Regen BioPharma Submits Application to FDA for Orphan Drug Designation for its HemaXellerate Product

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SAN DIEGO, January 26, 2016 /PRNewswire/ --

Regen BioPharma, Inc., (OTCBB: RGBP) and (PINK: RGBP) announced today submission to the Food and Drug Administration (FDA) of an application requesting Orphan Drug status for the use of HemaXellerate for the treatment of aplastic anemia.

"Because HemaXellerate is a personalized cell therapy product aimed at addressing an unmet medical need, we are hopeful that the FDA will grant it orphan status," said David Koos, Ph.D., Chairman and CEO of Regen BioPharma.

HemaXellerate is comprised of cells extracted from the patient's own fat tissue and processed using a proprietary method so as to induce a biological response in the patient that heals damaged bone marrow and restores ability of the body to generate healthy blood cells. The FDA recently cleared Regen to perform phase I clinical trials using HemaXellerate in aplastic anemia patients.

Having an Orphan Drug designation for HemaXellerate is important as it will allow for:

Annual grant funding to defray the cost of clinical testing

Tax credits for the costs of clinical research

Assistance in clinical research study design

Seven-year period of exclusive marketing after an orphan drug is approved

Waiver of Prescription Drug User Fee Act (PDUFA) filing fees

"Should HemaXellerate be fortunate enough to be designated an Orphan Drug, we will take advantage of the rich resources the National Institutes of Health provides in assisting development of such drugs to get HemaXellerate to market as quickly as possible," said Harry Lander, Ph.D., MBA, President and Chief Scientific Officer of Regen BioPharma.

About Regen BioPharma, Inc.

Regen BioPharma Inc. is a publicly traded biotechnology company (OTCBB: RGBP) and (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.

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