



# News Release

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## **RegeneRx and Lee's Pharm to Accelerate RGN-259 Development in China**

### *Lee's Pharm Participates in Recent RegeneRx Financing*

**ROCKVILLE, Md. and Hong Kong (April 2, 2019)** – **RegeneRx Biopharmaceuticals, Inc. (OTCQB: RGRX)** (“the Company” or “RegeneRx”), a clinical-stage drug development company focused on tissue protection, repair and regeneration, and **Lee's Pharmaceutical Holdings Limited (“Lee's Pharm”)**, a Hong Kong-based pharmaceutical company, are accelerating development of RGN-259 in China for ophthalmic indications. Lee's Pharm previously licensed RGN-259, RegeneRx's sterile, preservative-free, topical eye drop developed for the treatment of ophthalmic indications such as dry eye syndrome (DES), neurotrophic keratitis (NK), and other persistent corneal disorders, in China, Taiwan, Macau, and Hong Kong.

Earlier this year Lee's Pharm made a US\$200,000 investment in RegeneRx as part of a convertible debt transaction, along with RegeneRx's management and board of directors. Moreover, Lee's Pharm recently completed a 60,000 square foot (5,500 square meters) production area and a 22,000 square foot (2,000 square meters) warehouse area, state-of-the-art ophthalmic manufacturing facility in China and has created a new subsidiary specializing in the development, manufacturing and marketing of ophthalmic topical drugs.

Dry eye syndrome (DES) is a rapidly-growing problem in China due to the large urban populations, poor air quality, and the over-use of electronic monitors. DES is also associated with diabetes; the diabetes epidemic in China is thought to be the highest population of diabetes in the world. In 2016, China had the world's highest number of total prevalent cases of DES with 194 million followed by the U.S. with 23 million, according to GlobalData (2018).

“We are pleased Lee's Pharm is accelerating its effort to develop RGN-259 and recognize that it could have a significant impact on the treatment of numerous ophthalmic disorders in China. The Chinese market is the world's largest and growing rapidly according to most industry reports. With its new manufacturing facility, Lee's Pharm is now in a position to effectively develop and commercialize RGN-259. We look forward to helping in every way we can with this effort,” stated J.J. Finkelstein, RegeneRx's President and Chief Executive Officer.

“With our recently created subsidiary, China Ophthalmology Focus Limited, and our new ophthalmic manufacturing facilities, we are now well-positioned to accelerate development of RGN-259 in China for dry eye syndrome and other ophthalmic disorders. RGN-259 is an exciting product candidate, with significant clinical data supporting its safety and efficacy and fits well into our current product development strategy in the ophthalmic field,” said Dr. Benjamin Li, Lee's Pharm's Chief Executive Officer.

### **About RegeneRx Biopharmaceuticals, Inc. ([www.regenerx.com](http://www.regenerx.com))**

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

RegeneRx, through its U.S joint venture, ReGenTree LLC, sponsored its second Phase 3 clinical trial (ARISE-2) in approximately 600 patients with dry eye syndrome (DES) and reported positive clinical results with no safety issues. ReGenTree recently initiated ARISE-3, a follow-up Phase 3 trial in 700 patients with DES designed to confirm the positive results from ARISE-2. ReGenTree is also sponsoring a 46-patient Phase 3 clinical trial in patients with neurotrophic keratopathy (NK). Additionally, RGN-259 is being developed in patients with dry eye syndrome in Asia through RegeneRx's two Asian partnerships. RGN-259 has been designated an orphan drug in the U.S. for the treatment of NK.

RGN-352, the Company's T $\beta$ 4-based injectable formulation, is a Phase 2-ready drug candidate designed to be administered systemically to prevent and repair cardiac damage resulting from heart attacks and central nervous system tissue disorders such as peripheral neuropathy, multiple sclerosis and traumatic brain injuries such as stroke. It may also have applications in patients with severe septic shock.

RGN-137, also designated an orphan drug in the U.S., is the Company's T $\beta$ 4-based dermal gel formulation that is being developed for epidermolysis bullosa, a rare skin condition. The Company's licensee, GtreeBNT, has initiated a small, open clinical trial in the U.S. for this indication.

For additional information about RegeneRx please visit [www.regenerx.com](http://www.regenerx.com).

### **About Lee's Pharmaceutical Holdings Limited (<http://www.leespharm.com/en/>)**

Lee's Pharmaceutical Holdings Limited (Lee's Pharm or "the Group") is a public biopharmaceutical company with over 20 years operation in China's pharmaceutical industry. It is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing in China with global perspectives and currently markets 17 products in the PRC. Lee's Pharm focuses on several different areas such as cardiovascular and infectious diseases, ophthalmology, oncology, gynecology, dermatology and others. It has more than 50 products under different development stages stemming from both internal R&D as well as from the recent acquisition of licensing and distribution rights from various US, European and Japanese companies. Additional information is available at <http://www.leespharm.com>.

China Ophthalmology Focus Limited ("COPF"), a subsidiary of Lee's Pharm, is a company specialized in the development, manufacturing and marketing of ophthalmic topical drugs. It has built up a state-of-the-art development and production facility in Nansha, Guangzhou through its 100% subsidiary Zhaoke (Guangzhou) Ophthalmology Co., Limited. The facility supports the in-house development and future commercialization of over 15 proprietary products and difficult to manufacture generics (ranged from pre-clinical to phase III) for the Chinese and international markets. It is currently the only modern facility in China that is recognized as being designed and built for ophthalmic drugs according to all applicable GMP standards, namely China, PIC/S, EMEA, Japan and FDA.

## **Forward-Looking Statements**

Any statements in this press release 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. There can be no assurance that any current or future animal studies or clinical trials, sponsored by the Company or its licensees, will start on time, be completed within a projection time-frame, or result in future value or approved products. There can also be no assurance that the Company or any of its licensees will apply for regulatory approvals in the U.S. or abroad in the future or that if the Company or any of its licensee applies for regulatory approval, that it will be accepted by the FDA or any similar regulatory agency in another country. 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, 2018, 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 press release represent the Company's views only as of the date of this release 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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