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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 LATEST DATA FROM PHASE I AND PHASE II CLINICAL STUDIES FOR THE TREATMENT OF NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (nAMD)

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 clinical study progress of HX9428, the candidate drug molecule of the innovative drug project HXP056 independently developed by the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that the Chinese Phase I clinical study of HX9428 for the treatment of neovascular age-related macular degeneration (“**nAMD**”) has completed the observation of the 24-week treatment data, and the Chinese Phase II dose-expansion study is still ongoing and interim clinical data have been obtained.

PHASE I CLINICAL STUDY

The Chinese Phase I clinical study of HX9428 enrolled a total of 15 nAMD patients, covering five dose cohorts from 5 mg/QD to 40 mg/QD. Among them, 13 patients completed the 24-week treatment, including 10 patients previously treated with anti-vascular endothelial growth factor (anti-VEGF) therapy and 3 treatment-naïve patients.

Among the 13 patients who completed 24 weeks of treatment, best corrected visual acuity (“**BCVA**”) improved by an average of 5.2 letters from baseline, and central subfield thickness (“**CST**”) decreased by an average of 73.3 μm from baseline, demonstrating an improving trend in visual function and macular anatomical parameters.

In terms of safety, no dose-limiting toxicity (“**DLT**”) was observed at any of the five dose levels, and the overall tolerability was favourable. Neither common gastrointestinal adverse events such as diarrhea, nausea or vomiting nor hair whitening were observed during the study. With respect to hepatic and renal-related adverse events, one case of elevated alanine aminotransferase (ALT) and one case of elevated aspartate aminotransferase (AST) were observed, both of which were grade 1 and transient. Hypertension-related adverse events mainly occurred in the higher dose cohorts, including one grade 3 adverse event (a single systolic blood pressure of 160 mmHg) in the 25 mg/QD dose cohort and two grade 3 adverse events in the 40 mg/QD dose cohort, which were generally manageable through routine monitoring and antihypertensive treatment. All of the above adverse events occurred within the first 3 months after the initiation of treatment, and no new adverse events were observed during the 3- to 6-month treatment period.

PHASE II CLINICAL STUDY

The Chinese Phase II dose-expansion study of HX9428 is currently ongoing. As of 14 August 2026, a total of 80 nAMD patients have been enrolled across the three dose cohorts of 5 mg/QD, 10 mg/QD and 20 mg/QD, of which approximately 78% were patients previously treated with anti-VEGF therapy and approximately 22% were treatment-naïve patients; 45 patients have completed the week 13 visit and 11 patients have completed 24 weeks of treatment.

Interim data showed that, as the duration of treatment extended, the average BCVA and CST data continued to improve. As of the aforesaid date, among the 11 patients who completed 24 weeks of treatment, BCVA improved by an average of 5.4 letters from baseline, and CST decreased by an average of 72.5 μ m from baseline, with the overall efficacy trend being consistent with the results of the Phase I study. As the number of patients who have completed 24 weeks of treatment is currently limited, the above data are interim results and remain to be further validated as the study progresses and the sample size increases.

In terms of safety, the overall tolerability at the current stage is favourable, which is largely consistent with the observations of the Phase I study. Neither common gastrointestinal adverse events such as diarrhea, nausea or vomiting nor hair whitening were observed during the study. The other reported adverse events were mostly of low grade, including elevated blood pressure and fluctuations in hepatic, renal and metabolism-related laboratory parameters. The incidence of each of the above adverse events was below 10%. The Company will continue to monitor various safety indicators and further evaluate the long-term benefit-risk profile of HX9428.

INFORMATION ON HX9428

HX9428 is an oral small-molecule innovative drug independently developed by Haixi Pharmaceuticals, and clinical studies related to nAMD are currently being conducted. Existing treatments for nAMD mainly include intravitreal injection of anti-VEGF drugs. HX9428 is administered orally, and its safety and efficacy remain to be validated through ongoing and further clinical studies.

As of the date of this announcement, HX9428 has not received marketing approval from any drug regulatory authority in any country or region.

RISK WARNING

The research and development of innovative drug candidates involves a high degree of risk. Interim results of clinical trials may not necessarily be predictive of subsequent or final clinical trial results, and clinical development may also be affected by various factors, including but not limited to safety, efficacy, patient enrollment, adjustments to clinical protocols and regulatory approval requirements. Currently, HX9428 has not received marketing approval from any drug regulatory authority, and there is no assurance that it will successfully complete clinical development or obtain marketing approval.

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 interim clinical data 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, 16 September 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.