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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 PHASE III CLINICAL TRIAL OF OT-301 (NCX 470) APPROVED IN CHINA

The board (the "Board") of directors of Ocumension Therapeutics (the "Company", together with its subsidiaries, the "Group") is pleased to announce that one of the Group's pipeline, OT-301 (NCX 470), a first-in-class, second-generation nitric oxide (NO)-donating bimatoprost analog intended to lower intraocular pressure ("IOP") in patients with open-angle glaucoma and ocular hypertension, has recently been approved by the Center for Drug Evaluation of the National Medical Products Administration of the People's Republic of China (the "PRC") to carry out one of its two phase III clinical trials in the PRC that have been planned by the Company.

OT-301 (NCX 470) ophthalmic solution, 0.065%, demonstrated in its phase II clinical trial a superior IOP-lowering treatment effect compared with latanoprost ophthalmic solution, 0.005%, the most widely prescribed first-line therapy for glaucoma and ocular hypertension in the PRC. By adding NO-mediated efficacy to bimatoprost, which is considered the most efficacious prostaglandin analog approved to date, OT-301 (NCX 470) is a potential best-in-class treatment drug candidate for lowering IOP in glaucoma and ocular hypertension patients.

The approval recently obtained is the first approval obtained by the Company for carrying out phase III multi-regional clinical trial in the PRC. The Company and its licensing partner, Nicox S.A. ("Nicox"), the originator of NCX 470, intend to carry out two phase III multi-regional clinical trials of OT-301 (NCX 470) in the United States and the PRC, subject to regulatory approvals, both of which aim to evaluate the safety and efficacy of OT-301 (NCX 470) ophthalmic solution, 0.1%, compared to latanoprost ophthalmic solution, 0.005%, in subjects with open-angle glaucoma or ocular hypertension. In particular, these phase III clinical trials will aim to demonstrate that OT-301 (NCX 470) is non-inferior (primary endpoint) and superior to latanoprost ophthalmic solution 0.005%, as well as to demonstrate that it is well-tolerated when administered for a period planned to be up to 12 months. Nicox has initiated the first phase III clinical trial in the United States in June 2020. Such joint development with Nicox in the multi-regional clinical trials of OT-301 will further enhance the Company's research capability and will better support the expected new drug application of OT-301 in the PRC.

Further Information on OT-301 (NCX 470)

OT-301 (NCX 470) was invented and developed by Nicox. Nicox granted the Group exclusive rights under certain patents and know-how to develop, make, have made, import, export, use, distribute, market, promote, offer for sale and sell OT-301 (NCX 470) in the Greater China region, Korea and another 12 countries in Southeast Asia.

By order of the Board of
Ocumension Therapeutics
Dr. Lian Yong CHEN
Chairman and Executive Director

Shanghai, the PRC, October 23, 2020

As of the date of this announcement, the Board comprises Dr. Lian Yong CHEN, Mr. Ye LIU, Dr. Zhaopeng HU and Dr. Wei LI as executive Directors, Mr. Yanling CAO and Mr. Lefei SUN as non-executive Directors, and Mr. Ting Yuk Anthony WU, Mr. Lianming HE, and Mr. Yiran HUANG as independent non-executive Directors.