

## **Regen BioPharma, Inc. Responds to FDA on dCellVax Gene-Silenced Breast Cancer Immunotherapy**

Company Advances Development of Second Generation Immuno-Oncology Cellular Drug

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Regen BioPharma, Inc. (OTCQB: RGBP), (OTCQB: RGBPP), announced today submission to the Food and Drug Administration (FDA) of a revised Investigational New Drug (IND) application focused on using a novel method to unleash the body's innate ability to kill cancer. The package submitted contained preclinical experiments as well as details of the proposed clinical trial. Results of the studies clearly demonstrated that the approach outlined, using siRNA to silence a key enzyme related to inhibition of the immune system, is effective at stimulating the type of immune response associated with known checkpoint inhibitors.

The enzyme silenced is Indoleamine 2,3-dioxygenase (IDO) , an enzyme that is overexpressed in some cancers and which suppresses immune system response against the cancer. The Company believes it has supplied the additional data and clarifications the FDA requested.

"Because dCellVax is a personalized cell therapy product aimed at activating the immune system of patients with metastatic breast cancer, we are excited to potentially have a product to deliver to patients who at the moment have no other options," said Dr. David Koos, CEO of Regen BioPharma.

"dCellVax is comprised of cells extracted from the patient's own circulating immune cells and processed using a proprietary method so as to activate these immune cells in such a way that they can attack cancer cells. Studies in animal and human immune cells by Regen and other groups have shown that the cells in dCellVax are highly active and secrete the same cytokines that immune cells known to kill cancer cells do. Thus, we are optimistic that this treatment will be useful in patients with cancer."

The proposed dCellVax clinical trial involves generation of patient-specific immune stimulatory cells termed "dendritic cells" that are modified by gene-silencing so as to lose expression of the immune checkpoint gene IDO. Ten patients with advanced breast cancer will be treated in the proposed clinical trial.

"dCellVax is one of the programs we are developing to activate the immune system in order to allow the body to kill cancer. Immune modulation, both inhibitory and stimulatory, is unlocking many novel ways to have the human body heal itself. dCellVax is only one of our immune modulatory products that we expect to bring to market in the future. The data package we sent to the FDA is an important step in this process," 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 (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>.

Disclaimer: This news announcement 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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