



News Release

RegeneRx and Lee's Pharm Announce Acceleration of RGN-259 Development in China

ROCKVILLE, Md. (June 1, 2016) – RegeneRx Biopharmaceuticals, Inc. (“RegeneRx”, OTCQB: RGRX), a clinical-stage drug development company focused on tissue protection, repair and regeneration, and **Lee's Pharmaceutical Holdings Ltd., (“Lee's Pharm”, HKEx Stock Code: 0950)**, a fully integrated biopharmaceutical company headquartered in Hong Kong, today announced acceleration of development of RGN-259 in China. According to Lee's Pharm, the Company's licensee and partner in China, in April the Chinese Food and Drug Administration (CFDA) modified its regulations for conducting clinical trials in China with “locally” developed drug candidates that have been partially developed outside of the country, as is the case with RGN-259.

Previously, the CFDA required Phase 1 and Phase 2 clinical trials to be conducted with a drug candidate entirely made in China (including both the active pharmaceutical ingredient (API) and the finished product). In April, the CFDA changed its regulations to allow Phase 1 or Phase 2 clinical trials with drug candidates manufactured abroad. This rule change is intended to speed up drug development in China since “local” drug development in China may now rely on drugs sourced outside of the country in early clinical trials. Phase 3 and all registration studies must still be conducted with the drug candidate fully manufactured in China.

“This change should allow us to immediately resume our previous development activities in China for RGN-259 to treat ocular disorders prior to building a full manufacturing capability. We hope to begin our clinical trials later this year or early next year in China where we have a rapidly growing incidence of dry eye syndrome and other related ocular disorders,” commented Dr. Benjamin Li, Lee's Pharm's chief executive officer.

“We welcome this regulatory change in China, which could be of significant benefit to Lee's Pharm and RegeneRx, as China may eventually become one of the biggest markets in the world for RGN-259. Since we previously provided Lee's Pharm with thymosin beta 4 (Tβ4, the API in RGN-259) for their clinical trials, they should be in a position to begin the trials more quickly than if they had to re-manufacture, formulate and finish Tβ4 in China,” stated J.J. Finkelstein, RegeneRx's president and chief executive officer.

About RegeneRx Biopharmaceuticals, Inc. (www.regenerx.com)

RegeneRx is focused on the development of a novel therapeutic peptide, Thymosin beta 4, 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 China, Pan Asia (Korea, Japan, and Australia, among others) and in the U.S. RGN-259, the Company's Tβ4-based ophthalmic drug candidate is being developed for dry eye syndrome and for the treatment of neurotrophic keratopathy (NK), both of which are being developed in the U.S through its joint venture, ReGenTree. ReGenTree has recently announced results from its Phase 2b/3 U.S. trial in patients with dry eye syndrome and is conducting a Phase 3 clinical trial for the treatment of patients with NK, for which it has been granted orphan status by the U.S. FDA. RGN-352, the Company's Tβ4-based injectable drug candidate, is a phase 2-ready drug candidate designed to be administered systemically to prevent and restore tissue damage associated with acute events such as heart attacks, strokes, and other similar injuries. RGN-137, the Company's Tβ4-based dermal gel, is in Phase 2 clinical development. The Company currently has licensed RGN-259 and other Tβ4-based product candidates to Lee's Pharmaceuticals, Ltd., in China, Hong Kong, Taiwan and Macau. For additional information about RegeneRx please visit www.regenerx.com.

About Lee's Pharmaceutical Holdings Ltd. (www.leespharm.com)

Lee's Pharm is a research-based biopharmaceutical company listed in Hong Kong with more than 20 years of operation in China's pharmaceutical industry. It is fully integrated with a strong infrastructure in drug development, manufacturing, sales and marketing. It has established extensive partnership with more than 20 international companies and currently has 15 products in the market place. Lee's Pharm focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. The company's development program is lauded with over 40 product candidates stemming from both internal R&D efforts and collaborations with US, European and Japanese companies, including promising compounds to treat liver cancer and pulmonary hypertension. The mission of Lee's Pharm is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life. Additional information is available at <http://www.leespharm.com>.

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 and information presented by the company at investor conferences or via webcasts or to analysts involve risks and uncertainties that could affect any future outcomes expressed or implied by such forward-looking statements. Also, there also can be no assurance that any clinical trial, sponsored by the Company or any third party, will be performed on time and establish safety and efficacy necessary for regulatory approval, or that any drug candidate that is the subject of such trial will prove to be commercially valuable. There can be no assurance that any of the Company's drug candidates will result in any approved products in the U.S., China, or any other 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, 2014, 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.

Safe Harbour Statement

The performance and the results of operation of Lee's Pharm during the past years are historical in nature and past performance can be no guarantee of future results of the Lee's Pharm. This news release may contain forward-looking statements and opinions that involve risks and uncertainties. Actual results may differ materially from expectations discussed in such forward-looking statements and opinions. Neither Lee's Pharm nor the Directors, employees or agents of Lee's Pharm assume (a) any obligation to correct or update the forward-looking statements or opinions contained in this news release; and (b) any liability in the event that any of the forward-looking statements or opinions does not materialize or turns out to be incorrect.

For further information, please contact:

For RegeneRx:

Lori Smith
301.208.9191
las@regenerx.com

Investor Contact:

Stephanie Prince
PCG Advisory Group
646.762.4518
Sprince@pcgadvisory.com

Media Contact:

Sean Leous
PCG Advisory Group
646.863.8998
Sleous@pcgadvisory.com

For Lee's Pharm:

Vivian Fung
852.2314.6500
info@leespharm.com