomnia	康寧藥業有限公司 The Glory Medicina Limitada

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12.	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.
13.	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.
14.	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.
15.	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	利華行有限公司 Agência Lei Va Hong Lda.

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				diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies	
16.	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.
17.	Exkivity	mobocertinib	膠囊 Capsule	治療曾接受含鉑化療但疾病惡化的表皮生長因子受體外顯子 20 插入突變型局部晚期或轉移性非小細胞肺癌 Treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy	全昌行有限公司 Firma Chun Cheong - Produtos Farmacêuticos, Limitada

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18.	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.
19.	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	利華行有限公司 Agência Lei Va Hong Lda.

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				treatment with a platinum-containing regimen	
20.	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.
21.	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.
22.	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.

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23.	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.
24.	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
25.	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	康寧藥業有限公司 The Glory Medicina Limitada

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26.	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.
27.	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.
28.	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
29.	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($\geq 40\text{kg}$)或以上的患者 Treatment of mild-to-moderate COVID-19 in adults	康寧藥業有限公司 The Glory Medicina Limitada

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				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	
30.	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.
31.	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	康寧藥業有限公司 The Glory Medicina Limitada

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				regular RBC transfusions	
32.	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.
33.	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.
34.	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.

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35.	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.
36.	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	康寧藥業有限公司 The Glory Medicina Limitada
37.	Staquis	crisaborole	軟膏 Ointment	治療異位性皮膚炎 Treatment of atopic dermatitis	康寧藥業有限公司 The Glory Medicina Limitada

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38.	Sulanda	surufatinib	口服膠囊 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.
39.	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	康寧藥業有限公司 The Glory Medicina Limitada
40.	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
41.	Tazverik	tazemetostat	片劑 Tablet	治療不符合完全切除條件的成人及 16 歲以上患者的轉移性或局部晚期上皮樣肉瘤；曾接受過至少兩種全身性治療且其腫瘤經檢測為 EZH2 突變陽性的復發或難治性濾泡性淋巴瘤患者；治療沒有合適替代治療的復發性或	科達有限公司 Four Star Companhia Lda.

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				難治性濾泡性淋巴瘤患者 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	
42.	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	康寧藥業有限公司 The Glory Medicina Limitada
43.	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	科達有限公司 Four Star Companhia Lda.

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				cancer (mTNBC) who have received at least two prior systemic therapies, including at least one prior therapy for locally advanced or metastatic disease	
44.	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	利華行有限公司 Agência Lei Va Hong Lda.
45.	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.
46.	Veklury	remdesivir	注射劑	治療成人及 12 歲或以上(體重≥40kg)的新冠病毒感染	科達有限公司

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			Injection	To treat adults and children 12 years of age and older and weighing at least 40 kg with COVID-19 infection	Four Star Companhia Lda.
47.	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.
48.	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.
49.	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)	康寧藥業有限公司 The Glory Medicina Limitada
50.	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	邁極康 Saude Magicure

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
				(SCLC) that has progressed on or after prior platinum-containing therapy	
51.	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)	康寧藥業有限公司 The Glory Medicina Limitada
52.	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
53.	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.

*按商品名稱的字母/筆劃排序
Commercial names are listed in alphabetical/strokes order

資料截至：11/2023