Hansoh Pharmaceutical Group Company Limited
翰森製藥集團有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 3692)

VOLUNTARY ANNOUNCEMENT

UPDATE ON THE MARKETING AUTHORIZATION STATUS OF AUMOLERTINIB IN THE EU

Reference is made to the announcement of Hansoh Pharmaceutical Group Company Limited (the "**Company**", together with its subsidiaries, the "**Group**") dated February 20, 2026 in respect of the grant of marketing authorization of Aumolertinib, marketed as Aumseqa® outside China (the "**Product**"), in the European Union (the "**EU**") as monotherapy following the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (the "**EMA**") (the "**Marketing Authorization**"). Unless the context otherwise requires, capitalized words and expressions used herein shall have the same meanings as defined in the said announcement.

The board of directors (the "**Board**") of the Company has become aware that the Directorate-General for Health and Food Safety of the European Commission ("**EC**") published an implementing decision on September 25, 2026, pursuant to which the said marketing authorization was revoked (the "**Decision**").

The Decision was made after the EC initiated revocation proceedings, apparently following and without awaiting the outcome of the annulment proceedings brought by AstraZeneca against the EC before the General Court of the EU in respect of the Marketing Authorization (T-289/26).

The marketing application for the Product submitted in 2022 (the "**Data Package**") contains the Company's complete, independently generated Phase 3 clinical data and European pharmacokinetic bridging data. However, the Decision primarily found that certain TAGRISSO® clinical results contextually referenced by the Company in the Data Package were at the time still within the data protection period (such data protection period expired in 2024), which constituted a procedural issue in the regulatory assessment process.

Accordingly, the Decision relates solely to a procedural issue under the EU regulatory framework, and is not related to the quality, safety, efficacy or clinical value of the Product.

The Group has reserved all rights to challenge the Decision, including through EU court proceedings if necessary. The Group also intends to resubmit the marketing application for the Product to the EMA based on the original Data Package as soon as possible. The Board is cautiously optimistic that a new marketing authorization can be obtained within a reasonably short timeframe. The precise timeline will depend on the regulatory assessment process. Currently, the EMA has indicated its willingness to shorten the standard assessment timeline.

As at the date of this announcement, the Group has not generated any sales revenue from the Product outside of China, and the Decision is not expected to have any impact on any sales of the Product in China. The Board considers that the Decision and the resubmission process described above will not have any material adverse impact on the current financial position or business operations of the Group.

The Group will continue to progress additional applications for the Product that are under review or in preparation for submission with regulatory authorities in different jurisdictions. The Group remains firmly committed to its innovation and internationalization strategy and its mission of "continuous innovation for better life", and will continue its efforts to bring high-quality innovative medicines to patients worldwide.

The shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
Hansoh Pharmaceutical Group Company Limited
Zhong Huijuan
Chairlady

Hong Kong, September 27, 2026

As at the date of this announcement, the Board comprises Ms. Zhong Huijuan as chairlady and executive director, Ms. Sun Yuan and Dr. Lyu Aifeng as executive directors, and Mr. Lin Guoqiang, Mr. Chan Charles Sheung Wai, Ms. Yang Dongtao and Mr. Yan Jia as independent non-executive directors.