拨康视云™
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 SUCCESSFUL END-OF-PHASE 2 MEETING

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 announcement of the Company dated 8 December 2025 (the "**Announcement**") in relation to the arrangement of an End-of-Phase 2 ("**EOP2**") meeting with the FDA in respect of CBT-004, one of the clinical-stage drug candidates of the Group. Unless otherwise defined herein, capitalised terms have the same meanings given to them in the Announcement.

SUCCESSFUL END-OF-PHASE 2 MEETING FOR CBT-004

The Board is pleased to announce that, on 10 December 2025, Cloudbreak USA, a wholly-owned subsidiary of the Company, successfully held an EOP2 meeting with the FDA (the "**EOP2 Meeting**") in relation to the clinical development of CBT-004, a potential first-in-class preservative-free topical ophthalmic solution indicated for the treatment of vascularised pinguecula, a condition commonly affecting people with increased ultraviolet light exposure and increasing age.

At the EOP2 Meeting, the FDA provided feedback on questions regarding drug stability and specification studies, non-clinical studies to support the proposed new drug application to be made with the FDA (the "**New Drug Application**"), as well as the design and endpoints of the Phase 3 clinical studies for CBT-004. Amongst other things, the FDA and Cloudbreak USA have reached agreement on the statistical and clinical significance of hyperemia reduction as a primary endpoint and of symptom relief as a potential co-primary endpoint for the approval of CBT-004.

The EOP2 Meeting was conducted on the basis of the results of the Phase 2 clinical trials completed in May 2025 and the clinical trial report completed in July 2025, which indicated that CBT-004 was safe and well tolerated in subjects and met the primary endpoint and several secondary endpoints in efficacy. In particular, the Phase 2 clinical trial results demonstrated the efficacy of CBT-004 in the reduction of conjunctival hyperemia, with rapid effects seen as early as 7 days after dosage initiation. Improvements in symptoms, including burning or stinging, itching and foreign body sensation, were also observed during the 28-day treatment period, and some of the symptom improvement effects remained significant 4 weeks after stopping treatment. Treatment emergent adverse events were mild and transient and not considered to be related to the study drug.

The Company views the success of the EOP2 Meeting as a major step forward in the clinical development of CBT-004, in particular its advancement to Phase 3 clinical studies, paving the way for the New Drug Application and commercialisation of CBT-004 upon its approval. Further announcement(s) will be made by the Company 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-004 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, 12 December 2025

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*