

## **Selecta Biosciences Enters Into Exclusive License Agreement with 3SBio to Develop Drug Candidate to Treat Gout**

June 17, 2014 9:52 AM ET

*3SBio's pegsiticase has shown a promising efficacy and safety profile in early clinical trials and Selecta and 3SBio plan to advance clinical studies of pegsiticase-based treatments for refractory and tophaceous gout as well as tumor lysis syndrome*

*Selecta will combine pegsiticase with its novel immunomodulatory Synthetic Vaccine Particle (SVP™) platform to develop SEL-212, a treatment with improved efficacy and safety*

*3SBio will continue to develop Uricase PEG-20 in Greater China and Japan*

**Watertown, Mass. –June 17, 2014** – Selecta Biosciences Inc., a clinical stage biotechnology company developing a novel class of targeted antigen-specific immune tolerance treatments, today announced it has entered into an exclusive license with [3SBio](#) for pegsiticase (Uricase PEG-20), a pegylated recombinant uricase from *candida utilis*. Pegsiticase has shown the ability to efficiently reduce plasma uric acid levels in gout patients in successful U.S. Phase 1 clinical tests. The exclusive license enables Selecta to develop pegsiticase in patients with refractory and tophaceous gout and apply its immunomodulatory Synthetic Vaccine Particle (SVP) platform to optimize the safety and efficacy profile for patients at risk of immunogenicity. SEL-212 is a novel product that combines Selecta's proprietary SVP with 3SBio's pegsiticase and is designed to be the first non-immunogenic version of uricase.

"Pegsiticase has already shown significant efficacy signals in gout patients and we have the opportunity to develop a novel therapeutic approach with the goal of preventing the inhibitory antibodies and other complications of immunogenicity that have been a significant barrier to the widespread use of uricase-based drugs. With the combination of SVP and pegsiticase, we believe we can dramatically improve treatment for patients with refractory and tophaceous gout," said Werner Cautreels, PhD, President and Chief Executive Officer of Selecta. "Working with 3SBio, we have the potential to fulfill a key medical need expressed by physicians – the first non-immunogenic uricase. 3SBio's strength of enzyme manufacturing combined with Selecta's proprietary antigen-specific tolerance platform will ensure fast progress towards human proof of concept. If successful, Selecta's SVP platform may unlock the full therapeutic potential of many other biologic therapies adversely affected by immunogenicity."

Selecta will work with 3SBio to advance pegsiticase-based therapeutics as potential treatments for refractory and tophaceous gout as well as tumor lysis syndrome, with the ultimate goal of expeditiously moving toward regulatory approvals. Selecta and 3SBio have agreed to work together to achieve clinical proof of concept for SEL-212 and pegsiticase in human clinical trials in their territories; Selecta's territory includes US and all of Europe. Proof-of-concept clinical studies are expected to be initiated in 2015. Additional terms of the exclusive license granted by 3SBio to Selecta are not being disclosed.

"Patients with refractory and tophaceous gout have currently very limited treatment options. Indeed, these patients generally cannot be successfully treated by conventional oral gout drugs," said Dr. Jing Lou, MD, PhD, and CEO of 3SBio. "We are impressed with SVP's potential to greatly expand the safe and effective use of biological therapeutics. Our proven capabilities in manufacturing and development of biological therapeutics combined with Selecta's strong development capabilities and unique SVP platform, promise to be an effective partnership for expanding the use of pegsiticase. Together, we are committed to meeting the significant unmet needs of refractory and tophaceous gout patients."

### **About Refractory, Tophaceous Gout and Tumor Lysis Syndrome**

A painful inflammatory disease caused by elevated plasma uric acid levels, gout affects 2-3 million patients in the United States and more than 10 million patients worldwide. Chronic refractory gout represents approximately 2% of patients,

who cannot be effectively treated with available oral therapies. Tophaceous gout is a debilitating condition resulting from painful deposits of uric acid crystals in joints, tendons and surrounding tissue that affects 7-10% of gout patients. Tumor Lysis Syndrome (TLS) appears in approximately 20,000 cancer patients in the United States who have elevated uric acid levels as a result of chemotherapy. For all three indications, oral therapies are not indicated because the mechanism of these oral therapies interferes with the synthesis of uric acid but is ineffective in the breakdown of existing uric acid deposits. Approved uricase enzymes are highly effective for a short course of treatment, but can rapidly lose efficacy due to the formation of anti-drug antibodies. Their clinical use is further restricted due to high risks of allergic reactions.

### **About SEL-212 and Pegsiticase**

Pegsiticase is a pegylated urate oxidase or uricase, an enzyme not present in humans that is highly effective in catalyzing the oxidation of uric acid. Phase 1 studies completed in the United States with a single dose of pegsiticase confirmed safety and efficacy in reducing plasma uric acid levels in refractory gout patients.

SEL-212 applies Selecta's Synthetic Vaccine Particle (SVP) products for immune tolerance to pegsiticase. The product is designed to durably and specifically prevent undesired immune responses that can appear after multiple dosages of uricase.

Currently two versions of uricases are approved for use in the United States. Both products induce anti-drug antibodies in more than 50% of patients that can reduce efficacy and cause severe allergic reactions.

### **About Selecta Biosciences**

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](http://www.selectabio.com).

### **About 3SBio Inc.**

3SBio is a fully integrated, profitable biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products primarily in China. Since its founding in 1993, 3SBio's R&D efforts have resulted in four NDAs for biological medicines, including TPIAO, the first rhTPO approved worldwide. Pipeline candidates include Uricase PEG-20, a modified pegylated recombinant uricase from *Candida utilis* for the treatment of refractory gout and tumor lysis syndrome which has completed US Phase 1 trials; NuPIAO, a long-lasting rhEPO for anemia associated with renal failure or chemotherapy and peri-operative blood cell mobilization which has received SFDA approval to initiate clinical trials; and SSS07, an anti-TNF monoclonal antibody for treating rheumatoid arthritis, psoriasis, and potentially other inflammatory diseases. A new state-of-the-art mammalian biological manufacturing facility in Shenyang is the first and only rhEPO facility in China that conforms to both Chinese and European pharmacopeia standards. Planning is underway to develop monoclonal antibody manufacturing capabilities. 3SBio is China's leading specialist in nephrology and oncology supportive care with 580 sales professionals covering over 3,000 hospitals in key cities supported by a

nationwide network of 120 distributors and logistics providers. EPIAO has been the top selling rhEPO product in China since 2002 with a market share over 40%. Please see [www.3sbio.com](http://www.3sbio.com) for additional information.

# # #

**For media:**

Kathryn Morris

The Yates Network

+1-845-635-9828

[kathryn@theyatesnetwork.com](mailto:kathryn@theyatesnetwork.com)

**For investors:**

Stephanie Ascher

Stern Investor Relations

+1-212-362-1200

[stephanie@sternir.com](mailto:stephanie@sternir.com)