Wize Pharma Enters Exclusive License Agreement for Ophthalmic Non-viral Gene Therapy Technology

- Gene therapy product WP-REP1 comprised of DNA nanoparticles (NPs) to treat the Inherited Retinal Disease (IRD) Choroideremia
- With WP-REP1 and its existing LO2A, Wize plans to compete in the broader ophthalmology market projected to reach $43 billion by 2026
- Gene therapy is at an inflection point, marked by multiple recent billion-dollar acquisitions and a global market projected to reach $5.5 billion by 2026
- Wize will Host a Conference Call with Slide Presentation on Wednesday, September 11, 2019, at 11:00 a.m. EST

HOD HASHARON, Israel, Sept. 9, 2019 /PRNewswire/ -- Wize Pharma, Inc. (OTCQB: WIZP) a clinical-stage biopharmaceutical company focused on the treatment of ophthalmic disorders, today announced it has entered into an Exclusive License Agreement with U.S.-based Copernicus Therapeutics, Inc., pursuant to which, at the closing, it will be granted exclusive rights to license, develop and commercialize products based on a non-viral gene therapy technology developed by Copernicus for the treatment of Choroideremia (CHM).

"We are very pleased and excited to enter into this agreement with Copernicus. Their proprietary and innovative technology addresses what we believe to be the greatest challenges in gene therapy, including overcoming the potential immune system response to treatment, thereby allowing repeated treatments if necessary. As an ophthalmology focused company, Wize is eager to develop and commercialize this cutting-edge gene therapy to transform the treatment of eye related diseases," stated Mark Sieczkarek, Chairman of the Board of Directors of Wize.

Dr. Robert Moen, President and CEO of Copernicus, commented, "Copernicus's gene therapy approach uniquely offers efficacy for ocular therapeutics without toxicity. We believe our disruptive technology is a paradigm shift in the field of gene therapy because it is a non-viral option, as compared to the viral-based systems that have dominated the field to date. We are very excited to advance our ophthalmic indications into the clinic with Wize Pharma."

CHM and the Market Potential

CHM is a rare, degenerative, inherited retinal disorder which leads to blindness and currently has no FDA-approved treatments. It primarily affects males and is caused by loss of function in the CHM gene, which encodes the Rab escort protein-1 (REP-1). The REP-1 protein plays a role in intracellular protein trafficking. Loss of function of the CHM gene leads to abnormal intracellular protein trafficking and impaired elimination of waste products from the retinal pigment epithelium and photoreceptors. Initially, patients with CHM experience poor night vision, and over time progressive visual loss ultimately leads to complete blindness.

WP-REP1, Wize's gene therapy product to be based on the licensed technology from Copernicus, will be comprised of a DNA compacted nanoparticle (NP), administered by intraocular injection, which is designed to provide a functioning CHM gene to photoreceptors and retinal pigment epithelial (RPE) cells. Copernicus has demonstrated proof of concept data in multiple preclinical animal disease studies in IRD models utilizing its NPs to improve vision. As part of the planned regulatory path for WP-REP1, the parties will aim to demonstrate in a planned Phase 1/2 clinical study that the use of NPs targeting the REP-1 protein with CHM DNA NPs demonstrates a satisfactory safety and tolerability profile while also providing indications of clinical benefit.

Per the License Agreement, the companies contemplate to enter into a development agreement, in which Copernicus, led by Robert Moen, MD, PhD, President and CEO of Copernicus, and Mark Cooper, MD, Senior V.P. of Science and Medical Affairs of Copernicus, will prepare the planned clinical trials for the ophthalmic gene therapies licensed to Wize. Dr. Moen has been involved in over three dozen cellular and gene therapy clinical trials as VP of clinical and regulatory affairs at Baxter Healthcare, Genetic Sciences, and Genetic Therapy. Dr. Moen was a co-founder of Genetic Therapy, Inc., the first gene therapy company to enter the clinic, which was purchased by Sandoz (now Novartis) for $300 million. Dr. Moen also served at the National Institutes of Health (NIH), where he assisted in the development of the NIH's gene

therapy program. Dr. Moen is board certified in Pediatrics (Stanford) and Allergy/Immunology (U of Wisconsin) with a dual MD, PhD degree from the University of Washington, and a BA in Biochemistry from Harvard University. Dr. Cooper is Board Certified in Medicine (Johns Hopkins) and Oncology (NIH) and has a MD from Johns Hopkins and BA from Cornell University.

Wize believes that gene therapy has reached an inflection point, marked by several high-profile acquisitions over the past 18 months. For example, Novartis acquired AveXis for $8.7 billion in April 2018; Roche is currently in the process of acquiring Spark Therapeutics for $4.3 billion in a deal announced in February 2019; and, in March 2019, Biogen acquired Nightstar Therapeutics for a total transaction valued at approximately $800 million for two ophthalmic programs, including the treatment of CHM. The global gene therapy market is estimated to reach $5.5 billion by 2026, while the global ophthalmology market is projected to grow to $43 billion by 2026, both according to an April 2019 report issued by Grand View Research, Inc., a market research and consulting company.

Transaction Details

The closing of the transaction contemplated under the Exclusive License Agreement is subject to the satisfaction of certain customary closing conditions, including the completion of due diligence investigation of Copernicus and its technology to Wize's satisfaction.

According to the Exclusive License Agreement, at the closing, Copernicus will grant Wize a worldwide exclusive license to develop, manufacture and otherwise to commercialize the technology and patents of Copernicus for the treatment of CHM, with a right of sublicense (subject to the terms of the agreement). Before the closing, the parties agreed, among other things, to negotiate and enter into a mutually acceptable Development Agreement whereby Copernicus will provide development services to Wize with the aim to complete a Phase 1/2 clinical trial. Wize and Copernicus intend to also discuss (i) a potential future extension of their collaboration into other gene therapy ophthalmic indications based on Copernicus' gene therapy technology and (ii) other potential strategic transactions.

In consideration for the license, Wize agreed to pay Copernicus an initial one-time license fee as well as high single or low double digit royalty payments, depending on net sales thresholds reached. In consideration for the development services, Wize agreed to pay Copernicus amounts over time to fund and execute the workplan leading to the completion of a Phase 1/2 clinical study in subjects with Choroideremia as well as development milestone payments.

ThinkEquity, a division of Fordham Financial Management, Inc., is acting as financial advisor to Wize Pharma on this transaction.

Conference Call Information

Wize will host a conference call and live audio webcast with a slide presentation to discuss the transaction and the market for CHM treatment on Wednesday, September 11, 2019 at 11:00 a.m., Eastern Time.

To access the live webcast, go to the link: https://zoom.us/j/221827872

To participate in the call by phone, dial (669) 900 6833 or (929) 205 6099 or (877) 853 5257 (Toll Free) or (888) 475 4499 (Toll Free) - approximately five minutes prior to the scheduled start time.

Callers should use conference ID: 221 827 872.

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 (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, CCH and Sjögren's 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. Wize has finished

a Phase II trial of LO2A for patients with CCH ups), 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, expected to publish results in Q1/2020.

About Copernicus

Copernicus Therapeutics, Inc. is a U.S.-based privately held gene therapy company with a non-viral, nucleic acid platform technology. Copernicus' non-viral gene therapeutics programs address diseases of the eyes, lungs and brain. Key potential advantages offered by Copernicus' technology as compared to other gene therapies are that it is non-toxic, non-inflammatory, and non-immunogenic, enabling repeat dosing at high levels, long-term expression, efficient and consistent delivery, product stability, and scalable manufacturing. Copernicus completed a successful Phase I/II study of its gene therapy, which was found to be safe and well tolerated in subjects with cystic fibrosis while providing evidence it could correct the underlying cause of the disease. For its ophthalmic gene therapies, Copernicus has achieved proof of concept in multiple preclinical animal disease studies.

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 the potential benefits of the technology licensed from Copernicus or its 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, the possibility that we will not consummate the transaction with Copernicus or that we shall not meet certain financing conditions under our agreement with Copernicus, allowing Copernicus to terminate its agreement with us; the possibility that we will not be able to successfully operate our joint venture with Cannabics Pharmaceuticals, Inc.; 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 (or, if we consummate the transaction with Copernicus, our dependence on LO2A and WP-REP1); 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 (or, if we consummate the transaction with Copernicus, also WP-REP1) 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 (or, if we consummate the transaction with Copernicus, also WP-REP1); 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 (or, if we consummate the transaction with Copernicus, also WP-REP1) 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 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.

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