



FOR IMMEDIATE RELEASE

**RegeneRx and Lee's Pharmaceutical Complete License Agreement for  
Development of RegeneRx Product Candidates in China  
(including Hong Kong and Macau) and Taiwan**

**ROCKVILLE, Md. (July 16, 2012) – RegeneRx Biopharmaceuticals, Inc. (OTC Bulletin Board: RGRX)** ("the Company" or "RegeneRx") today announced that it has entered into a licensing agreement with Lee's Pharmaceutical (HK) Limited, headquartered in Hong Kong ("Lee's"), for the license to Lee's of Thymosin Beta 4-based products, including the Company's RGN-259, RGN-352 and RGN-137 product candidates, in China, including Hong Kong and Macau, and Taiwan. Lee's previously paid RegeneRx \$200,000 upon signing of a term sheet and will pay RegeneRx an additional \$200,000 with the completion of this license agreement.

The terms of the deal include aggregate potential milestone payments of up to \$3.6 million and royalties ranging from low double digit to high single digit royalties on commercial sales. RegeneRx also has the right to exclusively license any improvements made by Lee's to RegeneRx's products outside of the licensed territory. Lee's will pay for all development costs associated with each product candidate. RegeneRx will provide Tβ4 to Lee's at no charge for a Phase 2 ophthalmic clinical trial and will provide Tβ4 to Lee's for all other development and clinical work at a price equal to RegeneRx's cost.

The two firms will create a joint development committee to discuss and agree on the development of the licensed products and share information relating thereto. Both companies will also share all non-clinical and clinical data and other information related to the development of the licensed product candidates.

"We look forward to working closely with Lee's Pharmaceuticals to develop our Tβ4-based product candidates in China, Hong Kong, Macau and Taiwan, as Lee's has demonstrated an impressive track record of pharmaceutical product development and growth, including in the ophthalmology and cardiovascular areas. We believe this opportunity should enable us to accelerate the development of our product candidates in and outside of the licensed territory," stated J.J. Finkelstein, RegeneRx's president and chief executive officer.

"Kerato conjunctivitis sicca, commonly known as dry eye syndrome, affects a great number of people in China and could sometimes lead to severe consequences such as cornea damage and ocular inflammation. There is clearly an unmet medical need in this area. RegeneRx demonstrated in their successful phase II study that their TB4 based product is a promising agent in alleviating dry eye syndrome by addressing the underlying pathology with a unique mechanism of action. We are excited to work with RegeneRx on this opportunity. We look forward to developing the product expediently in China," commented Benjamin Li, chief executive officer of Lee's Pharmaceutical Holdings Limited.



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Sigma-Tau, through its affiliates and subsidiaries beneficially own approximately a 38.6% equity stake in RegeneRx and a 25.90% equity stake in Lee's. Mauro Bove is a member of the board of directors of both companies.

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

RegeneRx is focused on the development of a novel therapeutic peptide, Thymosin beta 4, or Tβ4, for tissue and organ protection, repair and regeneration. RegeneRx currently has three drug candidates in Phase 2 clinical development and has an extensive worldwide patent portfolio covering its products.

RGN-259 is a sterile, preservative-free topical eye drop for ophthalmic indications. Based on two Phase 2 clinical trials in patients with moderate and severe dry eye syndrome, RGN-259 was found to show statistically significant improvements in several signs and symptoms of dry eye, as well as positive trends in other outcome measures. RGN-352 is an injectable formulation to treat cardiovascular and central nervous system diseases, as well as other medical indications, and is Phase 2-ready. RegeneRx is initially targeting RGN-352 for the treatment of patients who have suffered an acute myocardial infarction, or heart attack. RGN-137, a topical gel formulation, is currently being evaluated by RegeneRx in a Phase 2 clinical trial for the treatment of the orphan skin disease epidermolysis bullosa. Other potential uses for RGN-137 include the treatment of chronic dermal wounds and reduction of scar tissue.

### **About Lee's Pharmaceutical**

Lee's Pharmaceutical Holdings Limited ("Lee's") is a research-based Hong Kong biopharmaceutical company with over 18 years operation in China's pharmaceutical industry. It is fully integrated with strong infrastructures in drug development, manufacturing, sales and marketing. It has established extensive partnership with 20 international companies and currently has 13 products in the market place. Lee's focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. Lee's development program is lauded with 30 products stemming from both internal R&D efforts and collaborations with US, European and Japanese companies and aspiring to combat diseases such as liver cancer and pulmonary hypertension. The mission of Lee's is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life. For further information about Lee's Pharmaceutical: Website: [www.leespharm.com](http://www.leespharm.com)



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**Safe Harbor Statement**

*The statements in this news release, other than the historical financial information, may contain forward-looking statements that involve risks and uncertainties that could cause actual results to differ from anticipated results. Further information on risk factor that could affect, among other things, Lee's financial condition and results of operations is detailed in Lee's IPO prospectus, as filed with the Main Board of the Stock Exchange of Hong Kong Limited.*

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