

Soligenix Receives Japanese Patent for ThermoVax® Vaccine Heat Stabilization Platform Technology

Patent describes application of ThermoVax® with RiVax®

PRINCETON, NJ – May 9, 2017 – 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 been granted a Japanese patent (number 6110845) further extending protection around ThermoVax® including coverage of the Company's ricin toxin vaccine candidate, RiVax®. ThermoVax® is a proprietary vaccine heat stabilization platform technology and the patent, entitled "Thermostable vaccine compositions and methods of preparing same," is also being pursued in other major markets worldwide, such as China, Europe, and the US.

The issued patent is complementary to previous patents, including US patents 8,444,991 granted on May 21, 2013 and 8,808,710 granted on August 19, 2014, that include claims for methods of making stabilized vaccines and their attendant compositions. In this new patent, the main claims cover formulations of Soligenix's proprietary thermostabilized ricin toxin vaccine, RiVax®. The thermostable formulation of RiVax® has been shown to be stable for at least 12 months at temperatures up to 40 degrees Celsius (104 degrees Fahrenheit) and to provide 100% protection to non-human primates exposed to aerosol ricin challenge.

Recent developments in the RiVax® program have also described immune correlates of protection for the ricin toxin vaccine, which are important to facilitating potential approval of thermostabilized RiVax® via the US Food and Drug Administration (FDA) "Animal Rule". As a biodefense vaccine, RiVax® also has the potential to qualify for a priority review voucher (PRV) upon FDA approval. Recent PRVs have sold for as much \$350 million.

"ThermoVax® has successfully demonstrated that it can thermostabilize a number of different alum-adsorbed protein antigens, including antigens for ricin, anthrax, human papillomavirus and Ebola," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The RiVax® program continues to progress towards potential approval under the Animal Rule, and as our most advanced product candidate using the ThermoVax® technology, it also provides positive proof-of-concept for use of this proprietary heat stabilization platform with other development and commercial vaccines. While we advance RiVax® with the support of NIAID contract funding, we also look forward to potentially applying the ThermoVax® technology to other vaccine candidates in the future."

About ThermoVax®

The ThermoVax® technology is designed to eliminate the cold chain production, distribution and storage logistics required for most vaccines. The technology utilizes precise lyophilization of protein immunogens with conventional aluminum adjuvants in combination with secondary adjuvants for rapid onset of protective immunity with the fewest number of vaccinations. Cold chain requirements add considerable cost to the production and storage of current conventional vaccines. Elimination of the cold chain would also enhance the utility of these vaccines for emerging markets and for other applications requiring but lacking reliable cold chain capabilities. For vaccines that are intended for long-term stockpiling, such as for use in biodefense or in pandemic situations, the utilization of ThermoVax® has the potential to facilitate easier storage and distribution of Strategic National Stockpile vaccines in emergency situations. The underlying ThermoVax® technology has been developed by Drs. John Carpenter and Theodore Randolph at the University of Colorado.

By employing ThermoVax® during the final formulation of RiVax®, the vaccine has demonstrated enhanced stability and the ability to withstand temperatures at least as high as 40 degrees Celsius (104 degrees Fahrenheit) for up to one year. Similar stabilization at temperatures as high as 50 degrees Celsius for up to 3 months (maximum timepoint tested) have also been demonstrated with other antigens (e.g., human papillomavirus, Ebola and anthrax).

About RiVax®

RiVax® is Soligenix's proprietary heat stable recombinant subunit vaccine developed to protect against exposure to ricin toxin. With RiVax®, Soligenix is a world leader in the area of ricin toxin vaccine research.

RiVax® contains a genetically altered version of a Ricin Toxin A (RTA) chain containing two mutations that inactivate the toxicity of the ricin molecule. A Phase 1A clinical trial was conducted with a formulation of RiVax® that did not contain an adjuvant. This trial revealed dose dependent seroconversion as well as lack of toxicity of the molecule when administered intramuscularly to human volunteers. The adjuvant-free formulation of RiVax® induced toxin neutralizing antibodies that lasted up to 127 days after the third vaccination in several individuals.

To increase the longevity and magnitude of toxin neutralizing antibodies, RiVax® was subsequently formulated with an adjuvant of aluminum salts (known colloquially as Alum) for a Phase 1B clinical trial. Alum is an adjuvant that is used in many human vaccines, including most vaccines used in infants. The results of the Phase 1B study indicated that Alum-adsorbed RiVax® was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax®. In preclinical animal studies, the Alum formulation of RiVax® also induced higher titers and longer-lasting antibodies

than the adjuvant-free vaccine. Vaccination with the thermostabilized Alum-adjuvanted RiVax® formulation in a large animal model provided 100% protection ($p < 0.0001$) against acute exposure to aerosolized ricin, the most lethal route of exposure for ricin. The protected animals also had no signs of gross lung damage, a serious and enduring ramification with long-term consequences for survivors of ricin exposure. These results are described in a publication available [here](#).

The development of RiVax® has been sponsored through a series of grants from both NIAID, part of the National Institutes of Health, and the FDA, which were granted to Soligenix and to the University of Texas Southwestern (UTSW) where the vaccine protein originated. To date, Soligenix, Dr. Ellen Vitetta and her colleagues at UTSW have collectively received approximately \$25 million in funding from NIAID for development of RiVax® and related vaccine technologies. Currently, Soligenix is developing RiVax® under NIAID contract #HHSN272201400039C, worth up to \$26 million, assuming all options are exercised. RiVax® has received orphan drug designation from the FDA.

RiVax® potentially would be added to the Strategic National Stockpile and dispensed in the event of a terrorist attack. As a new chemical entity, an FDA approved RiVax® vaccine also has the potential to qualify for a biodefense PRV, which allows the holder accelerated review of a drug application. Approved under the 21st Century Health Cures Act in late 2016, the biodefense PRV is awarded upon approval as a medical countermeasure when the active ingredient(s) have not been otherwise approved for use in any context. PRVs are transferable and can be sold, with sales in recent years varying from between \$125 million to \$350 million.

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 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 Vaccines/BioDefense business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome therapeutic candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. 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) 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 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 timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the PRV program or the amount for which a PRV for RiVax® can be sold. 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.

technology