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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 SUBMISSION OF INVESTIGATIONAL NEW DRUG APPLICATION

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.

SUBMISSION OF INVESTIGATIONAL NEW DRUG APPLICATION

The board of directors of the Company (the “**Board**”) announces that, on 12 December 2025, ADS Therapeutics LLC, a wholly-owned subsidiary of the Company, submitted to the Food and Drug Administration of the United States of America (the “**FDA**”) an investigational new drug application (the “**IND Application**”) in respect of CBT-199, a potential best-in-class ophthalmic drug candidate being developed by the Group.

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 parasymphomimetic 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.

As disclosed in the prospectus of the Company dated 24 June 2025, the Group began the drug discovery process for 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 submission of the IND Application represents the first step to initiate the drug review process by the FDA and to obtain regulatory approval to commence clinical trials for CBT-199.

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-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, 15 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*