

Soligenix Announces Exclusive Licensing Agreement for Novel Vaccine Adjuvant from BTG Specialty Pharmaceuticals

Potential use in improving effectiveness of coronavirus and pandemic flu vaccines

PRINCETON, N.J., April 16, 2020 /PRNewswire/ -- Soligenix, Inc. (Nasdaq: SNGX) ("Soligenix"), 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 executed an agreement for the exclusive worldwide license of CoVaccine HT™, a novel vaccine adjuvant, from BTG Specialty Pharmaceuticals ("BTG"), a division of Boston Scientific Corporation (NYSE: BSX), for the fields of SARS-CoV-2, the cause of COVID-19 and pandemic flu.

CoVaccine HT is a novel adjuvant, which has been shown to enhance both cell-mediated and antibody-mediated immunity. Soligenix and its collaborators, including the University of Hawai'i at Mānoa and Dr. Axel Lehrer, have successfully demonstrated the utility of CoVaccine HT in the development of its heat stable filovirus vaccine program, with vaccine candidates against Ebola and Marburg virus disease. Given this previous success, CoVaccine HT will potentially be an important component of Soligenix's vaccine technology platform currently being assessed for use against coronaviruses including SARS-CoV-2, the cause of COVID-19.

"BTG has a long track record of technological innovation in the production of antibodies for rescue medicines. We're pleased that, in the hands of Soligenix, CoVaccine HT could potentially play a role in helping to address the current pandemic," said Anthony Higham, President of BTG.

"We are very excited to include CoVaccine HT into our heat stable vaccine platform technology. It has the potential to provide a distinct advantage over other vaccines currently in development," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With the rapid advancement of the vaccine platform, we feel the program is optimally poised to look at other viruses, including coronaviruses."

The agreement was executed between Soligenix and Protherics Medicines Development, one of the companies that make up the BTG Specialty Pharmaceutical business, which owns the CoVaccine HT intellectual property. Terms of the deal are not being disclosed.

About CoVaccine HT™ Adjuvant

An adjuvant is a substance which enhances the immune response and so helps maximize the production of antibodies. The CoVaccine HT adjuvant is a sucrose fatty acid sulphate ester that increases both humoral and cell-mediated immune responses to experimental vaccines following intramuscular administration.

About Coronavirus Infection

Coronavirus infections can cause a wide spectrum of disease in humans, ranging from a common cold to a more severe respiratory infection such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), which have a case mortality rate of approximately 10% and 30%, respectively. Similar to filoviruses, coronaviruses are also endemic in wildlife populations and can be transmitted to humans with close contact. The COVID-19 outbreak, caused by SARS-CoV-2, is the most recent example of species crossover seen with this virus family. Although the case fatality rate of COVID-19 is still under investigation, the global impact of this emerging infection demonstrates the need for a robust technology platform to rapidly develop new vaccines for novel diseases. There is currently no approved treatment for any coronavirus infection, nor any approved vaccine.

About BTG Specialty Pharmaceuticals

BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation, provides rescue medicines typically used in emergency rooms and intensive care units to treat patients for whom there are limited treatment options. BTG is dedicated to the development, manufacture, and commercialization of quality medicines that make a real difference to patients and their families. BTG's current portfolio of antidotes counteracts certain snake venoms and the toxicity associated with some heart and cancer medications. To learn more, please visit: btgsp.com.

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 SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of 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) and acute radiation enteritis (SGX201).

Our Public Health Solutions business segment includes active development programs for RiVax[®], our ricin toxin vaccine candidate, SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and our research programs to identify and develop novel vaccine candidates targeting viral infection including Ebola, Marburg and SARS-CoV-2 (the cause of COVID-19). 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 Agents (DTRA) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website at www.soligenix.com.

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. 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 US 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 US 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 the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy, or any of our other clinical/preclinical trials. Despite the statistically significant result achieved in the 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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