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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
IND APPLICATION OF HX9428 FOR THE TREATMENT OF
NEOVASCULAR AGE-RELATED MACULAR DEGENERATION
APPROVED BY THE U.S. FDA TO COMMENCE PHASE II
CLINICAL TRIAL; AND
INITIATION OF THE SECOND POSITIVE-CONTROLLED
PHASE II CLINICAL TRIAL IN CHINA

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 the Investigational New Drug Application (the “**IND**”) of HX9428, the candidate molecule of HXP056, which was discovered and developed by the Company for the treatment of neovascular age-related macular degeneration (“**nAMD**”, also called wet age-related macular degeneration (“**wAMD**”)), has been approved by the U.S. Food and Drug Administration (the “**FDA**”). This approved IND includes a Phase II clinical trial, aiming to evaluate the efficacy and safety of different oral doses of HX9428 in treating American patients with nAMD.

At the same time, the Company officially commenced the second Phase II clinical trial of HX9428 (Registration No.: CTR20262884) for the treatment of nAMD in China, and the related information has been published on the Drug Clinical Trial Registration and Information Disclosure Platform of the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA). This study is a randomized and positive-controlled Phase II clinical trial further initiated by the Group based on the prior Phase I and Phase II dose expansion studies of HX9428.

The clinical study (Project No.: HXP056-CTPII-01), a multi-center, randomized, open-label and positive-controlled Phase II clinical trial, plans to recruit 60 nAMD subjects from multiple clinical research centers in China, for the purpose of evaluating the efficacy and safety of HX9428 in a head-to-head comparison with Aflibercept, a standard clinical therapy.

nAMD is a chronic ocular fundus disease that severely threatens the vision of the elderly. Its primary pathological feature is the abnormal formation of choroidal neovascularization, leading to subretinal fluid exudation, hemorrhage and vision decline. Currently, anti-vascular endothelial growth factor (anti-VEGF) therapy remains the standard of care in the treatment of nAMD. However, existing treatments require intravitreal injections, exposing patients to the healthcare burden, adherence challenges and injection-related risks associated with long-term, repeated therapy. HX9428 is an oral therapeutic solution developed for nAMD. Compared to traditional injection therapies, it offers superior ease of administration, effectively improving long-term patient adherence, addressing current clinical pain points and providing a more convenient and accessible new option for long-term disease management in nAMD patients.

The approval of the U.S. FDA Phase II clinical trial IND application and the initiation of the standard-therapy controlled Phase II clinical trial in China mark significant progress in HX9428's global clinical development and lay a solid foundation for the comprehensive verification of the clinical value of HX9428 in the treatment of nAMD.

The Company will continue to accelerate its global clinical development of HX9428 and will publish updated information on the clinical study when appropriate.

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 fundus neovascularization-related diseases, including nAMD. HX9428 aims to achieve therapeutic intervention in the disease process of nAMD through oral administration. As an innovative oral drug candidate, HX9428 is expected to break through the limitations of current nAMD treatments 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, 4 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.