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Ocumension Therapeutics

歐康維視生物

(Incorporated in the Cayman Islands with limited liability)
(Stock code: 1477)

VOLUNTARY ANNOUNCEMENT PRIMARY ENDPOINT ACHIEVED IN THE SECOND PHASE III CLINICAL TRIAL OF OT-301

This announcement is made by Ocumension Therapeutics (the "Company", together with its subsidiaries, the "Group") on a voluntary basis to keep the shareholders of the Company and potential investors informed of the latest business updates of the Group.

The board (the "Board") of directors of the Company is pleased to announce that one of the Group's key drug candidates, OT-301 (NCX 470), a first-in-class, nitric oxide (NO)-donating prostaglandin analog under joint development by Nicox S.A. ("Nicox") and the Group, has achieved the primary endpoint of non-inferiority, as compared to latanoprost, in its second phase III clinical trial (the "Denali trial"), meeting the efficiency requirements for new drug approval in China. OT-301 demonstrated a favorable safety profile and was well tolerated by patients in the Denali trial. Additionally, OT-301 demonstrated statistically superior intraocular pressure ("IOP") reduction from baseline compared with latanoprost in a pre-specified secondary efficacy analysis, with a p-value of less than 0.05 at three out of six timepoints.

The Denali trial is a three-month phase III multi-regional clinical trial evaluating the safety and efficacy of OT-301 (NCX 470) ophthalmic solution, 0.1%, versus the current standard of care, latanoprost ophthalmic solution, 0.005%, for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension. The Denali trial, which includes a long-term safety extension, has enrolled 696 patients at approximately 90 clinical sites in the United States and China. The first phase III clinical trial of NCX 470, namely the Mont Blanc trial, was successfully completed by Nicox in the United States and China in 2022, in which robust efficacy and safety was demonstrated in topline results.

OT-301 (NCX 470) is a new chemical entity invented by Nicox and designed to release both bimatoprost, a United States Food and Drug Administration approved prostaglandin analog, and NO, for the lowering of intraocular pressure in patients with open-angle glaucoma and ocular hypertension. The Group obtained an exclusive license from Nicox to develop, make, have made, import, export and sell OT-301 (NCX 470) in greater China in December 2018, and extended the exclusive right to Korea and 12 countries in Southeast Asia in March 2020.

Cautionary Statement: The Company cannot guarantee that it will ultimately commercialize OT-301 (NCX 470) successfully. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Ocumension Therapeutics
Dr. Lian Yong CHEN
Chairman and Non-executive Director

Hong Kong, August 21, 2025

As of the date of this announcement, the Board comprises Mr. Ye LIU and Dr. Zhaopeng HU as executive directors, Dr. Lian Yong CHEN, Mr. Yanling CAO and Dr. Qin XIE as non-executive directors, and Mr. Ting Yuk Anthony WU, Mr. Yiran HUANG and Mr. Zhenyu ZHANG as independent non-executive directors.