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撥康視云™
Cloudbreak Pharma

CLOUDBREAK PHARMA INC.

撥康視雲製藥有限公司*

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2592)

VOLUNTARY ANNOUNCEMENT

BUSINESS UPDATE IN RELATION TO INVESTIGATIONAL NEW DRUG APPLICATION FOR CBT-009

This announcement is made by Cloudbreak Pharma Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis for the purpose of keeping the shareholders and potential investors of the Company informed of the latest business development of the Group.

Reference is made to the Company’s announcement dated 6 January 2026 (the “**Announcement**”) in relation to, among other matters, the Investigational New Drug (“**IND**”) application for CBT-009, one of the Group’s core products. As disclosed in the Announcement, the Group has successfully submitted the IND application for CBT-009 to the Center for Drug Evaluation (“**CDE**”) of the National Medical Products Administration of China.

The Company conducted a pre-IND application consultation meeting in January 2024 with the CDE regarding a possible placebo-controlled Multi-regional Clinical Trial (“**MRCT**”), including in China, for CBT-009 ophthalmic emulsion, a Semi-fluorinated Alkane (“**SFA+**”) based atropine eye drop to treat juvenile myopia. Based on the communication at that time, the Group formally submitted the IND application in December 2025, which was accepted in January 2026.

Following the submission of the IND application, the CDE approved a comparable drug for marketing in China. After subsequent communications with the CDE, the Company believes it might be difficult to include China in MRCT due to the different regulatory requirements across regions. To avoid subsequent research and development risks and better concentrate the Group’s resources, the Company has decided to voluntarily withdraw the current IND application for the possible phase 3 trial in China.

The Company is committed to continue developing its SFA+ platform and will reassess the clinical development strategy for CBT-009 in accordance with the latest regulatory requirements and market conditions. Upon completion of relevant supplementary studies or adjustments to the clinical trial protocol, the Company will, depending on the circumstances, either hold pre-submission consultation meetings with the CDE or resubmit a clinical studies application.

The R&D and IND application status of the Group's other core products (including CBT-004 and CBT-199) remain on course. Regarding CBT-001, one of the Group's core products, the Company expects to complete the Phase 3 MRCT in the third quarter of 2026.

The Company will issue further announcements as and when appropriate to ensure that the shareholders and potential investors of the Company are kept informed of the latest business developments of the Group.

Warning Statement: There is no guarantee that CBT-009 or any other core product of the Group will ultimately be successfully developed, launched or marketed.

Shareholders and potential investors of the Company should exercise caution and due care when dealing in the shares of the Company.

By order of the Board
Cloudbreak Pharma Inc.
Dr. NI Jinsong

Chairman of the Board, Executive Director and Chief Executive Officer

Hong Kong, 19 March 2026

As at the date of this announcement, the board of directors of the Company comprises: (i) Dr. Ni Jinsong, Mr. Dinh Son Van and Dr. Yang Rong as executive directors; (ii) Dr. Li Jun Zhi, Mr. Cao Xu and Mr. Xia Zhidong as non-executive directors; and (iii) Ms. Nie Sijiang, Mr. Ma Yiu Ho Peter and Mr. Lee Alex Jao Jang, as independent non-executive directors.

* For identification purposes only