

Regen BioPharma, Inc. Cancer Stem Cell Gene Target Shown to be a Key Mediator of Cancer Immune Surveillance by Independent Researchers

Company anticipates its small molecule discovery program can be used to promote anti-tumor immunity

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Regen BioPharma Inc. (OTCBB: RGBP) and (PINK: RGBP) reported today that an independent research laboratory has published that the cancer stem cell target gene NR2F6 is a key gene that controls anti-tumor immune surveillance. Regen BioPharma has several pieces of intellectual property related to NR2F6 including issued United States patent # 9,091,696, Modulation of NR2F6 and methods and uses thereof, that covers methods for identifying compounds that can modulate the function of NR2F6 in mammalian cells and several other applications with priority dates of 2008 including patent application # 14571262 that covers use of gene silencing with short interfering nucleic acid (siNA) antisense, short interfering RNA (siRNA), double-stranded RNA (dsRNA), micro-RNA (miRNA), and short hairpin RNA (shRNA) for treatment for cancer.

An independent research group has now published that turning off the NR2F6 gene using genetic means can fight cancer by another important mechanism: by activating anti-tumor immune responses. In the article "The Nuclear Orphan Receptor NR2F6 Is a Central Checkpoint for Cancer Immune Surveillance," published in the prestigious peer-reviewed journal Cell Reports[1], scientist at the Medical University of Innsbruck in Austria reported that animals that had silenced the NR2F6 gene at the genetic level spontaneously rejected implanted tumors and develop host-protective immunological memory against tumor rechallenge. NR2F6 protein functioned to control the amplitude of tumor immunity, while ablation of the NR2F6 gene induced anti-tumor immune surveillance by controlling the cytokines that were expressed in CD4+ and CD8+ T cells.

"The data just published in Cell Reports are extremely exciting," said Dr. Christine Ichim, Director of Molecular Therapeutics of Regen BioPharma Inc. "The work from Austria gives us reason to believe that the therapeutics we are developing to turn off NR2F6 in the body will not only target cancer stem cells, directly instructing them to differentiate, but will also recruit the body's immune system to kill the cancer cells. Not only have we found a cancer stem cell target gene, but this study validates that NR2F6 is also a cancer immunotherapy drug target gene as well. Many existing cancer therapies are immunosuppressant as a side-effect-it is so exciting to

be developing a cancer therapy that mechanistically acts as a double-whammy: on one level directly affecting the ability of cancer cells themselves as to divide, on another level having the side-effect of acting on the non-cancerous immune system cells, stimulating an anti-cancer immune-response."

"Since its inception, Regen BioPharma has held immunotherapy as one of its core competencies," said David Koos, Chairman of Regen BioPharma. "The discovery of NR2F6 as a cancer immunotherapy target gene is not only exciting scientifically but also strategically since immunotherapy is the cutting edge and small molecules that can modulate the immune response are highly sought after. The journal Science has chosen cancer immunotherapy as the 2013 'breakthrough of the year.' In April 2015 Bristol Myers Squibb acquired Flexus Biosciences Inc. (a startup biotechnology company with a preclinical IDO1 immunotherapy that shows promise in treating cancer) for approximately \$1.25 billion and cancer immunotherapy companies like Juno Therapeutics and Kite Pharma have attained multi-billion dollar valuations.

The discovery that one of our existing platforms is also a new cancer immunotherapy target is profound for the Company, since, to our knowledge, we are the first commercial entity to be perusing this drug-target therapeutically. Regen BioPharma has long been committed to standing on the vanguard of discovery. It is extremely reassuring to see that our courage to pursue drug discovery of novel cancer target-genes has been rewarded by independent third-party validation, making us pioneers in drug-discovery of this particular gene target. We hope our innovation and courage to pursue novel cancer target-genes will be well rewarded by granting of first-in-class designation when the time comes to bring future drug candidates to the FDA." FDA designations related to expedited development and approval have been preferentially attached to first-in-class drugs. [2]"

The company has commenced confirmatory screening of small molecule hits that can turn off the function of NR2F6 as a part of the Company's Differentiation Therapy Platform. High throughput screening and curation of data led to the generation of a list of 170 hits that the company is now using to validate using orthogonal assay methods. The company is also working on development of DiffronC, a gene silencing technology targeting NR2F6 for the treatment of cancer and leukemia.

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.ncbi.nlm.nih.gov/pubmed/26387951>

[http://www.cell.com/cell-reports/pdf/S2211-1247\(15\)00920-1.pdf](http://www.cell.com/cell-reports/pdf/S2211-1247(15)00920-1.pdf)

2. <http://onlinelibrary.wiley.com/doi/10.1002/cpt.1/epdf>

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