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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)

INSIDE INFORMATION ANNOUNCEMENT

PATIENT ENROLLMENT OF PHASE II STUDY EVALUATING ORELABRUTINIB IN MULTIPLE SCLEROSIS PAUSED

This announcement is made by InnoCare Pharma Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09(2) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The Company announced today that the U.S. Food and Drug Administration (FDA) has placed orelabrutinib in multiple sclerosis (MS) on partial clinical hold. As a result, new enrollment of the Phase II study in the United States (U.S.) will not be initiated. Participants in the U.S. who have been on orelabrutinib for less than or equal to 70 days will be discontinued, and study participants who have completed more than 70 days in the study will be permitted to continue receiving orelabrutinib.

The FDA action was based on a limited number of drug-induced liver injury cases that have been observed with orelabrutinib in the ongoing MS Phase II study and other studies in non-MS autoimmune diseases. For all cases, the elevated laboratory values used for monitoring liver injury were reversible following the suspension of orelabrutinib administration. The Company will work closely with the FDA in an effort to resolve the issues, including the implementation of enhanced safety measures.

In addition, the enrollment at sites outside of the U.S. will be temporarily on hold, and participants who have completed more than 70 days in the study will continue, and participants who have been on orelabrutinib for less than or equal to 70 days will be discontinued, while the Company will work with the Independent Data Monitoring Committee and Health Authorities to assess the impact of this partial clinical hold on studies conducted at those sites.

The study has completed most of the enrollment to date. This partial clinical hold impacts a limited number of patients towards the study enrollment goal.

The Company remains committed to evaluating the potential of orelabrutinib for the treatment of individuals living with MS.

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

Hong Kong, 23 December 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 Jason Zhang, Ms. Lan Hu and Dr. Kaixian Chen as independent non-executive Directors.