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**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)**

**VOUNTARY ANNOUNCEMENT  
ON  
APPROVAL OF COMMERCIAL PRODUCTION IN THE GROUP'S  
GUANGZHOU FACILITY**

InnoCare Pharma Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) wishes to inform the shareholders and potential investors of the Company of the attached press release in respect of the approval from the China National Medical Products Administration (“**NMPA**”) to begin the production of commercial supply of our self-developed Bruton’s tyrosine kinase (“**BTK**”) inhibitor Orelabrutinib at the manufacturing facility located in Guangzhou, China, which empowers the Company to officially enter self-production stage.

This is a voluntary announcement made by the Company. The Company considers this a major milestone to its business commercialization and is thankful to its shareholders’ support. 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, 4 July 2022

*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, Mr. Ronggang Xie, Mr. Shan Fu and Mr. Ming Jin as non-executive Directors, and Dr. Zemin Zhang, Ms. Lan Hu and Dr. Kaixian Chen as independent non-executive Directors.*



## APPROVAL OF COMMERCIAL PRODUCTION IN INNOCARE'S GUANGZHOU FACILITY

**Beijing, China, 1 July 2022** - InnoCare (HKEX: 09969), a leading biopharmaceutical company, announced today that InnoCare's pharmaceutical production facility in Guangzhou (hereinafter referred to as the "Guangzhou Base") has been granted an official approval for the commercial production of Orelabrutinib tablets with immediate effect on 30 June 2022. The approval marked the embarking of InnoCare's self-production, thereby providing patients with high-quality products and services.

Dr. Jisong Cui, the co-founder, Chairperson and CEO of InnoCare, commented: "The approval of InnoCare's Guangzhou Base for commercial production is a significant step for InnoCare to build a comprehensive industrial chain. High-quality production can improve the availability of international high-quality innovative drugs for the treatment of patients. InnoCare always adheres to the core concept of "Science-driven Innovation for Patients's Needs", with a view to better catering for the needs of patients for high-quality innovative drugs."

Drug quality is crucial for innovative pharmaceutical companies. InnoCare's Guangzhou Base always regards quality management as the top priority. With international quality standards as the benchmark, Guangzhou Base has adopted international advanced production technology and equipment, and established a quality management system with reference to the GMP standards of China, Japan, the United States and the European Union. In April this year, InnoCare's Guangzhou Base successfully passed the audit carried out by the Qualified Person ("QP") of EU, indicating that InnoCare's Guangzhou Base is enabled to provide clinical drugs for the European market.

Improving the solubility of poorly soluble drugs has become a focus and challenge in the research and development of innovative drug formulation. InnoCare's Guangzhou Base has built a technical platform to solve such problems, including the establishment of international advanced production lines of spray-dried solid dispersion, hot melt extrusion solid dispersion and solid dosage forms, and equipped with three major technology platforms, namely the solubilization preparation technology for poorly soluble drugs, the modified release drug delivery system and the targeted drug delivery technology, thereby solving the common problems faced by the industry. InnoCare's solid dispersion technology is the core technology in the solubilization process, which can accelerate the solubility and dissolution rate of poorly soluble drugs, thus improving the bioavailability of drugs and better catering for the needs of the development and production of new drugs.

InnoCare's Guangzhou Base is located at Sino-Singapore Guangzhou Knowledge City, which is a major project for the biomedical industry introduced by Guangzhou Development Zone. The construction of InnoCare's Guangzhou Base has been progressing rapidly in a safe and efficient way. In July 2019, the construction of InnoCare's Guangzhou Base kicked off with the commencement of its foundation work. The topping of the superstructure was completed in January 2020 and the first phase of the project was completed at the end of 2020, leading to the approval for production today.

Sino-Singapore Guangzhou Knowledge City is one of the major innovation platforms for the construction of the Guangdong-Hong Kong-Macao Greater Bay Area. It is a national-level bilateral cooperation project and an international knowledge innovation platform jointly built by China and Singapore. Huangpu District and Guangzhou Development Zone, where Sino-Singapore Guangzhou Knowledge City is located, are currently developed into a world-class advanced manufacturing cluster, with a focus on the development of strategic emerging industries including biomedicine industry, thus facilitating the industry to enter the high end of the global value chain.

## **About Orelabrutinib**

Orelabrutinib is a new drug developed by InnoCare. It is a highly selective new BTK inhibitor developed for the treatment of lymphoma and autoimmune diseases.

Orelabrutinib had conditionally received approval in China on 25 December 2020 for the treatment of relapsed/refractory chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), and the two indications of relapsed/refractory mantle cell lymphoma (MCL). At the end of 2021, Orelabrutinib was included in the National Reimbursement Drug List to benefit more lymphoma patients.

In addition, multi-center and multi-indication clinical trials are underway in China and the United States for using Orelabrutinib as monotherapy or in combination therapies.

Clinical trials of Orelabrutinib are also underway in China for the treatment of various B-cell lymphomas including marginal zone lymphoma (MZL), central nervous system lymphoma (CNSL), Waldenstrom's macroglobulinemia (WM) and diffuse large B-cell lymphoma (DLBCL).

Orelabrutinib was granted Breakthrough Therapy Designation for the treatment of relapsed/refractory mantle cell lymphoma (R/R MCL) by U.S. Food and Drug Administration (FDA).

Orelabrutinib are being evaluated in the global Phase II clinical study for the treatment of multiple sclerosis (MS), as well as in clinical trials in China for the treatment of systemic lupus erythematosus (SLE), immune thrombocytopenia (ITP) and neuromyelitis optica spectrum disorder (NMOSD).

## **About InnoCare**

InnoCare (HKEX: 09969) is a commercial stage biopharmaceutical company committed to discovering, developing, and commercializing first-in-class and/or best-in-class drugs for the treatment of cancer and autoimmune diseases. We strategically focus on lymphoma, solid tumors, and autoimmune diseases with high unmet medical needs in China and worldwide. InnoCare has branches in Beijing, Nanjing, Shanghai, Guangzhou, Hong Kong and the United States.