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 SUBMISSION OF INVESTIGATIONAL NEW DRUG APPLICATION FOR CBT-358

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**") is pleased to announce that, on 21 May 2026, the Group submitted to the Food and Drug Administration (the "**FDA**") of the United States of America an investigational new drug application (the "**IND Application**") in respect of CBT-358.

As disclosed by the Company in its annual report 2025, CBT-358 is the latest addition to the Group's product pipeline and is a drug candidate from Semi-fluorinated Alkane ("**SFA+**") technology platform for the treatment of dry eye disease, which represents a multi-billion dollar global market. Dry Eye Disease ("**DED**"), scientifically known as keratoconjunctivitis sicca, is a complex, multifactorial breakdown of the ocular surface's "life support system." At its core, DED is an imbalance in the tear film, the sophisticated fluid layer that keeps vision crisp and corneas comfortable. DED is commonly caused by decreased tear production, excessive evaporation of tears, or both of these processes, leading to damage and inflammation of the surface of the eye. Common symptoms of dry eye patients include a gritty or burning sensation in the eyes, blurry vision and sometimes paradoxical tearing. DED is one of the most frequent reasons for patient visits to eye care professionals.

The proposed investigational product of CBT-358 is formulated in a novel non-aqueous ophthalmic solution designed for the treatment of aqueous deficiencies. Unlike traditional passive lubricants, this formulation leverages the physiological "cooling" reflex to stimulate endogenous tear production. This activation mimics the effect of cold temperature, triggering a reflex arc that increases basal lacrimation and blink frequency, thereby restoring the ocular surface moisture naturally. Therefore, CBT-358 is expected to address aqueous deficiency of dry eye disease. At the same time, the novel non-aqueous formulation utilised SFA+ technology, and yielded unexpected findings that suggest CBT-358 may also minimize evaporation of tears, as indicated by the in vitro assay and in vivo animal model results. Consequently, CBT-358 could potentially address both aqueous deficiencies and evaporative dry eye, the root causes of the majority of dry eye diseases.

As a result of this promising breakthrough, we have expedited the development timeline of CBT-358 and successfully completed IND-enabling studies much sooner than anticipated. 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-358.

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-358 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, 22 May 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*