



WIZE PHARMA COMPLETES PATIENT ENROLLMENT IN PHASE IV STUDY OF LO2A FOR THE TREATMENT OF DRY EYE SYNDROME IN PATIENTS WITH SJÖGREN'S SYNDROME

Posted on January 21, 2020

- Topline Results Expected Q2 2020
 - Study designed to support approval pathway in the U.S. and other major markets
- HOD HASHARON, Israel, Jan. 21, 2020 /[PRNewswire](#)/ -- Wize Pharma, Inc. (OTCQB: WIZP) ("Wize"), a clinical-stage biopharmaceutical company focused on the treatment of ophthalmic disorders, today announced it has completed enrolment in its Phase IV clinical trial of its eye drop formula to evaluate the efficacy of LO2A for the symptomatic treatment of dry eye syndrome (DES) in patients with Sjögren's syndrome.

"We are very pleased to have completed enrolment in this Phase IV study. We expect to announce topline results during the second quarter of this year," stated Wize CEO Noam Danenberg. "LO2A is already approved for the symptomatic treatment of DES in patients with Sjögren's syndrome in Hungary and the Netherlands."



Wize_Pharma_Logo

LO2A is approved for marketing in Israel under the tradename EyeCon®. Although it is not yet approved for the symptomatic treatment of DES in patients with Sjögren's syndrome in Israel, this study was classified as a post-marketing, Phase IV study by the Israeli Ministry of Health. The Phase IV trial is a randomized, double-masked study to evaluate LO2A versus Alcon's Systane® Ultra UD, an over-the-counter lubricant eye drop product used to relieve dry and irritated eyes. Approximately 60 evaluable patients with Sjögren's syndrome who are experiencing DES are being randomized in a 1:1 ratio to one of two treatment groups, LO2A or Systane® Ultra UD. Drops are administered topically to the eye over a three-month period. The primary endpoint of the study is change in corneal/conjunctival staining score using the National Eye Institute (NEI) Industry Grading System after 3 months of study treatment. This is an objective measure used to determine the severity of the damage caused by dryness of the eye. Secondary endpoints include corneal/conjunctival staining score after one month of treatment and change in Ocular Surface Disease Index (OSDI) score after one and three months of treatment.

This study is designed to support Wize's clinical approval pathway for LO2A for the



treatment of DES in patients with Sjögren's syndrome in the USA and other markets.

Following successful completion of the Phase IV study in Sjögren's syndrome, Wize plans to submit data from both this Phase IV study and the formerly announced completed Phase II CCh study to the U.S Food and Drug Administration through a pre-Investigational New Drug (IND) meeting, where Wize will seek guidance on the regulatory approval path for LO2A in the U.S.

About Wize Pharma

Wize Pharma, Inc. is a clinical-stage biopharmaceutical company currently focused on the treatment of ophthalmic disorders, including DES. Wize has in-licensed certain rights to purchase, market, sell and distribute a formula known as LO2A, a drug developed for the treatment of DES, and other ophthalmological illnesses, including CCh and Sjögren's syndrome.

LO2A is currently registered and marketed by its inventor in Germany and Switzerland for the treatment of DES, in Hungary for the treatment of DES, CCH and Sjögren's syndrome and in the Netherlands for the treatment of DES and Sjögren's syndrome. Wize's strategy involves engaging local or multinational distributors to handle the distribution of LO2A. Wize has finished a Phase II trial of LO2A for patients with CCh), demonstrated a statistical significance result enrolled, using a mixed model with repeated measures (MMRM), and is currently conducting a Phase IV study for LO2A for DES in patients with Sjögren's syndrome, expected to publish topline results in the second quarter of 2020.

Forward Looking Statements

Wize cautions you that statements in this press release that are not a description of historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as "expect," "intend," "plan," "anticipate," "believe," and "will," among others. For example, when Wize discusses the potential timing, the progress of Wize's clinical trials, it is using forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These



forward-looking statements are based upon Wize's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the need for additional financing; our dependence on a single compound, LO2A and on the continuation of our license to commercialize LO2A; its inability to expand its rights under our license of LO2A; the initiation, timing, progress and results of its trials and product candidate development efforts; its ability to advance LO2A into clinical trials or to successfully complete its preclinical studies or clinical trials; its receipt of regulatory approvals for LO2A, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of LO2A; its ability to establish and maintain corporate collaborations; the implementation of its business model and strategic plans for its business and product candidates; the scope of protection it is able to establish and maintain for intellectual property rights covering LO2A and its ability to operate its business without infringing the intellectual property rights of others; estimates of its expenses, future revenues, and capital requirements; competitive companies, technologies and its industry; and statements as to the impact of the political and security situation in Israel on its business. More detailed information about the risks and uncertainties affecting Wize is contained under the heading "Risk Factors" included in Wize's Annual Report on Form 10-K filed with the SEC on April 1, 2019, and in other filings that Wize has made and may make with the SEC in the future. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Wize does not undertake any obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as may be required by law.

The contents of any website or hyperlinks mentioned in this press release are for informational purposes and the contents thereof are not part of this press release.

For all investor enquiries, please contact:

Or Eisenberg
Chief Financial Officer
+972-72-260-0536
or@wizepharma.com



SOURCE Wize Pharma, Inc.