

Regen BioPharma Inc. Progresses in FDA Responses to dCellVax Clinical Trial Questions

The Company reports successful inhibition of its target gene, indolamine 2,3 deoxygenase (IDO) has been achieved in pre-clinical studies.

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SAN DIEGO, August 10, 2015 /PRNewswire/ -- Regen BioPharma Inc. (OTCBB: RGBP) and (PINK: RGBP) updated shareholders regarding progress achieved in its ongoing experiments performed to address FDA questions on its Investigational New Drug Application (IND) #16200 for dCellVax. IND #16200 is an application to conduct a Phase I clinical trial of the Company's dCellVax immunotherapeutic product as a treatment for advanced breast cancer patients.

The Company has reported that, in collaboration with Dr. Santosh Kesari, successful inhibition of its target gene, indolamine 2,3 deoxygenase (IDO) has been achieved. Currently experiments are ongoing to demonstrate modulation of T cell responses in vitro, as well as several other molecular and cellular endpoints that were requested by the FDA before permission to initiate the clinical trial will be granted.

Dr. Kesari is Professor of Neurosciences at University of California San Diego School of Medicine, and Director of Neuro-oncology at Moores UCSD Cancer Center.

"The immune suppressive enzyme IDO has attracted much attention as a fundamental immunological checkpoint, whose inhibition may potentially lead to a new class of immunotherapeutic drugs" stated Dr. Kesari. "While the majority of checkpoint inhibitors that are in the clinic or in clinical development are antibody-based, the work with Regen BioPharma involves gene-silencing in dendritic cells, which is a very novel and potentially superior approach."

Checkpoint inhibitors include drugs like Yervoy (ipilimumab) which block molecules that naturally inhibit the immune system, called "immunological checkpoints". There is currently great interest in checkpoint inhibitors, as witnessed by the \$760 million sales of Yervoy in the first year subsequent to receiving FDA approval[1].

"The approach we are taking in dCellVax is that we are specifically silencing the gene that encodes the checkpoint inhibitor in the cells where it is most relevant. By selectively targeting the IDO gene in dendritic cells we hope to cause a much more targeted means of inducing the immune system to kill tumors", said Thomas Ichim, PhD, Chief Scientific Officer of Regen BioPharma.

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.

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[1] <http://www.fiercepharma.com/special-reports/yervoy-top-15-drug-launch-superstars>

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