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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 THE TOPLINE RESULTS FROM THE PHASE 3 STUDY OF CBT-001 IN PATIENTS WITH PTERYGIUM

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.

Topline Results from the Phase 3 Study of CBT-001

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce the topline results from the Phase 3 study of CBT-001 as a potential treatment for pterygium. Statistical significance was obtained for both major primary endpoints. Both doses of CBT-001 demonstrated highly statistically significant improvements versus vehicle in conjunctival hyperemia at Month 3 and pterygium lesion length at Month 12. The findings mark the first time a drug has demonstrated therapeutic effects in pterygium through a statistically significant improvement in hyperemia and lesion size. Additional analyses are ongoing.

Key data highlights:

- **Conjunctival hyperemia:** This study directly targeted the most prominent symptom of ocular surface hyperemia in patients with pterygium, which aimed at objectively verifying the rapid effect of the drug in alleviating local inflammation and redness. The clinical data from this study showed that at Month 3, both dose groups of CBT-001 (0.1% and 0.2%, administered twice daily) demonstrated a highly statistically significant improvement in conjunctival hyperemia as compared with the control group ($p<0.001$). An even more encouraging signal is that this clinical improvement was observable as early as Week 2 after administration and persisted throughout the entire 12-month follow-up cycle. This result is consistent with that of the Phase II clinical trial.

  Pterygium lesion length: This indicator is designed to assess the drug's capacity to inhibit the continued expansion of the lesion towards the cornea. As shown by the preliminary results from the Phase 3 Study in this publication, at Month 12, both dose groups demonstrated a statistically significant reduction in pterygium lesion length as compared with the control group ($p<0.001$). In terms of lesion size, the benefit in the treatment group compared with the vehicle was approximately

10% of the baseline value. Notably, at Month 12, the observed treatment effect had not yet plateaued.

- **Safety:** Superficial punctate keratitis was the most commonly reported adverse event in the CBT-001 0.1% group (20% versus 8% in the vehicle group), and the majority of events resolved after treatment with artificial tears. Other individual adverse events occurred in fewer than 10% of patients in the 0.1% group. Similar adverse events were reported with the 0.2% dose at a moderately higher rate.

"p<0.001" means that the probability of this clinical improvement by chance is less than one thousandth. This indicator signifies that the drug has demonstrated proven and effective therapeutic benefits.

Pterygium is a condition that has both vision and quality of life impact on millions of people in the United States of America (the "**U.S.**") and for which there are currently no drug therapies approved to our knowledge by any regulatory agencies including the Food and Drug Administration (the "**FDA**") of the U.S..

The Company is conducting additional analyses of the Phase 3 results, including secondary endpoints and subgroup analyses, and intends to meet with the FDA to review the study findings and discuss potential next steps for the CBT-001 development programme, including the clinical and regulatory implications of the results.

About the Phase 3 Trial

CBT-CS301 (NCT05456425) is a multi-regional, double-masked, randomised, vehicle-controlled Phase 3 trial in patients with pterygium comparing two doses of CBT-001 ophthalmic emulsion (0.1% and 0.2%) administered twice daily over 24 months versus vehicle. The primary efficacy endpoints include a reduction in conjunctival hyperemia related to the vascularized pterygium lesion at three months and prevention of pterygium progression at 12 months. The study protocol also includes a 12-month extension for an additional 12 months of safety data.

Enrolment began in the U.S. in June 2022 and expanded to China, New Zealand, Australia, and India. The topline results summary reports 659 patients: 164 assigned to CBT-001 0.1%, 329 to CBT-001 0.2%, and 166 to vehicle. The study included 58% male and 42% female participants.

About Pterygium

Pterygium is a triangular fibrovascular growth on the cornea, connected to the conjunctiva. It is commonly caused by excessive UV exposure and can lead to redness, irritation, foreign body sensation, dry eye, and, with continued progression, potentially serious vision problems. The company estimates that pterygium impacts just under one billion people globally, including 13 million in the U.S. alone. Of those, approximately 7.5 million in the U.S. alone are seen annually by an eye doctor, and 2.5 million are formally diagnosed each year by an ophthalmologist or optometrist that report to medical databases in the U.S.

There are currently no FDA-approved drug-based treatments for pterygium in the U.S.. Most patients with pterygium are alleviated for their symptoms using artificial tears, prescription dry eye products and/or off-label NSAIDs or corticosteroids, with significant limitations for long-term use in terms of safety hazards.

About CBT-001

CBT-001 is a novel multi-kinase inhibitor (MKI) eye drop being developed for the treatment of pterygium, a common ocular surface disease. Currently, there is no drug-based therapeutic solution targeting pterygium approved by any regulatory agencies including the FDA globally. Surgical resection is currently the only intervention option capable of altering the progress of the disease. CBT-001 has been developed precisely to address this significant and unmet medical need. Currently in Phase 3 clinical development across multiple regions, CBT-001 is designed for the treatment mechanism to target the underlying angiogenic and fibrogenic drivers of the disease rather than just providing symptomatic relief. In earlier studies, the therapy demonstrated meaningful and durable reductions in pterygium vascularity and ocular redness, with a favourable safety profile. If approved, CBT-001 has the potential to become the first pharmacologic treatment for pterygium in the world, addressing a significant unmet medical need.

Forward-Looking Statements

This announcement contains forward-looking statements regarding the future performance, plans and prospects of the Company. These statements may include research and development (R&D) activities, clinical trial progress and outcomes, regulatory submissions, timelines and approvals, manufacturing and supply operations, product launches and partnerships and/or financial outlook and business strategy.

All forward-looking statements are based on the Company's management's current expectations and assumptions only as at the date of this announcement. The financial and other data relating to the Group, as disclosed in this announcement, have not been audited or reviewed by its auditors. Actual results may differ due to various factors, including clinical or regulatory outcomes (e.g., U.S. or other markets), competitive developments and market dynamics, and/or economic or operational uncertainties.

Continued Suspension of Trading

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

Shareholders and potential investors of the Company should exercise caution when dealing in the securities of the Company.

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

Hong Kong, 5 November 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, Mr. Lee Alex Jao Jang, Mr. Chan Sheung Yan Andrew and Mr. Kwai Sze Kit as independent non-executive directors.

* *For identification purposes only*