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)

BUSINESS UPDATES AND SUPPLEMENTAL ANNOUNCEMENT IN RELATION TO 2025 ANNUAL REPORT

Reference is made to the annual report of Cloudbreak Pharma Inc. (the "**Company**", together with its subsidiaries, the "**Group**") for the year ended 31 December 2025 (the "**2025 Annual Report**"). This announcement is made by the Company to provide supplemental information to the 2025 Annual Report 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. Unless otherwise defined, capitalised terms used in this announcement shall have the same meanings as those defined in the 2025 Annual Report.

Business Updates to the Core Products of the Company

CBT-001

Multi-regional clinical trials (MRCT) of CBT-001 were completed, and database lock has taken place. The topline analysis results are scheduled to be released accordingly. If successful, the Company is expected to communicate with the regulatory agencies, including the United States Food and Drug Administration (FDA) and the Centre for Drug Evaluation of the National Medical Products Administration (國家藥品監督管理局), regarding a further development plan and potential new drug application (NDA) regulatory submission. Based on current estimation, the commercialisation of CBT-001 in the USA will take place between 2030 and 2032.

CBT-009

The Company is currently in the process of developing a global clinical and regulatory plan for the Phase 3 MRCT for the pediatric myopia indication. Based on current estimation, the commercialisation of CBT-009 could take place between 2032 and 2034 if a global Phase 3 MRCT is successfully executed.

Business Updates to Other Products of the Company

CBT-199

CBT-199 is a novel, once-daily preservative-free topical ophthalmic emulsion containing a parasympathomimetic miotic agent formulated in the Group's proprietary non-aqueous platform for the treatment of presbyopia. In an IND application, CBT-199 has received FDA authorization to proceed to Phase 2 clinical trials. The clinical trials can be expected to start in 2027 after clarification with the FDA on a question regarding study design.

CBT-358

CBT-358 is a combination SFA+ and TRPM8 agonist drug candidate under development for the treatment of dry eye disease ("**DED**"). The proposed investigational product of CBT-358 is formulated in a novel non-aqueous ophthalmic solution designed for the treatment of aqueous deficiencies. In an IND filing, CBT-358 has received FDA authorization to proceed to Phase 2 clinical trials. After a few minor revisions of study protocol recommended by the FDA, the clinical trials can start in 2027.

CBT-004

CBT-004 is a potential first-in-class ophthalmic drug using MKI targeting VEGFRs and PDGFRs, indicated for the treatment of pinguecula.

There are no approved pharmacological treatments for pinguecula. Current off-label treatments are either not adequate or not effective. CBT-004 was developed under the 505(b)(2) pathway in the United States. The Company completed a successful Phase 2 clinical trial and in an end-of-phase 2 ("**EOP2**") meeting with the FDA, gained FDA approval for Phase 3 trials with endpoints similar to that of the Phase 2 trial. The planned Phase 3 trial will be longer than the completed Phase 2 trial and the Company is currently performing animal toxicology studies to meet the requirements for Phase 3 trials that can start in late 2027 pending demonstration of safety in animals.

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: There is no assurance that any of Core Products or any other products will ultimately be successfully developed and marketed by the Group. Shareholders and potential investors should exercise caution when dealing in the Shares.

Continued Suspension of Trading

All dealings in the shares of the Company have been suspended by the Stock Exchange as directed by the Securities and Futures Commission since 9:00 a.m. on 10 September 2026 and will remain suspended until further notice.

Shareholders and potential investors of the Company are advised to exercise caution when dealing in the Company's securities.

By order of the Board
Cloudbreak Pharma Inc.
Dr NI Jinsong
Chairman, Executive Director and Chief Executive Officer

Hong Kong, 18 September 2026

As at the date of this announcement, the Board 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*