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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-199 EFFECTIVE SUBMITTED TO FOOD AND DRUG ADMINISTRATION

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.

The board of directors of the Company (the “**Board**”) is pleased to announce that ADS Therapeutics LLC (“**ADS USA**”), a wholly-owned subsidiary of the Company registered under the laws of Delaware, the United States of America (the “**USA**”), the review period of the Investigational New Drug application (the “**IND Application**”) in respect of CBT-199 submitted on 12 December 2025, a potential best-in-class ophthalmic drug candidate being developed by the Group, to the Food and Drug Administration (the “**FDA**”) of the USA has concluded. As the FDA has not issued any clinical hold, the IND Application has become effective, and the clinical trial is considered Safe-to-Proceed.

As disclosed by the Company in its prospectus dated 24 June 2025, the interim report of the Group for the six months ended 30 June 2025 and the voluntary announcement dated 15 December 2025 in relation to business update:

CBT-199 is a novel topical ophthalmic emulsion indicated for the treatment of presbyopia, a common aged-related condition in which the lens in the eye gradually becomes thicker and loses flexibility, causing progressive inability to focus on close objects. CBT-199, which contains a parasympathomimetic miotic agent formulated in the Group’s proprietary non-aqueous platform, treats presbyopia by inducing pupil constriction to create a pinhole effect that increases depth of focus, thereby improving near vision. The water-free formulation aims to improve drug stability by preventing decomposition of the active ingredient over time and to provide a comfortable, soothing dosing experience in a consumer-friendly self-preserved multi-dose bottle with long shelf-life.

The Group began the drug discovery process in respect of CBT-199 in the People's Republic of China in 2023. Since June 2023, CBT-199 has been evaluated for safety and tolerability in pre-clinical animal studies, which are expected to facilitate future clinical trials.

The Company considers that as the clinical trial of CBT-199 is now considered Safe-to-Proceed, it represents a critical milestone in the clinical development of CBT-199, and the Group has become officially authorized to initial its Phase 2 clinical trials. The Group will continue to closely monitor the evaluation progress and make further announcement(s) to keep the shareholders and potential investors of the Company informed of the latest developments in relation to the Group's business as and when appropriate.

Warning Statement: There is no guarantee that CBT-199 or any other drug candidate 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, 16 February 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 purpose only*