

## **List of Pharmaceutical Products Registered Under "1+" Mechanism (as of 19 February 2025)**

With a view to facilitating good drugs for use in Hong Kong, since 1 November 2023, the “1+” mechanism has come into operation for the registration of pharmaceutical products containing New Chemical or Biological Entities (“NCE products”). Since 1 November 2024, the “1+” mechanism has been extended from NCE products that are beneficial for treatment of life-threatening or severely debilitating diseases to all NCE products, including vaccines and advanced therapy products. Under the extended “1+” mechanism, NCE products used for any disease can apply for registration.

The applications for registration of the following pharmaceutical products were accepted and evaluated under the “1+” mechanism in accordance with section 4.1.2 of the [“Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity”](#).

	<b>Product Name</b>	<b>Registration No.</b>	<b>Certificate Holder</b>	<b>Active Ingredient(s)</b>
1.	ELUNATE CAPSULES 1MG	HK-68111	HUTCHMED (HONG KONG) LIMITED O/B HUTCHMED (HONG KONG) LIMITED	Fruquintinib
2.	ELUNATE CAPSULES 5MG	HK-68112	HUTCHMED (HONG KONG) LIMITED O/B HUTCHMED (HONG KONG) LIMITED	Fruquintinib
3.	FABHALTA CAPSULES 200MG	HK-68402	NOVARTIS PHARMACEUTICALS (HK) LIMITED	Iptacopan (as hydrochloride monohydrate)
4.	ORKEDIA TABLETS 1MG*	HK-68424	DKSH HONG KONG LIMITED	Evocalcet
5.	ORKEDIA TABLETS 2MG*	HK-68425	DKSH HONG KONG LIMITED	Evocalcet
6.	EVRENZO CAPSULES 20MG*	HK-68439	FIBROGEN INTERNATIONAL (HONG KONG) LIMITED	Roxadustat
7.	EVRENZO CAPSULES 50MG*	HK-68440	FIBROGEN INTERNATIONAL (HONG KONG) LIMITED	Roxadustat
8.	IMDELLTRA POWDER FOR CONCENTRATE AND SOLUTION FOR SOLUTION FOR INFUSION 10MG/VIAL	HK-68549	AMGEN HONG KONG LIMITED	Tarlatamab
9.	IMDELLTRA POWDER FOR CONCENTRATE AND SOLUTION FOR SOLUTION FOR INFUSION 1MG/VIAL	HK-68550	AMGEN HONG KONG LIMITED	Tarlatamab

	<b>Product Name</b>	<b>Registration No.</b>	<b>Certificate Holder</b>	<b>Active Ingredient(s)</b>
10.	ORPATHYS TABLETS 100MG*	HK-68581	HUTCHMED (HONG KONG) LIMITED O/B HUTCHMED (HONG KONG) LIMITED	Savolitinib
11.	ORPATHYS TABLETS 200MG*	HK-68582	HUTCHMED (HONG KONG) LIMITED O/B HUTCHMED (HONG KONG) LIMITED	Savolitinib

\*The product can only be supplied to institutions or registered medical practitioners.