Soligenix Investor Relations

Soligenix Announces Strategic Partnership with SERB Pharmaceuticals to Supply its Novel Ricin Antigen

SERB Pharmaceuticals pursuing therapeutic treatment against ricin poisoning using Soligenix ricin antigen

PRINCETON, N.J., July 25, 2022 /PRNewswire/ -- Soligenix, Inc. (Nasdaq: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need, announced today that it has signed a worldwide exclusive license to supply its ricin antigen to SERB Pharmaceuticals (SERB), for development of a novel therapeutic treatment against ricin toxin poisoning. There is an unmet need for protection against this highly potent toxin for which there is no vaccine or therapeutic intervention available.

"We are pleased to be partnering with Soligenix on the use of their antigen to accelerate our ricin therapeutic program. With no current therapeutic options, the threat of ricin represents a significant unmet need in the field of biodefense and medical countermeasures," said Anthony Higham, CEO of SERB Pharmaceuticals. "Our expertise in antibody development and the commercial scale manufacturing capabilities acquired with BTG together with SERB's track record of reliably providing a portfolio of high-quality Chemical, Biological, Radiological, and Nuclear (CBRN) antidotes, uniquely positions us to successfully deliver a solution."

"Beyond our own development of a heat stable ricin vaccine (RiVax®) to protect against lethal ricin poisoning, which has been supported with more than $30 million dollars to date by the U.S. government, we felt it important to also partner with SERB in the development of its ricin therapeutic drug candidate," stated Christopher J. Schaber, PhD, President and CEO of Soligenix. "SERB is a leader in the field of medical countermeasures to protect the public and military forces. By supplying our novel ricin antigen as an important component of their formulation, we are hopeful that it will assist in accelerating development of this early-stage program."

In pursuit of a ricin antidote, SERB will leverage its unique broad-spectrum polyclonal antibody platform, gained in its acquisition of BTG Specialty Pharmaceuticals. This specialized manufacturing process generates binding fragments from antibodies that are specific to a given antigen, helping to ensure potency and purity. This platform is currently used to manufacture two of the company's currently marketed products, CroFab® and DigiFab®.

The antibodies will be generated using a modified form of the ricin toxin, developed by Soligenix. The modifications have removed the biological activity of the protein so that it is not toxic, while still retaining its shape to trigger an effective antibody response.

The specific licensing terms have not been disclosed at this time, but consist of a manufacturing supply agreement and small royalty percentage upon commercialization.

The Ricin Threat

Ricin is a source of concern because it is a relatively easy to obtain, easy to weaponize and highly potent toxin. Ricin can be extracted from the seeds of the castor oil plant, *Ricinus communis*. Ricin is one of the most toxic biological agents known—a Category B bioterrorism agent and a Schedule number 1 chemical warfare agent.

Ricin has been a threat since governments began experimenting with it during World War I. Most famously used in the assassination of Bulgarian writer Georgi Markov in 1978, ricin has been developed and deployed with alarming frequency. Several ricin attacks have been prevented in Europe and the United States in recent years, ranging from a militant group in Germany prevented from launching a ricin attack by police in 2017 to the 2020 delivery of letters laced with ricin to the White House.

About SERB Pharmaceuticals

SERB is a growing pharmaceutical company and a dedicated ally to healthcare providers treating patients with critical conditions, focusing on emergency care and rare diseases. For over 30 years we have made treating these complex and life-threatening conditions possible, supporting clinicians, healthcare systems and governments while offering hope to patients and their families. As a fully integrated company, we have the experience and capabilities to acquire, develop, and manufacture our medicines to the highest standards, and make them available worldwide through our secure supply chain. SERB acquired BTG Specialty Pharmaceuticals in March of 2021.

About Soligenix, Inc.

Soligenix is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. Our Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (SGX301 or synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With a successful Phase 3 study completed, regulatory approval is being sought and commercialization activities for this product candidate are being advanced initially in the U.S. Development programs in this business segment also include our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation including pediatric Crohn's disease (SGX203).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases (NIAID), the Defense Threat Reduction Agency (DTRA) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website at https://www.soligenix.com and follow us on LinkedIn and Twitter at @Soligenix_Inc.

This press release may contain forward-looking statements that reflect Soligenix, Inc.'s current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations and clinical trial enrollment. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "hopes," "intends," "plans," "expects," "goal," "may," "suggest," "will," "potential," or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual events or results in future periods to differ materially from what is expressed in, or implied by, these statements, such as experienced with the COVID-19 outbreak. Soligenix cannot assure you that it will be able to successfully develop, achieve regulatory approval for or commercialize products based on its technologies, particularly in light of the significant uncertainty inherent in developing therapeutics and vaccines against bioterror threats, conducting preclinical and clinical trials of therapeutics and vaccines, obtaining regulatory approvals and manufacturing therapeutics and vaccines, that product development and commercialization efforts will not be reduced or discontinued due to difficulties or delays in clinical trials or due to lack of progress or positive results from research and development efforts, that it will be able to successfully obtain any further funding to support product development and commercialization efforts, including grants and awards, maintain its existing grants which are subject to performance requirements, enter into any biodefense procurement contracts with the U.S. Government or other countries, that it will be able to compete with larger and better financed competitors in the biotechnology industry, that changes in health care practice, third party reimbursement limitations and Federal and/or state health care reform initiatives will not negatively affect its business, or that the U.S. Congress may not pass any legislation that would provide additional funding for the Project BioShield program. In addition, there can be no assurance as to the timing or success of any of its clinical/preclinical trials. Despite the statistically significant result achieved in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that a marketing authorization from the FDA or EMA will be successful. Further, there can be no assurance that RiVax® will qualify for a biodefense Priority Review Voucher (PRV) or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. Also, no assurance can be provided that the Company will receive or continue to receive non-dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission, including, but not limited to, Soligenix's reports on Forms 10-Q and 10-K. Unless required by law, Soligenix assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

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Supply-its-Novel-Ricin-Antigen