Regen BioPharma, Inc. Receives FDA Clearance to Initiate Clinical Trial of HemaXellerate

Company to Initiate Phase I Clinical Trial for Immune Modulatory Personalized Cell Therapy in Treatment of Aplastic Anemia

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Regen BioPharma, Inc., (OTCBB: RGBP) and (PINK: RGBP) announced today receipt of a communication from the U.S. Food and Drug Administration, allowing for initiation of clinical trials under its Investigational New Drug (IND) #15376.

The clearance of the IND allows the company to initiate clinical trials of HemaXellerate, a personalized immune-modulatory cell therapy that has demonstrated benefit in animal models of aplastic anemia.

Aplastic anemia, a condition that occurs when the body stops producing enough blood cells, is a potentially fatal disease of the bone marrow that leads to bleeding, infection and fever. Severe and very severe aplastic anemia can have a mortality rate of greater than 70% and are considered a hematologic emergency. Current treatments include blood transfusions, immunosuppression and stem cell transplantation.

The Company's initial Phase I clinical trial will treat patients having refractory aplastic anemia - aplastic anemia patients who haven't responded to first-line immunosuppressive therapy - with HemaXellerate and follow them for safety parameters and signals of efficacy. Therapeutic effects will be quantified based on immunological and hematological measurements. Because the trial will be unblinded, data will be available as the study progresses.

"Current drug-based approaches for healing bone marrow dysfunction involve flooding the body with growth factors, which is extremely expensive and causes unintended consequences because of lack of selectivity," said Harry Lander, Ph.D., President and Chief Scientific Officer of Regen Biopharma. "By utilizing a cell-based approach that both modulates the immune system and stimulates production of blood cells, we aim to offer alternatives to the current approaches

to treating patients with aplastic anemia. This product will complement our immune-modulatory pipeline that includes a potential novel checkpoint inhibitor."

If the clinical trial is successful, the company plans to expand the use of HemaXellerate to other conditions associated with bone marrow dysfunction, with the overall goal of entering the hematopoietic growth factor market. This market is substantial in size and currently includes drugs such as Neupogen®, Neulasta®, Leukine® and Revolade®.

"The FDA clearance marks a substantial step for Regen, in that we are now a clinical-stage company. We are grateful to our collaborators and scientific advisory board members who have worked tirelessly in bringing our product to the point where the FDA has permitted treatment of patients," said David Koos, Ph.D., Chairman and Chief Executive Officer of Regen BioPharma. "We believe the success of today will not only allow for the rapid execution of HemaXellerate's development plan, but will also allow for more rapid translation of the company's other immune modulatory products to the clinic."

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.

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