

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



INNOCARE

诺 诚 健 华

InnoCare Pharma Limited

諾誠健華醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9969)

INSIDE INFORMATION ANNOUNCEMENT

APPROVAL OF ZURLETRECTINIB FOR THE TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH SOLID TUMORS HARBORING NTRK GENE FUSIONS IN CHINA

This announcement is made by InnoCare Pharma Limited (the “**Company**”) pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The board of directors of the Company (the “**Board**”) is pleased to announce that the National Medical Products Administration (NMPA) has granted approval for zurletrectinib (ICP-723), a second-generation small molecule pan-inhibitor of tropomyosin-related kinase (pan-TRK inhibitor), for the treatment of adult and adolescent patients (aged 12 years and older) with solid tumors harboring NTRK gene fusions.

In the registrational clinical trial for patients with NTRK fusion-positive solid tumors, zurletrectinib demonstrated outstanding efficacy and a favorable safety profile. The study results showed an objective response rate (ORR) of 89.1%, a disease control rate (DCR) of 96.4%, and 24-month progression-free survival (PFS) and overall survival (OS) rates of 77.4% and 90.8% respectively.

As a next-generation TRK inhibitor, zurletrectinib demonstrated superior efficacy compared to first-generation TRK inhibitors. It delivered durable deep remissions and exhibits strong brain penetration activity with a good safety profile. Moreover, it was also shown to overcome acquired resistance to the first-generation TRK inhibitors. The once-daily, two-tablet oral dosing has brought great convenience to patients.

Zurletrectinib has been included in the “SPARK Program” by NMPA, a pilot initiative to encourage the development of pediatric anti-tumor drugs. The Company anticipates submitting a new drug application (NDA) for zurletrectinib to treat pediatric patients (aged 2 to 12) in the near future.

NTRK fusion genes are present in various types of tumors and have been identified in over 26 solid tumors. It is estimated that approximately 6,500 new cases of tumors carrying NTRK fusion genes occur annually in China. These patients often have short survival periods, rapid disease progression, and high disability rates. Due to the low adoption rate of the current gold-standard detection method-next-generation sequencing (NGS)-diagnosis is often delayed, resulting in unmet clinical needs.

Cautionary Statement as required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that the Company will ultimately commercialize zurletrectinib successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board
InnoCare Pharma Limited
Dr. Jisong Cui
Chairperson and executive Director

Hong Kong, 11 December 2025

As at the date of this announcement, the Board of Directors comprises Dr. Jisong Cui as Chairperson and executive Director, Dr. Renbin Zhao as executive Director, Dr. Yigong Shi and Mr. Ronggang Xie as non-executive Directors, and Ms. Lan Hu, Dr. Dandan Dong and Prof. Kunliang Guan as independent non-executive Directors.