INNOCARE
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InnoCare Pharma Limited
諾誠健華醫藥有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock code: 9969)

VOLUNTARY ANNOUNCEMENT

POSITIVE PHASE IIB CLINICAL TRIAL RESULTS OF ORELABRUTINIB IN SYSTEMIC LUPUS ERYTHEMATOSUS AND PHASE III CLINICAL TRIAL INITIATION

This announcement is made by InnoCare Pharma Limited (the "**Company**") on a voluntary basis to inform shareholders and potential investors of the Company's latest business developments.

The Board of Directors (the "**Board**") is pleased to announce that, the Center for Drug Evaluation (CDE) has approved the initiation of the Phase III clinical trial of orelabrutinib for systemic lupus erythematosus (SLE). The Phase III study will evaluate the 75 mg once-daily dosing regimen, which is strongly supported by the robust data generated in the Phase IIb clinical trial.

Orelabrutinib demonstrated outstanding efficacy and well-tolerated safety in patients with SLE who had received 48 weeks of treatment in the phase IIb study. A total of 187 patients were enrolled and randomized (1:1:1) into three groups: orelabrutinib 75 mg once-daily (QD), orelabrutinib 50 mg QD and placebo.

The primary endpoint of this study was the SLE Response Index-4 (SRI-4) response rate at week 48. At week 48, the orelabrutinib 75 mg QD group achieved a statistically significant improvement in SRI-4 response rate compared with placebo (57.1% vs. 34.4%, $p < 0.05$), meeting the primary endpoint. Additionally, the efficacy of orelabrutinib at 75 mg QD and 50 mg QD showed a dose-dependent trend in the treatment of SLE.

At week 48, the orelabrutinib 75 mg QD group demonstrated significantly higher SRI-6 response rate and British Isles Lupus Assessment Group (BILAG) response rate compared to the placebo group ($p < 0.05$), meeting the secondary endpoint.

In the subgroup of patients with baseline BILAG ≥1A or ≥2B, the placebo-adjusted difference in SRI-4 response rate for orelabrutinib 75 mg QD was 35%. In the subgroup of patients with baseline BILAG ≥1A or ≥2B and a clinical SLEDAI-2K score ≥4, the placebo-adjusted difference in SRI-4 response rate for orelabrutinib 75 mg QD was 43%.

The study showed that orelabrutinib was well tolerated in SLE patients. The safety profile was consistent with the mechanism of action of BTK inhibition and the underlying disease biology of SLE.

Orelabrutinib is the first BTK inhibitor to demonstrate significant efficacy in a phase II clinical trial for SLE. Phase IIa clinical data on orelabrutinib for SLE was previously presented as a late breaking oral presentation at the European Union Congress of Rheumatology (EULAR). Orelabrutinib is expected to become a first-in-class oral BTK inhibitor for the treatment of SLE.

The Company remains committed to accelerating the clinical development of orelabrutinib and bringing innovative, accessible therapies to patients living with autoimmune diseases.

About Orelabrutinib

Orelabrutinib (宜諾凱®) is a late-stage, potentially best-in-class, highly CNS-penetrant, selective, irreversible, oral small molecule Bruton's Tyrosine Kinase (BTK) inhibitor. In SLE, orelabrutinib has demonstrated positive results in a Phase IIb trial, supporting its clinical benefit and favorable safety profile. The Phase III SLE trial has been approved to commence, with first patient in (FPI) targeted for the first quarter of 2026. In other autoimmune diseases, a registrational Phase III trial for immune thrombocytopenia (ITP) in China has completed enrollment, with NDA submission planned for the first half of 2026. The Company retains rights for SLE and other autoimmune indications in Greater China and Southeast Asia, while other international rights have been licensed to Zenas.

In multiple sclerosis (MS), the Phase III trial for primary progressive MS (PPMS) has been initiated in the third quarter of 2025, and the Phase III trial for secondary progressive MS (SPMS) is expected to initiate in the first quarter of 2026. Both MS Phase III trials have obtained FDA and EMA alignment, and global rights for MS have been licensed to Zenas.

In hemato-oncology, since its launch in mainland China, orelabrutinib has achieved significant clinical recognition and market penetration. It was included in China's National Reimbursement Drug List (NRDL) in 2022 for relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (r/r CLL/SLL) and relapsed/refractory mantle cell lymphoma (r/r MCL), and was further expanded in 2024 to cover relapsed/refractory marginal zone lymphoma (r/r MZL), making it the first and only BTK inhibitor approved for r/r MZL in China. The NDA for orelabrutinib in first-line CLL/SLL was approved by the CDE in April 2025, and this indication has also been included in the NRDL.

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 develop, market and/or commercialize orelabrutinib in SLE 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, 14 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.