Selecta Accelerates Immune Tolerance Therapeutics and Announces New Product Candidate, SEL-212, for Refractory and Tophaceous Gout

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Selecta's immune tolerance pipeline includes programs in gout, hemophilia A and food allergies

Selecta continues to advance key immune activation programs, with newly-announced funding totaling $9.35 million from the Bill & Melinda Gates Foundation and NIH/NIDA

Watertown, Mass. – June 17, 2014 – Selecta Biosciences, Inc.,a clinical stage biotechnology company developing a novel class of targeted antigen-specific immune therapies, today provided an update on the company's product development pipeline, revealing its focus on immune tolerance applications of its proprietary Synthetic Vaccine Particle (SVP) platform. The company announced a new product candidate for its pipeline of tolerogenic immunotherapies: SEL-212 will be the first non-immunogenic treatment for refractory and tophaceous gout. Selecta is now developing products for three applications of antigen-specific tolerance, the inhibition of immunogenicity for biologic therapies, treatment of allergies, and treatment of autoimmune diseases. While the company is focused to accelerate product opportunities in immune tolerance in the near-term, Selecta continues to advance its key SVP immune activation programs, with a grant of $1.25 million from The Bill and Melinda Gates Foundation for malaria vaccines and an award of $8.1 million from the National Institutes of Health (NIH) for Selecta's nicotine vaccine for smoking cessation and relapse prevention.

"Our SVP platform is highly versatile, providing us with the opportunity to develop breakthrough products for immune tolerance and differentiated vaccines to prevent and treat disease," said Werner Cautreels, PhD, President and Chief Executive Officer of Selecta. "We are rapidly advancing our first-in-class tolerogenic products to the clinic. Grants and partnerships enable us to develop more effective vaccines in parallel."

Selecta's latest immune tolerance SVP compound is SEL-212, a novel drug candidate for refractory and tophaceous gout. SEL-212 is designed to be the first non-immunogenic version of uricase, addressing the undesired immunogenicity that has been observed in more than 90% of patients[i] treated with a marketed version of uricase. Treatment-related immunogenicity can lead to a loss of efficacy and severe allergic responses. Through an exclusive license to pegsiticase, Selecta is applying its immunomodulatory SVP platform to dramatically reduce the risk of immunogenicity of other uricase products.

"Severe gout is a highly debilitating disease without good treatment options that affects around 100,000 patients in the US," said Tony Fiorino, MD, PhD, former CEO of EnzymeRx, a company that pioneered the early clinical development of uricase compounds for the treatment of severe gout. "Initial clinical studies with pegsiticase demonstrated its efficacy in clearing plasma uric acid, however immunogenicity could hamper its long term use. SEL-212 has the potential to significantly reduce immunogenicity and unlock the full potential of uricase for the treatment of severe gout."

In addition to the lead immune tolerance drug candidate, SEL-212, Selecta has built a pipeline of immune tolerance drug programs through collaborations as follows:

- **Anti-Drug Antibody (ADA) program for Hemophilia A:** Selecta has collaborated with researchers at the Uniformed Services University (USU) on SEL-201, a candidate for use as an adjunct to Factor VIII therapy in the treatment of hemophilia A. Approximately 25-30%[ii] of severe Hemophilia A patients develop anti-drug antibodies against Factor VIII, which can compromise its efficacy and lead to bleeding complications. Pre-clinical proof of concept for SEL-201 in Factor VIII-deficient mice was presented at the 2013 American Society for Hematology (ASH) International Conference.
- **Food allergen program:** Selecta and Sanofi are engaged in a strategic global collaboration to discover highly targeted, antigen-specific immunotherapies for life-threatening allergies. Under the agreement, Sanofi has obtained an exclusive license to develop an SVP immunotherapy designed to abate acute immune responses against one life

threatening food allergen and an option to develop two additional candidate immunotherapies for allergies each to a specific food or aeroallergen.

- **Type 1 diabetes program:** Selecta has partnered with the Juvenile Diabetes Research Foundation (JDRF) to demonstrate pre-clinical proof of concept for SVP induction of antigen-specific T regulatory cells, which have the potential to inhibit undesired immune reactions in autoimmune diseases. Selecta is planning to translate these results into immunomodulating SVP therapeutics that contain up to four antigens that are responsible for the immune attack on insulin producing beta cells in Type 1 diabetes.

The application of Selecta's SVP platform for immune activating vaccine programs includes several therapeutic programs involving research with government agencies and foundations, as follows:

- **Nicotine vaccine program:** SEL-068, the company's nicotine vaccine candidate for smoking cessation and relapse prevention, successfully completed a Phase 1 clinical trial. This trial included 80 subjects and demonstrated that SEL-068 was safe and well-tolerated. Today's announcement that Selecta has secured an $8.1 million research grant from the National Institute on Drug Abuse (NIDA), an institute at NIH, is based on the data from the Company's Phase 1 clinical trial. The NIDA award will support the advancement of Selecta's nicotine vaccine program for smoking cessation and relapse prevention with the goal of optimizing therapeutic efficacy. Under a previous research contract initiated in 2010, NIDA funded $3 million of research by Selecta on pre-clinical development and Phase 1 clinical testing of its nicotine vaccine.
- **Malaria vaccine program:** Selecta has been awarded a $1.25 million grant from the Bill & Melinda Gates Foundation to support the advancement by Selecta of a novel dual action, immune-activating SVP vaccine for malaria. With this grant, Selecta's malaria program will build on efforts that began in 2011 under a Leidos' (formerly SAIC) Malaria Vaccine Production and Support Services contract with the National Institute of Allergy and Infectious Diseases (NIAID). Selecta's malaria vaccine candidate was selected based upon its demonstrated ability in preclinical studies to outperform benchmarks in terms of antibody levels and protection in a malaria parasite challenge model in mice.
- **Human Papilloma Virus (HPV) Cancer program:** Selecta is collaborating with the Skolkovo Foundation to establish a development program of a therapeutic vaccine for head and neck cancers caused by HPV. The vaccine candidate is designed to elicit strong and durable cytolytic T cell responses targeted to kill tumor cells expressing the E6 and E7 protein of HPV.

About Selecta

Selecta Biosciences, Inc. is a clinical-stage biotechnology company developing novel drugs that use immune modulating nanomedicines to generate targeted antigen-specific immune responses to prevent and treat disease. Selecta's proprietary Synthetic Vaccine Particle (SVP™) platform creates a novel paradigm in immunotherapeutics and vaccines, enabling completely new applications while offering the potential of improved efficacy and safety profiles.

Selecta's immunomodulatory SVPs can induce antigen-specific immune tolerance, enabling them to be applied in a variety of therapeutic areas with large unmet medical need. The company is focused on three key near-term applications: inhibition of immunogenicity for biologic therapies, treatment of allergies, and treatment of autoimmune diseases. Immunogenicity adversely affects the safety and efficacy profile for many biological therapies, and has caused the termination of a number of promising biological therapies in clinical development. Selecta's SVP is a product engine that has the potential to unlock the full therapeutic value of biological therapies.

Through proprietary products and collaborations with leading pharmaceutical companies and research organizations, Selecta is building a pipeline of product candidates to address unmet medical needs in serious and chronic diseases. Selecta Biosciences, Inc. is based in Watertown, Massachusetts, USA. For more information, please visit www.selectabio.com.

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For media:
Kathryn Morris
The Yates Network
+1-845-635-9828
kathryn@theyatesnetwork.com

For investors:
Stephanie Ascher
Stern Investor Relations
+1-212-362-1200
stephanie@sternir.com

[i] The KRYSTEXXA® product label states that, in a clinical trial, anti-pegloticase antibodies developed in 92% of patients treated with KRYSTEXXA every 2 weeks, see (http://krystexxa.com/pdfs/KRYSTEXXA_Prescribing_Information.pdf section 6.2 on p.8)

[ii] van den Berg HM. Epidemiological aspects of inhibitor development redefine the clinical importance of inhibitors. **Haemophilia**. 2014 May; 20 Suppl 4:76-9. and
Gouw SC et al.; PedNet and RODIN Study Group. Factor VIII products and inhibitor development in severe hemophilia A. **N Engl J Med.** 2013 Jan 17;368(3):231-9. doi: 10.1056/NEJMoa1208024.