Regen BioPharma President Harry Lander Provides Mid-year Update on Company's Progress and Developments

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Regen BioPharma, Inc.,(OTCQB: RGBP) and (OTCQB: RGBPP) President Harry Lander provided the following update for its shareholders:

As we pass the midway point of 2016, I would like to review Regen BioPharma's progress during the last 6 months and look forward at our plans for the rest of 2016.

Regen BioPharma, Inc. is focused on developing innovative treatments using autologous cell therapies, immunotherapy and small molecule approaches to treat disorders in large and significant markets.

Scientific Development

Regen has several major programs in different stages of development, with one FDA-cleared Investigational New Drug Application ("IND") and two INDs that have been submitted for clearance. The Company has an extensive patent portfolio, with 23 patents and applications, as well as an experienced and robust scientific team.

THERAPEUTIC PROGRAMS

Program 1 - HemaXellerate: HemaXellerate is the Company's most advanced therapeutic asset, having received IND clearance in December 2015 to target aplastic anemia, a $2.4 billion market opportunity (MedTrack, 2016). In addition, the Company plans to file a separate IND, with clearance expected in Q4 2016, to target Chemotherapy-Induced Myelosuppression, a $12.9 billion market opportunity (MedTrack, 2016).

HemaXellerate is the subject of an FDA-cleared IND and Phase I/II clinical trial that is intended to determine safety and potential efficacy of intravenously administered autologous SVF cells in patients with severe, immune suppressive refractory aplastic anemia. HemaXellerate is also currently being tested in a first-in-human proof of concept study ex-US, with no safety issues seen to date. This data will support further testing under a US IND. Management presently estimates that the investment needed to go through Phase I/II development will be approximately $1.0 million for aplastic anemia and $1.5 million for myelosuppression.

Regen is targeting multi-billion dollar markets for both clinical indications using a novel and potentially disruptive approach, by offering new treatment options that have the potential to be superior to presently accepted standards. Aplastic anemia is a rare and serious condition in which the bone marrow stops producing enough red and white blood cells to keep the body healthy, resulting in an increased risk of infection and uncontrollable bleeding. Due to its rare condition status, we have applied for Orphan Drug Designation. The FDA has responded with some comments and we are addressing those. HemaXellerate has a different mechanism of action versus current therapies as it uses stromal vascular fraction cells to repopulate the bone marrow and may offer benefits over current treatment regimens.

Program 2 - dCellVax: dCellVax is comprised of autologous dendritic cells which have been treated with an siRNA (small interference RNA) inhibitor of indoleamine-2,3-dioxygenase ("IDO"), an immunosuppressive enzyme. By inhibiting this enzyme in dendritic cells, the patient's cells can attack cancers. The Company is planning to resubmit an IND for dCellVax to treat metastatic breast cancer to the FDA in Q3. Management presently estimates that the investment to go through Phase I/II development will be approximately $2.0 million for this clinical indication.

Breast cancer is the most common cancer in women and has the largest market in terms of numbers of patients diagnosed. Globally, breast cancer is the most common type of cancer, representing around 10% of all cancer types[1]. Stage IV of the disease is the least favorable stage for which there is no cure. Stage IV is termed metastatic breast cancer in which a tumor of any size or type has been metastasized to another part of the body. Public health experts estimate there will be a 43% increase in breast cancer-related deaths globally from 2015 to 2030, the majority of which are a result of metastatic disease, resulting in a significant economic burden to society[2]. Despite the availability of numerous drugs for the treatment of breast cancer, the unmet need in the global market is vast[3]. Sales performance of competitive treatments for metastatic breast cancer in 2015, indicate more than a $33 billion global market (MedTrack, 2016).

Program 3 - NR2F6: NR2F6 is an immune checkpoint for which Regen has a strong patent portfolio. NR2F6 is becoming recognized as a key regulator of T cell function[4]. NR2F6 is an orphan nuclear receptor which naturally suppresses the Nuclear Factor of activated T-cells ("NFAT") and cytokines that require NFAT for expression including IL-18, IL-17 and IL-2. Regen is developing three approaches to modulating this protein - tCellVax, ucVax and small molecules - for cancer and autoimmune disorders and believes that they will be in position to accelerate clinical implementation and diversify the product pipeline by using independent approaches towards targeting NR2F6.

1. tCellVax: In the Company's work with tCellVax, immune cells would be removed from the patient, treated with siRNA to inhibit NR2F6 and the cells re-infused into the patient. There is currently an IND application under review by the FDA on this cellular therapy for the treatment of solid tumors. Clinical testing is expected to start in 2017.

2. ucVax: Regen recently initiated a preclinical development program aimed at creating the first cord blood-based cancer immunotherapeutic product leveraging its NR2F6 immunological checkpoint. The target product profile in development will be a "universal donor" cellular immunotherapy, which can be shipped frozen to the site of use and does not involve complex cellular manipulations by the treating institution. To the Company's belief, "universal donor" cellular immunotherapies have not been developed to date and believes ucVax will possess both therapeutic and commercial advantages as compared to other immunotherapies.

3. Small Molecules: The Company is actively identifying small molecules via a high throughput screening program that inhibit or activate NR2F6 leading to immune cell activation for oncology applications. Inhibiting NR2F6 in mice creates highly activated immune systems which reject tumor growth[4]. Development of a small molecule inhibitor of NR2F6 would create a new set of first-in-class immune checkpoint inhibitors.

Management presently estimates that the investment required to its next value inflection is $0.3 million, $0.5 million and $2 million for tCellvax, ucVax and small molecules, respectively. Immunotherapy has become a clinically validated treatment for many cancers. The immunotherapy drugs market is expected to reach $73 billion by 2020[5]-[7]. The growing focus on effective cancer therapies with fewer side effects is a key factor driving the growth of the global immunotherapy drugs market. From a patient perspective, development of a small molecule "checkpoint inhibitor pill" offers numerous potential advantages to currently utilized

checkpoint inhibitors in terms of cost, lack of need for injections and potentially better control of the drug's activities.

Figure 4

Conversely, activating NR2F6 will suppress these same cytokines resulting in suppression of immune activation. This is an ideal approach to treating autoimmune disorders. The Company plans to develop these molecules as oral formulations and address large, significant markets (rheumatoid arthritis, lupus, IBS). To the Company's knowledge, no other group is developing small molecule inhibitors or activators of NR2F6. The Company has identified two activators of NR2F6 and is now turning these into lead compounds.

Autoimmune diseases are defined as the body's own immune system attacks its own tissues which can cause inflammation. It is one of the top ten causes of death in women under the age of 65, is the second highest cause of chronic illness and is the top cause of morbidity in women in the United States[8]. A high prevalence of autoimmune diseases is one of the major drivers of an increase in demand for new drug approaches. According to MedTrack data source, global sales of competitive inflammatory and auto-immune therapies by conditions in 2015 is $40 billion for the top 6 autoimmune disorders. Other sources indicate higher annual costs ($51.8 billion-$70.6 billion)[9]. The global market for autoimmune disease therapeutics is anticipated to have robust growth for the next ten years due to innovative approaches such as small molecule activation of NR2F6.

Figure 5

Regen's management believes its approach of autologous and universal donor cell therapies, as well as the creation of small molecule checkpoint inhibitors and activators differentiates Regen's portfolio. The current "me-too" approach of anti-PD1/PDL1 or anti-CTLA4 antibodies to immunotherapy is approaching asymptotic efficacy. Cracking that barrier will require new targets (e.g., NR2F6) and new approaches (e.g., small molecule and cellular therapies). Management believes Regen's pipeline and IP portfolio will provide major new programs to move to second- and third-generation treatments of cancer and autoimmune disorders.

Summary

The Company's management team is extremely positive about the progress made during the first six months of 2016. The three broad programs outlined above address robust markets that have enormous growth potential. As previously disclosed, the Company is moving forward in efforts to establish strategic alliances for the purpose of drug development. Regen BioPharma Inc. is positioned in what management believes to be some of the most promising areas in biotechnology, anticipating a strong future.

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 aims to rapidly advance these technologies through pre-clinical and Phase I/II clinical trials. Currently the company is focusing on checkpoint inhibitor and gene silencing therapies for treating cancer, along with developing stem cell treatments for aplastic anemia.

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1. Breast Cancer, Epidemiological Report, 2012 Life Science Analytics, Inc.

2. World Health Organization. Projections of mortality and causes of death, 2015 and 2030. http://www.who.int/healthinfo/global_burden_disease/projections/en/. Updated July 2013.

3. Global Status of Metastatic Breast Cancer: Decade Report, March 2016

4. Hermann-Kleiter et al. The Nuclear Orphan Receptor NR2F6 Is a Central Checkpoint for Cancer Immune Surveillance. Cell Reports 12, 2072-2085.

5. Immunotherapy Drugs Market by Type of Drug (Monoclonal Antibodies, Interferon-Alpha, Interleukins, Vaccines, (Therapeutic Vaccines and Preventive Vaccines), Checkpoint Inhibitors), Epidemiology, Regulatory and Pipeline Analysis - Global Forecast to 2020, marketsandmarkets.com, November 2015

6. Cancer Immunotherapy: immune checkpoint inhibitors, cancer vaccines, and adoptive T-cell therapies, Insight Pharma Reports, September 2014.

7. Distribution of global inflammation and autoimmunity therapy market by condition in 2015. Statistica 2016.

8. Walsh SJ, Rau LM. Am J Public Health 2000; 90:1463-6, PMID: 10983209

9. The Cost Burden of Autoimmune Disease: The Latest Front in the War on Healthcare Spending, American Autoimmune Related Diseases Association (AARDA), 2011

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