

Regen BioPharma, Inc. Files Patent Application Covering Innate Immune Activating NR2F6 Silenced CAR-T Cell for Solid Tumors

Company Augments Potency of its Existing NR2F6 Silenced CAR-T Approach By Leveraging Innate Immune Activation Molecules

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Regen BioPharma, Inc. , (OTCBB: RGBP) and (PINK: RGBP) announced the filing of an application for a United States patent covering synergies between NR2F6 gene-silenced CAR T cells combined with proprietary activators of the innate immune system. While previous work demonstrated that methodologies developed by Regen (protected under Regen's issued US patent #9,091,696) are useful in stimulation of T cell activity, the current application further modifies T cells to express molecules that act as a localized "danger signal" to the immune system.

Remarkable clinical results have been obtained by numerous investigators utilizing CAR T cells in the treatment of leukemia and lymphomas[1]. Unfortunately, results for solid tumors have been limited[2]. This is believed to be because solid tumors produce numerous immune suppressive factors that coax the cells that surround the tumor to protect the tumor against the immune response. By utilizing "alarmin" technologies together with NR2F6 silencing, Regen believes to have developed a new method of potentially reprogramming the cells that surround the tumor to allow for immune response destruction of the tumor to occur.

"When we look at other chronic diseases, it is important to note that effective treatment protocols always involve multifactorial attacks on the disease process. This is best illustrated in the case of HIV where only after the introduction of the "cocktail therapy" approach, have significant extensions of lifespan been achieved," said Harry Landers, Ph.D., President and Chief Scientific Officer of Regen BioPharma. "By combining means of concurrently activating the adaptive arm of the immune system, in the form of NR2F6-silenced, while subsequently stimulating the innate immune system, we anticipate to achieve synergistic effects in killing of solid tumors, something which has not been observed previous CAR-T approaches."

Augmentation of CAR-T cells has previously been performed with cytokines such as IL-12[3], however, IL-12 is one signal out of many signals involved in alerting the immune system to "danger". By going "upstream" in the pathway of immune activation, Regen believes it will possess enhanced ability to stimulate innate immunity as compared to previous attempts. The innate immune system is believed to be critical to successful treatment of cancer because of its ability to: a) shift macrophages within the tumor from a "M2" phenotype to an "M1" phenotype, this is associated with stopping the tumor from producing new blood vessels, a process critical to tumor growth[4]; b) Secrete factors that directly kill tumors such as perforin and granulysin; and c) remodel the tumor microenvironment so as to sensitize tumors to killing by the adaptive immune system.

"At Regen BioPharma we are committed to remaining on the cutting edge of immune-oncology, by combining silencing of our checkpoint inhibitor NR2F6, with next generation CAR-T approaches, we believe to possess not only an exciting product for development, but also intellectual property in this crowded and rapidly evolving field," said David Koos, Chairman and Chief Executive Officer of Regen BioPharma.

1. Davenport et al. Oncoimmunology. 2015 Jun 1;4(12):e1053684.
<http://www.ncbi.nlm.nih.gov/pubmed/26587330>

2. Beavis et al. Semin Immunol. 2015 Nov 20. pii: S1044-5323(15)00074-3
<http://www.ncbi.nlm.nih.gov/pubmed/26611350>

3. Koneru et al. J Transl Med. 2015 Mar 28;13:102.
<http://www.ncbi.nlm.nih.gov/pubmed/25890361>

4. Mills et al. Cancer Res. 2016 Jan 15. <http://www.ncbi.nlm.nih.gov/pubmed/26772756>

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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