Soligenix Investor Relations

Soligenix Initiates Clinical Trial of its Heat Stable Ricin Toxin Vaccine

Improved thermostabilized vaccine formulation advances into humans

PRINCETON, N.J., Dec. 12, 2019 /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 opened the study titled "A Phase 1C, Double-Blind, Placebo-Controlled, Randomized Study to Evaluate the Safety of RiVax®, a Lyophilized Ricin Toxin A-Chain Subunit Vaccine with Alum-Adjuvant, in Healthy, Normal Adults." Preliminary safety results from the trial are expected in the second quarter of 2020 with longer-term safety and immunogenicity results from throughout the 6-month follow-up period expected in the fourth quarter of 2020.

RiVax® is the Company's vaccine candidate for the prevention of death following exposure to a lethal dose of ricin toxin using a unique antigen that is completely devoid of the toxic activity of ricin. The RiVax® antigen has demonstrated safety in two previous Phase 1 clinical studies. When formulated using Soligenix's proprietary heat stabilization technology (ThermoVax®), RiVax® has demonstrated significantly enhanced thermostability and up to 100% protection in non-human primates (NHPs) in preclinical aerosol challenge models. RiVax® is being developed under the US Food and Drug Administration (FDA) "Animal Rule" and previous studies have identified potential immune correlates of protection between NHPs and humans that will be measured in this study.

The Phase 1C, double-blind, placebo-controlled, randomized study in healthy adult volunteers is designed to evaluate the safety and immunogenicity of a standard 3-dose vaccine regimen of RiVax® utilizing ThermoVax®, administered monthly, followed by a 6-month follow-up period. In addition to evaluating the overall safety and tolerability of the vaccine, immunogenicity endpoints will be measured during and after vaccination throughout the follow-up period. The study is expected to enroll 8 subjects (2 placebo, 6 RiVax®).

"We are pleased to initiate this study and advance our world-leading vaccine candidate to protect against ricin toxin poisoning," stated Richard C. Straube, MD, Senior Vice President and Chief Medical Officer of Soligenix. "Ricin toxin is easily made in large quantities and is lethal in extremely small quantities. RiVax® is an orphan designated product in both the US and Europe. We are pleased that RiVax® may be able to provide significant protection against this deadly bioweapon."

Previous studies with less refined formulations have demonstrated safety and immunogenicity of the vaccine antigen, but suffered from suboptimal stability. The thermostabilized RiVax® formulation is stable for up to 12 months at temperatures as high as 40 degrees Celsius (104 degrees Fahrenheit). This thermostabilization is achieved with specific changes in formulation conditions, including the use of Generally Regarded as Safe (GRAS) stabilizing excipients and lyophilization (freeze-drying). Both the Phase 1A study conducted with liquid formulated antigen alone and the Phase 1B study conducted with antigen and an alum-adjuvant have already demonstrated the safety and immunogenicity of these critical components of the RiVax® formulation.

The development of RiVax® has been funded through a series of grants from both the National Institute of Allergy and Infectious Diseases (NIAID) and the FDA and ongoing development is sponsored by NIAID contract #HHSN272201400039C. Non-dilutive funding for the development of RiVax® has exceeded $40M to date.

About Ricin Toxin

Ricin toxin is a lethal plant-derived toxin and potential biological weapon because of its stability and high potency, and the fact that it is readily extracted from by-products of castor oil production. Ricin comes in many forms including powder, mist or pellet. Ricin can also be dissolved in water and other liquids. The US Centers for Disease Control and Prevention estimates that the lethal dose in humans is about the size of a grain of salt. Ricin toxin illness causes tissue necrosis and general organ failure leading to death within several days of exposure. Ricin is especially toxic when inhaled. Ricin works by entering cells of the body and preventing the cells from making the proteins they need. Without the proteins, cells die, which is eventually harmful to the entire body.

There are currently no effective treatments for ricin poisoning. The successful development of an effective vaccine against ricin toxin may act as a deterrent against the actual use of ricin as a biological weapon and could be used to vaccinate military personnel and civilian emergency responders at high risk of potential exposure in the event of a biological attack.

About RiVax®

RiVax® is Soligenix's proprietary heat stable recombinant subunit vaccine developed to protect against exposure to ricin toxin, the threat of which has been highlighted recently in the news with an envelope addressed to President Trump that was thought to contain this potent and potentially lethal 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-adjuvanted RiVax® was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax®. In 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.

Heat stabilization of RiVax® is achieved with the Company's proprietary ThermoVax® technology, 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. 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. These results are described in a publication available here.

The development of RiVax® has been funded through a series of grants from both NIAID and the FDA and ongoing development is sponsored by NIAID contract #HHSN272201400039C. RiVax® potentially would be added to the Strategic National Stockpile and dispensed in the event of a terrorist attack. RiVax® has received orphan drug designation in the U.S. and in Europe.

As a new chemical entity, an FDA approved RiVax® vaccine has the potential to qualify for a biodefense Priority Review Voucher (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 in excess of $100 million. When redeemed, PRVs entitle the user to an accelerated review period of six months, saving a median of seven months' review time as calculated in 2009. However, the FDA must be advised 90 days in advance of the use of the PRV and the use of a PRV is associated with an additional user fee ($2.7 million in 2017).

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, 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), 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 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 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 the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. 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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