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December 17, 2024

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).

In early December we were contacted by our Korean partner from HLB Therapeutics (HLBT) updating us on the status of the phase 3 NK trials. As stated previously, topline data of our SEER-3, 70- patient trial being conducted in Europe is expected to be available by early next year if everything continues to go as planned. After enrollment, it will take approximately three months to clean and close the patient database and conduct the top-line biostatistical analysis, which will be reported to you as soon as practicable thereafter.

As we reported in our last letter, the U.S. accrual rate is slower due to one available drug for NK on the market that reduces the number of patients eligible to participate in the clinical trial for this orphan disease. ReGenTree has recently submitted a clinical trial application to the European Medicines Agency to expand this U.S.-based trial into three countries in the EU to accelerate patient accrual.

Also, as reported previously, ReGenTree has engaged a pharmaceutical product valuation company to evaluate the commercial value of RGN-259 for the treatment of NK to help guide a potential licensing deal with big pharma when data is received from the NK trial in Europe. According to the draft report as reported by HLBT, the value of RGN-259 as an NK treatment is estimated to range from approximately US$800 million to US$2.2 billion, assuming success of the two phase 3 NK trials and potential market dominance expected upon approval of RGN-259.

The potential U.S. market value considers the only other pharmaceutical product approved for NK, Oxervate, which is sold by the Italian company, Dompé, has a treatment period of eight weeks, needs refrigerated storage by the patient, and has a complicated preparation process before its administration. The treatment cost is also approximately $100,000 for an eight-week treatment course. In contrast, RGN-259 treatment is four weeks, can be stored at room temperature by the patient, and is easy to administer using a traditional single-use squeeze vial. The pricing of RGN-259 has not yet been determined.

According to HLBT, the number of NK patients in the U.S. is estimated to be around 60,000. Oxervate's sales revenue in 2023 is estimated at over $800 million, and the market is growing rapidly, with a compound

annual growth rate of 35% over the past five years. If RGN-259, which is more patient-friendly, is approved in the U.S. and followed by Europe, revenue from RGN-259 for NK treatment is expected to be substantial and expand faster.

An HLB Therapeutics official confirmed that multiple global big pharma companies are conducting due diligence on RGN-259 as an NK treatment, and we expect the negotiation process to accelerate if statistical significance is secured in a primary endpoint in the European phase 3 (SEER-3) study.

If the trials are successful and depending on what ReGenTree decides to do in this case, we would determine an appropriate valuation for our asset and seek to raise capital to either "relist" the Company or sell the Company and declare a special dividend to distribute to our stockholders, among other possibilities.

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/download/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 jjfnk@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.

On a sad note, our acting CFO, Dane Saglio, passed away earlier this month after a long-term illness. Dane was a significant part of our team, as well as a friend, and he will be truly missed. The Company will be enacting a plan to replace his significant contributions to our financial and accounting responsibilities as necessary. We offer his family our sincere condolences for their loss.

We will continue to update you as appropriate and look forward to the results of our first phase 3 trial. We wish everyone a prosperous and peaceful holiday season and New Year.

Best regards,

J.J. Finkelstein
President & CEO

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