

## **Selecta Biosciences Announces Successful Pre-clinical Study of SEL-201 As An Antigen-Specific Immune Tolerance Treatment for Patients Receiving Factor VIII Therapy**

December 9, 2013 9:56 AM ET

### ***Presentation of Data at the ASH 2013 Annual Meeting***

Watertown, Mass. —December 9 2013 – Selecta Biosciences, Inc., a clinical stage biotechnology company developing a novel class of targeted antigen-specific immune tolerance treatments, today announced that data from a pre-clinical proof of concept study in Factor VIII-deficient mice were presented in a poster presentation at the 2013 American Society for Hematology (ASH) International Conference in New Orleans. SEL-201 demonstrated the ability to induce immune tolerance in a model of hemophilia A, showing that SEL-201 has the potential to serve as an adjunct therapy to avoid harmful neutralizing antibody response to Factor VIII treatment severely affecting hemophilia A patients.

The presentation was made by Dr. Aihong Zhang, an employee of The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF) and a scientist in the Department of Medicine laboratory of David W. Scott, Ph.D., at the Uniformed Services University of the Health Sciences (USU). Dr. Zhang and Dr. Scott are collaborating with Selecta under a Cooperative Research and Development Agreement among HJF, USU and the company to apply Selecta's proprietary targeted tolerogenic Synthetic Vaccine Particles (t<sup>2</sup>SVP) to Hemophilia.

"Inhibitory antibodies to coagulation factors occur in approximately 25 percent to 30 percent of hemophilia A patients, representing a major medical complication for clinicians and the affected patients," said David W. Scott, Ph.D., Vice Chair for Research and Professor of Medicine at USU. "SEL-201 has the potential to become the first drug to dramatically mitigate the immunogenicity of Factor VIII, which would be a breakthrough in the treatment of patients afflicted with neutralizing antibodies."

Researchers at USU demonstrated that Selecta's SEL-201 nanoparticles added onto standard Factor VIII treatment prevented the formation of neutralizing antibodies and led to durable tolerance without affecting the immune response to other antigens. Specifically, SEL-201 conferred antigen-specific and lasting immune tolerance for at least 166 days after the last treatment, while untreated animals developed high levels of neutralizing antibodies. SEL-201 was found to be effective when administering the treatment concomitantly or after priming with FVIII.

Selecta Biosciences is working to translate the findings to other approved biologic drugs where undesired immune responses, such as neutralizing antibodies, anaphylaxis and injection site reactions, are major complications.

"Anti-drug antibodies are a major issue for many biologic drugs and can affect both drug safety and efficacy. We have identified a significant number of approved and experimental biologics, where antigen-specific inhibition of drug-therapy-related immunogenicity would be highly beneficial and could be enabled by Selecta's proprietary targeted tolerogenic Synthetic Vaccine Particles," said Kei Kishimoto, Ph.D., Chief Science Officer at Selecta Biosciences. "In certain classes of biologics, we see tremendous potential to significantly improve the standard of care provided by these important biologic therapies."

### **About Factor VIII Immunogenicity and SEL-201**

Hemophilia, a rare and predominantly genetic disease, is characterized by the lack of blood-clotting factors. The most common form is hemophilia A, where patients are missing all or part of the coagulation Factor VIII (FVIII). The disease can be effectively treated by regular administration of recombinant replacement factors. Approximately 25 to 30 percent of hemophilia A patients develop neutralizing antibodies that compromise drug efficacy. Anti-drug antibodies are considered a severe complication in hemophilia that can lead to joint bleeding and delay of surgery and result in significantly higher annual treatment costs.

SEL-201 is a targeted tolerogenic Synthetic Vaccine Particle (t<sup>2</sup>SVP) designed to induce T regulatory cells that confer

FVIII-specific tolerance. Administered in conjunction with standard FVIII replacement therapy for a limited period, SEL-201 durably inhibits the antibody response to the coagulation factor without causing general immune suppression. The concept of antigen-specific inhibition of undesired immune responses to biologic treatment has a wide range of applications. Selecta has achieved pre-clinical proof of concept for its  $t^2$ SVP platform to inhibit complications arising from anti-drug antibodies, such as formation of neutralizing antibodies, alteration of drug pharmacokinetics, anaphylaxis and injection-site reactions.

### **About Selecta Biosciences**

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company developing an entirely new class of targeted vaccines that induces an antigen-specific immune activation or antigen-specific immune tolerance for therapeutic and prophylactic applications. Selecta was founded based on complementary research by three academic pioneers, the technology innovations of Professors Robert Langer (M.I.T.) and Omid Farokhzad (Harvard Medical School) combined with the immunological insights of Professor Ulrich von Andrian (Harvard Medical School). Selecta's proprietary Synthetic Vaccine Particle (SVP<sup>TM</sup>) platform creates a new paradigm in vaccine development, enabling completely new therapeutic and prophylactic applications while offering the potential of improved efficacy and safety profiles.

Selecta's fully synthetic engineering of novel vaccines offers a number of compelling benefits, including flexible modular vaccine design and accelerated development timelines using robust manufacturing processes. Selecta's SVP<sup>TM</sup> platform technology is readily adaptable to enable diverse tolerogenic immunotherapies and vaccines based on their proprietary antigen-specific *targeted tolerogenic* Synthetic Vaccine Particles ( $t^2$ SVP<sup>TM</sup>) and antigen-specific *targeted* Synthetic Vaccine Particles ( $t$ SVP<sup>TM</sup>).

*Targeted tolerogenic* Synthetic Vaccine Particles ( $t^2$ SVP<sup>TM</sup>) are designed to induce antigen-specific immune tolerance. Examples for applications include autoimmune diseases, allergies, as well as the inhibition of drug induced immune reactions such as anti-drug antibodies (ADA), anaphylaxis and injection site reactions.

*Targeted* Synthetic Vaccine Particles ( $t$ SVP<sup>TM</sup>) activate immune responses to a wide array of relevant antigens, including small molecules, peptides, oligosaccharides, and proteins. These particles can target humoral or cellular pathways of the immune system. Examples for applications include cancer, infectious diseases and addiction.

Selecta's pipeline currently contains tolerogenic immunotherapies for type-1 diabetes, allergies and drug induced immunogenicity as well as vaccines for smoking cessation, malaria and cancer. Building on the company's novel approach, Selecta's product candidates have the potential to become first-in-class or best-in-class therapeutics to treat and prevent diseases. Selecta Biosciences, Inc. is based in Watertown, Massachusetts, USA. For more information, please visit [www.selectabio.com](http://www.selectabio.com).

### **About Uniformed Services University of the Health Sciences**

The Uniformed Services University of the Health Sciences, founded by an act of Congress in 1972, is the nation's federal health sciences university and the academic heart of the Military Health System. USU students are primarily active duty uniformed officers in the Army, Navy, Air Force and Public Health Service who receive specialized education in tropical and infectious diseases, TBI and PTSD, disaster response and humanitarian assistance, global health, and acute trauma care in addition to their regular medical school curriculum. The University has a robust research program that covers a wide range of areas important to both the military and public health. For more information about USU and its programs, visit [www.usuhs.edu](http://www.usuhs.edu).

### **About The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.**

The Henry M. Jackson Foundation for the Advancement of Military Medicine is a private, not-for-profit organization established in 1983 and authorized by Congress to support medical research and education at the Uniformed Services University of the Health Sciences and throughout the broader military medical community. For more information, visit [www.hjf.org](http://www.hjf.org).

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