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Fujian Haixi Pharmaceuticals Co., Ltd.
福建海西新藥創制股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2637)

VOLUNTARY ANNOUNCEMENT
HX9428 FOR THE TREATMENT OF NEOVASCULAR
AGE-RELATED MACULAR DEGENERATION
GRANTED FAST TRACK DESIGNATION (FTD) BY THE U.S. FDA

This announcement is made by Fujian Haixi Pharmaceuticals Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**” or “**Haixi Pharmaceuticals**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business updates of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that HX9428, the candidate molecule of the innovative drug project HXP056 independently developed by the Company, was granted Fast Track Designation (“**FTD**”) by the U.S. Food and Drug Administration (the “**FDA**”) for the development of a treatment for neovascular age-related macular degeneration (“**nAMD**”, also called wet age-related macular degeneration (“**wAMD**”)). The grant of the FTD will facilitate closer communication between the Company and the FDA on the clinical development of HX9428 and advance its global clinical development process.

HX9428 is a novel oral small-molecule innovative drug independently developed by Haixi Pharmaceuticals, intended for the treatment of nAMD. Currently, anti-vascular endothelial growth factor (anti-VEGF) therapy remains the standard treatment for nAMD. However, existing treatments require intravitreal injection in eye, and patients may face the medical burden of long-term and repeated treatments, compliance challenges and injection-related risks. Administered orally, HX9428 is expected to provide nAMD patients with a more convenient dosing option as compared with traditional injection therapies, help improve patients’ long-term treatment compliance and address the major challenge of existing clinical treatments.

The Fast Track Designation (FTD) is an expedited program designed by the FDA to facilitate the development, and expedite the review of innovative drugs to treat serious conditions and fill an unmet clinical need. Upon the grant of such designation, a drug may enjoy a number of key policy supports: Frequent and timely specialized communication between the FDA and a drug company is encouraged throughout the entire drug development and review process; Eligibility for Priority Review and Accelerated Approval in the subsequent application; Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed, thus may facilitate the whole review process.

Two core criteria must be met for the FDA's grant of the FTD: first, the drug targets a serious disease; and second, it is able to fill an unmet clinical medical need, which is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. The FTD granted by the FDA to HX9428 for the nAMD indication is a recognition of its innovation in drug design and potential clinical value. With the policy support of the FTD, the global clinical development of HX9428 is expected to be further accelerated.

At present, the research and development of HX9428 in China is progressing steadily: the Phase I clinical study has been successfully completed, and the Phase II dose-expansion study and the second positive-controlled Phase II clinical study are currently underway. Overseas development is also progressing concurrently - HX9428 has been approved by the FDA to commence the Phase II clinical trial for the nAMD indication in the United States, and the Company is making every effort to advance its clinical development plans in the United States, with every hope to benefiting patients worldwide as soon as possible.

Information on HX9428

HX9428 is an innovative drug candidate discovered and developed by the Company for the treatment of ophthalmic diseases. It is intended for the treatment of retinal vascular diseases, including neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME) and retinal vein occlusion (RVO). HX9428 aims to achieve therapeutic intervention in the above diseases through oral administration. As an innovative oral drug candidate, HX9428 is expected to break through the limitations of current treatments for retinal vascular diseases that rely heavily on intraocular injections. It has the potential to offer patients a more convenient treatment option and further expand long-term disease management models.

As of the date of this announcement, HX9428 has not received marketing approval from any drug regulatory authority in any country or region, and its safety and efficacy remain to be validated through further clinical studies.

Information on Haixi Pharmaceuticals

Haixi Pharmaceuticals is a biopharmaceutical company focused on the development and commercialisation of innovative drugs, striving to develop innovative drug products with clinical value for the treatment of oncology, ophthalmology and other major diseases. The Company will continuously accelerate its global clinical development and commercialisation layout of innovative drugs to meet the underserved clinical needs. The Company was listed on the Main Board of The Stock Exchange of Hong Kong Limited in October 2025 (stock code: 2637).

Risk Warning

HX9428, as referenced in this announcement, is a drug candidate currently in the clinical development stage. The research and development of drug candidates involves a high degree of risk, and clinical trial results may be affected by various factors, including but not limited to safety, efficacy, patient enrollment, clinical protocol adjustments, regulatory approval requirements and other unforeseen factors.

Currently, HX9428 has not received marketing approval from any drug regulatory authority. There is no assurance that it will successfully complete clinical development or obtain marketing approval. Investors and shareholders are advised to fully consider the aforementioned risks and other factors that may affect the Company when evaluating the Company's prospects.

Forward-looking Statements

There is no assurance that any forward-looking statements regarding the business development of the Group in this announcement or any of the matters set out herein are attainable, will actually occur or will be realized or are complete or accurate. The financial and other data relating to the Group as disclosed in this announcement has also not been audited or reviewed by its auditor.

Shareholders and/or potential investors of the Company are advised to exercise caution when dealing in the shares of the Company and not to place any excessive reliance on the information disclosed herein. Any shareholder or potential investor who is in doubt is advised to seek advice from professional advisors.

By Order of the Board
Fujian Haixi Pharmaceuticals Co., Ltd.
Dr. Kang Xinshan
Executive Director, Chairman and General Manager

Hong Kong, 17 August 2026

As of the date of this announcement, the Board comprises (i) Dr. Kang Xinshan, Ms. Feng Yan, Dr. Chen Guangming, Mr. Li Junqing and Mr. Chen Tingze as executive Directors; (ii) Mr. Xu Dong as non-executive Director; and (iii) Ms. Wang Shan Shan, Ms. Pu Meiting and Mr. Lin Bin as independent non-executive Directors.