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Dear Stockholder:

This letter is to update you on the status of our phase 3 neurotrophic keratitis (NK) clinical trials in the U.S. and EU (SEER-2 and SEER-3, respectively). The following is an announcement by HLB Therapeutics of completion of the SEER-3 phase 3 clinical trial. The announcement below is “as received” by HLBT this morning with minor typographical and clarification edits:

“HLB Therapeutics announced that ReGenTree, a joint venture company between HLB Therapeutics and RegeneRx Biopharmaceuticals, has completed the administration of RGN-259 and the two-week follow-up period for the last subject of the SEER-3 clinical trial in Europe, which is one of two ongoing phase 3 NK [neurotrophic keratitis] clinical trials with RGN-259.

From now on, it will accelerate the progress of data cleaning at each clinical site and related organizations that are already in progress and will begin statistical analysis work after the database lock within a short period of time. In other words, the company plans to draw a topline [results] as soon as possible by shortening the data cleaning period on scattered clinical trial sites in EU countries, which is the most time-consuming.

ReGenTree's phase 3 (SEER-3) NK clinical study in Europe began in June 2023 at 25 hospitals in Spain, Italy, Poland and Germany, and a total of 78 patients exceeding the target number were recruited in February this year. The recruitment period took about 20 months after the first patient was enrolled in August 2023, a result that was about four months earlier than the company had initially targeted.

In the case of the other phase 3 clinical trial, U.S. Clinical Trial (SEER-2), ReGenTree plans to expand clinical sites to Europe to speed up the SEER-2 study, and this expansion has recently been approved by European authorities, and the company is expecting that the SEER-2 patient enrollment will be significantly accelerated.

Oxervate from Dompe, Italy, is the only drug that has been approved as a NK treatment worldwide, and Oxervate has disadvantages such as eight weeks of administration, complicated administration methods, and many side effects are reported. ReGenTree's NK treatment (RGN-259), in the form of a disposable container, has a short four-week medication period, so if RGN-259 is approved, it is likely to become a game changer in the NK treatment market. In particular, Oxervate's drug price is about \$110,000 in the U.S. market alone, which is a rare drug that generates about \$1.0 billion in sales in 2023, and it is monopolized by Dompe, which has a relatively small global marketing force. And now many global big pharmas are paying a lot. of attention to NK market potential in the US.

On the other hand, through a prominent U.S valuation specialized firm, the value of RGN-

259 treatment for neurotrophic keratitis (NK) has been estimated to range from approximately \$800 million to \$2.2 billion assuming success of the two phase 3 NK trials and potential market dominance expected upon approval of RGN-259.

Ahn Ki-Hong, CEO of HLB Therapeutics, said, 'As the administration and follow-up period of phase 3 clinical trials for NK therapy is completed, we will strategically focus on all of ReGenTree's global clinical capabilities to derive a top line data as soon as possible, prepare detailed analysis, and engage in license-out negotiations with global big pharma which have been waiting for our SEER-3 results in Europe.' "

Regarding any shares that are held by our stockholders that have not been exchanged pursuant to the 2023 reverse split, we recommend that you download the "2023 Reverse Split Letter of Transmittal" by clicking the following link, <https://www.regenerx.com/image/2023+Reverse+Split+Letter+of+Transmittal.pdf>, fill it out and send it to Equiniti Trust Company at the address on the Transmittal Letter. If you have any questions, you may call Equiniti's Shareholder Services at 877.248.6417. Feel free to contact me at jjfkn@regenerx.com. Additionally, while stockholders can sign up on our email list on our website, it is a bit difficult to utilize so some of your questions may not have been answered. If you have any questions, please contact us at the email above and we will do our best to answer expeditiously.

We will continue to update you as appropriate and look forward to the top line statistical results of SEER-3.

Best regards,



J.J. Finkelstein
President & CEO



Allan L. Goldstein, Ph.D.
Chairman and Chief Scientific Advisor