



WIZE PHARMA ANNOUNCES MEETING ITS PHASE II STUDY PRIMARY OBJECTIVE TO DEMONSTRATE LO2A EFFECTIVELY TREATS DRY EYE SYNDROME IN PATIENTS WITH CONJUNCTIVOCHALASIS

Posted on November 20, 2018

Topline results show reduction in LGCS, a standard measure in this indication, at 3 months from baseline

HOD HASHARON, Israel, Nov. 20, 2018 /[PRNewswire](#)/ -- Wize Pharma, Inc. (OTCQB: WIZP) a clinical-stage biopharmaceutical company focused on the treatment of ophthalmic disorders, today announced top line results from its Phase II clinical trial in Israel of LO2A for the symptomatic treatment of dry eye syndrome (DES) in patients with moderate to severe conjunctivochalasis (CCh).

CCh is present in up to one-third of dry eye patients in the US. CCh refers to the presence of redundant folds of loose conjunctiva. These folds can irritate the eye and disrupt tear film and its outflow, leading to DES. The global DES treatment market was valued at approximately \$3.7 billion in 2017 and is expected to grow to \$4.9 billion by 2022 according to Market Scope.

The Phase II multi-center, randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of LO2A as compared to placebo in patients with CCh. While this Phase II study was conducted in Israel, it was designed according to U.S. standards and supported by a U.S. full-service ophthalmic clinical research organization and product development firm. Patients were randomly assigned in a 1:1 ratio to one of two treatment groups, LO2A or placebo and were treated with topical eye drops for three months. The primary endpoint was a change from baseline in Lissamine green conjunctival staining (LGCS) score, a standard measurement tool for this indication, at three months.



The top line results describe analysis of the primary endpoint, defined as the reduction in Lissamine green conjunctival staining (LGCS) score from baseline to 3 months. The originally planned primary analysis was based upon recruitment of a sample size of 62 patients. Analysis was performed on the 49 fully evaluable patients using a mixed model with repeated measures (MMRM) and utilized all post baseline observations, (1-month and 3-month follow-ups) demonstrating statistical significance between the LO2A group and the placebo group (P=0.0079).

The planned primary endpoint analysis compared average reduction in LGCS score from baseline to three months. This analysis also demonstrated a strong trend towards significance (P=0.0713) with average reduction in LGCS score between baseline and 3 months of -3.5 and -1.6 in the LO2A and placebo groups, respectively.

The Company expects the full statistical report to be published as soon as the statistical results and conclusion are available and approved.

"We are very pleased with these top line results and we look forward to analyzing the full results. We believe the full results from this study, will support our clinical development path and provide firm basis for presentation and discussions with the FDA for the approval pathway of LO2A in the U.S. and additional countries," stated Wize's Chairman, Noam Danenberg.

LO2A is already approved for DES in CCh patients in Hungary.

About Dry Eye Syndrome (DES) and Conjunctivochalasis (CCh)

DES is caused by the reduced production and/or improper quality of tear film. Conjunctivochalasis (CCh) is present in up to one-third of dry eye patients in the US. CCh refers to the presence of redundant folds of loose conjunctiva. These folds can irritate the eye and disrupt tear film and its outflow, leading to DES.

About Wize

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 market, sell and distribute a formula known as LO2A, a drug developed for the treatment of



DES, and other ophthalmological illnesses, including Conjunctivochalasis (CCh) and Sjögren's.

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 and CCH and in the Netherlands for the treatment of DES and Sjögren's. Wize's strategy involves engaging local or multinational distributors to handle the distribution of LO2A.

In addition to the above mention study, Wize is currently conducting a randomized, double-masked, study of LO2A versus Alcon's Systane® Ultra UD. This Study is a multi-center trial in three different medical centers in Israel and will evaluate the safety and efficacy of LO2A for symptomatic improvement of DES in 60 adult patients with Sjögren's.

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 we discuss our market potential, we are using a forward-looking statement. 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, risks related to the substantial debt that we have incurred; our needs for additional financing; our dependence on a single compound, LO2A and on the continuation of our license to commercialize LO2A; our inability to expand our rights under our license of LO2A; the initiation, timing, progress and results of our trials and product candidate development efforts; our ability to advance LO2A into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for LO2A, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of LO2A; our ability to establish and maintain corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering LO2A and our ability to



operate our business without infringing the intellectual property rights of others; estimates of our expenses, future revenues, and capital requirements; competitive companies, technologies and our industry; and statements as to the impact of the political and security situation in Israel on our business. More detailed information about the risks and uncertainties affecting Wize is contained under the heading "Risk Factors" included in 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.