

## **Regen BioPharma, Inc. Successfully Completes in Life Portion of Experiments Requested by FDA for HemaXellerate Pre-Clinical Study**

Company anticipates pre-clinical study to lead to clearance of its Aplastic Anemia Therapy (IND # 15376) for clinical trials

21 Jul, 2015, 08:30 ET from Regen BioPharma, Inc.

SAN DIEGO, California, Jul. 21, 2015 /PRNewswire/ -- Regen BioPharma Inc. (OTCBB: RGBP) and (PINK: RGBP) announced today positive preliminary safety results from the in life portion of an experimental study requested by the US Food and Drug Administration (FDA) assessing toxicity in mice treated with high doses of HemaXellerate, a proprietary therapy under development by Regen Biopharma, Inc. After a 14 day observation period, male and female mice administered with higher than 10-fold the proposed human dose on a per kilogram basis exhibited no adverse effects. Regen expects to receive an audited report on full completion of the experiments in mid-September.

"The fact that no adverse effects related to HemaXellerate administration were observed during the in life portion of this study, even at extremely high doses, in my opinion is a very strong confirmation of the safety of our product," said Thomas Ichim, PhD, Chief Scientific Officer of Regen BioPharma. "We are impressed with the diligence, expedience, and thoroughness that Charles River Laboratories exhibited in conducting this study."

The experiment is being conducted under Good Laboratory Practices (cGLP) by Charles River Laboratories. Charles River Laboratories, established in 1947, is a well respected NYSE-traded contract research organization with 8,500 employees specializing in a variety of pre-clinical and clinical laboratory services for the pharmaceutical, medical device and biotechnology industries.

"HemaXellerate is a stem cell-based cellular therapy. At Regen safety of patients is our first priority. We are thankful to the FDA for discussing and advising us on our safety studies, which will ensure we deliver a high quality product to patients with aplastic anemia, who currently have no other therapeutic options," said David Koos, Chairman and CEO of Regen BioPharma. "Subsequent to receiving the audited toxicology report in mid-September, we plan to respond to the FDA with the results of the toxicology study. Once reviewed by the FDA, we anticipate being in a position to initiate our 10 patient clinical trial."

HemaXellerate is a personalized stem cell therapy that stimulates production of blood cells from the bone marrow of patients. Regen is planning to utilize HemaXellerate to treat patients

with aplastic anemia, a condition associated with reduced ability of the bone marrow to make blood. The Company's CEO also stated, "If successful, the Company may expand into other conditions such as poor blood production associated with chemotherapy which is a potential multibillion dollar per year market."

ABOUT REGEN BIOPHARMA INC.: Regen BioPharma Inc. is a publicly traded biotechnology company (OTCBB: RGBP) (OTC PINK: RGBP). The Company seeks to identify undervalued regenerative medicine applications in the immunotherapy and stem cell space. The Company is focused on rapidly advancing these technologies through pre-clinical and Phase I/ II clinical trials. Currently the Company is centering on gene silencing therapy for treating cancer, telomeres and small molecule therapies, along with developing stem cell treatments for aplastic anemia.

Disclaimer: This news release may contain forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by, or underlying the forward-looking statements. The risks and uncertainties to which forward looking statements are subject include, but are not limited to, the effect of government regulation, competition and other material risks.

#### CONTACT INFORMATION

Regen BioPharma Inc.

David R. Koos, PhD

Chairman & Chief Executive Officer

+1-619-702-1404 Phone

+1-619-330-2328 Fax

<http://www.regenbiopharma.com>

[david.koos@regenbiopharma.com](mailto:david.koos@regenbiopharma.com)

SOURCE Regen BioPharma, Inc.

## RELATED LINKS

<http://www.regenbiopharma.com>