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# RegeneRx Provides Regulatory Update Regarding RGN-259

**ROCKVILLE, Md. (January 12, 2022) – RegeneRx Biopharmaceuticals, Inc. (OTCQB: RGRX) ("RegeneRx"),** a clinical-stage drug development company focused on tissue protection, repair and regeneration has posted information released by HLB Therapeutics in Korea pursuant to the upcoming pre-BLA meeting with the FDA. HLB recently acquired GtreeBNT and is RegeneRx's U.S. joint venture partner developing RGN-259 for the treatment of ophthalmic injuries and disorders, including dry eye syndrome and neurotrophic keratitis.

The following is a translation by HLB of its press release, with some minor language modifications by RegeneRx:

*HLB announced that its plan for the pre-BLA meeting with FDA is well underway as expected in relation to its new drug for dry eye treatment (RGN-259), which is being developed by its U.S. subsidiary ReGenTree. The company completed its third Phase-3 clinical trial (ARISE-3) last year and will hold a meeting with the FDA on February 28 to discuss the contents and validity of the BLA application before submission to FDA. For this meeting, HLB Therapeutics team is working very hard to prepare a pre-BLA meeting package which will include an overview of clinical data as well as non-clinical, manufacturing, and quality of drug, and then it will be submitted to the FDA 30 days before the meeting.*

*Recently, the Company retained Dr. Stephen C. Pflugfelder, an ophthalmologist and Key Opinion Leader (KOL) in the US, especially in the ocular surface space, to review the clinical summary parts in the pre-BLA package, and he gave positive feedback to the company. According to his comments, 'The design and outcomes from ReGenTree's Phase 3 clinical trials so far were well described. The pooled data from the three Phase 3 trials that enrolled almost 1000 subjects demonstrates that RGN-259 improves dry eye signs and symptoms as well as its safety and tolerability. The FDA has already well-recognized that it would be very difficult to demonstrate dry eye symptom and sign efficacy in a single clinical trial, hence, it is anticipated they may be willing to evaluate the RGN-259 clinical data package on a data totality basis'.*

*Dr. Pflugfelder is currently a professor at Baylor College of Medicine in the United States, one of KOL ophthalmologist who has numerous clinical experiences and more than 300 papers published. He was acting as the president of ARVO until 2021, the world's leading ophthalmology academic organization consisting of more than 10,000 ophthalmologists and industry people around the world.*

**About RegeneRx Biopharmaceuticals, Inc.**

RegeneRx is focused on the development of novel therapeutic peptides, including Thymosin beta 4 (Tβ4) and its constituent fragments, for tissue and organ protection, repair, and regeneration. RegeneRx currently has three drug candidates in clinical development for ophthalmic, cardiac/neuro and dermal indications, four active strategic licensing agreements in the U.S., China, and Pan Asia (Korea, Japan, and Australia, among others), and the EU, and has patents and patent applications covering its products in many countries throughout the world.

**About ReGenTree, LLC**

ReGenTree is a U.S. joint venture company owned by HLB Therapeutics (which recently acquired GtreeBNT) and RegeneRx Biopharmaceuticals, Inc., specifically to develop RGN-259 in both the U.S. and Canada for ophthalmic indications. ReGenTree licensed the rights to RGN-259 from RegeneRx in 2015. Thus far, ReGenTree has sponsored three Phase 3 studies in the U.S. for dry eye, which are ARISE-1 (Phase 2b/3), ARISE-2, and ARISE-3. In addition to dry eye, the Company completed a Phase 3 study (SEER-1) for neurotrophic keratopathy (NK), an orphan indication in ophthalmology. SEER-1's primary endpoint, "the ratio of corneal wound healed patients after four weeks' administration" showed a strong efficacy trend in only 18 patients ($p = 0.0656$ and $p = 0.0400$, Fisher's exact test and Chi square test, respectively) with a similar safety profile as demonstrated in our dry eye trials. For additional information about ReGenTree, please visit www.regentreellc.com.

**Forward Looking Statements**

Any statements in this update that are not historical facts are forward-looking statements made under the provisions of the Private Securities Litigation Reform Act of 1995. Any forward-looking statements involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Forward-looking statements in this update include, but are not limited to, information on phase 3 trial results, pooled data from several phase 3 trials, competitive products, statements from us, or HLB Therapeutics, Ora, Inc. and its biostatistics affiliates and expert physicians, or derived from independent market research reports. These statements may relate to strategic and research partnerships, status of clinical trials, timing and quality of regulatory applications and approvals, the development and value of our drug candidates, and the use of our drug candidates to treat various conditions. Moreover, there is no guarantee any product or licensing application to regulatory agencies in the U.S. or elsewhere will be successful. All forward-looking statements are expectations and estimates based upon information obtained and/or calculated by the Company or its joint venture partner and their affiliates at this time and are subject to change. Please view these and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"), including those identified in the "Risk Factors" section of the annual report on Form 10-K for the year ended December 31, 2020, and subsequent quarterly reports filed on Form 10-Q, as well as other filings it makes with the SEC. Any forward-looking statements in this update represent the Company's views only as of the date herein and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any obligation to update this information, as a result of future events or otherwise, except as required by applicable law.

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