Regen BioPharma Responds to FDA Comments on Its Application for Orphan Drug Designation on its Aplastic Anemia Therapy

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Regen BioPharma Inc. (OTCQB: RGBP), (OTCQB: RGBPP) has submitted additional data and other responses to the United States Food and Drug Administration (FDA) supporting its application requesting Orphan Drug status for the use of HemaXellerate in aplastic anemia.

While aplastic anemia impacts a small percentage of the population, it is an extremely lethal disease. In fact, patients with aplastic anemia typically die within one year of diagnosis. Immunosuppressive therapy has shown some positive impact on the disease but researchers are very cautious as to its efficacy in treating aplastic anemia. See R. Storb for detailed discussion (http://www.ncbi.nlm.nih.gov/pubmed/9423394)

Currently there is no effective treatment for severe aplastic anemia. Regen BioPharma believes its HemaXellerate treatment offers hope to those suffering from this disease. The fact that it impacts such a small segment of the population allows Regen to file for orphan drug status. If approved, Regen would be able to receive annual grant funding to defray costs associated with clinical testing, tax credits for clinical research, assistance with clinical research design and a seven year exclusive marketing period after orphan drug status is approved. These benefits of orphan drug status make addressing this deadly disease viable for companies like Regen interested in these specific market niches.

Aside from the social benefit in helping those with this disease, these specialized niches can be extremely profitable. There are several biotechnology companies that successfully focus on orphan drug products, such as Shire Pharmaceutical Inc.

Regen's 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.

"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.

"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.

About Regen BioPharma Inc.:

Regen BioPharma Inc. is a publicly traded biotechnology company (OTCQB: RGBP) and (OTCQB: RGBPP). 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 focused on gene silencing therapy and small molecule therapies for treating cancer, along with developing stem cell treatments for aplastic anemia and disorders of the bone marrow. Additional information on Regen BioPharma is available at http://www.regenbiopharmainc.com.

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