Soligenix Investor Relations

Soligenix Announces Publication Demonstrating Thermostabilization of an Ebola Subunit Vaccine Candidate

Princeton, NJ – February 7, 2019 – 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 publication of a scientific article demonstrating the successful thermostabilization of an Ebola subunit vaccine candidate. The article titled, "Thermostable Ebola virus vaccine formulations lyophilized in the presence of aluminum hydroxide", is published in the European Journal of Pharmaceutics and Biopharmaceutics online and is available here.

As previously announced, Soligenix has been collaborating with the University of Hawai'i at Mānoa (UH Mānoa) and Hawaii Biotechnology, Inc. (HBI) on the development of a multivalent subunit vaccine for Ebola and Marburg infections. Axel Lehrer, PhD, Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), UH Mānoa, a co-inventor of the Ebola vaccine with HBI, has shown proof of concept efficacy with subunit Ebola vaccines in non-human primates. Soligenix evaluated its proprietary vaccine thermostabilization technology, ThermoVax®, to stabilize components of the vaccine with Dr. Carly Chisholm and Dr. Theodore Randolph of the University of Colorado. These studies identified a formulation that maintained the physical state of the Ebola subunit protein despite incubation at 40 degrees Celsius (104 degrees Fahrenheit) for 12 weeks. Ultimately, the objective is to produce a thermostable Ebola vaccine for worldwide distribution that does not require cold storage. In preclinical studies, ThermoVax® has been previously demonstrated to enhance thermostability of ricin (RiVax®) and anthrax subunit vaccines. Further work optimizing a trivalent Ebola vaccine is ongoing under a National Institute of Allergy and Infectious Diseases (NIAID) grant awarded to the UH Mānoa in collaboration with Soligenix and HBI.

The most advanced Ebola vaccines involve the use of vesicular stomatitis virus (VSV) and adenovirus vectors – live, viral vectors which complicate the manufacturing, stability and storage requirements. Dr. Lehrer's vaccine is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI have developed a robust manufacturing process for the required proteins. Application of ThermoVax®may allow for a product that can avoid the need for cold-chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world.

"None of the other Ebola vaccines under development have the ability to withstand high temperatures, which is an ongoing concern in areas of the world where Filoviruses are endemic," stated Dr. Lehrer, Assistant Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology at JABSOM, UH Mānoa. "The ability to stabilize our vaccine candidate to retain immunogenicity may not only have an impact on logistics, but also has the potential to reach more persons in need with fewer vaccine doses. This would be a tremendous advantage, especially in endemic areas, increasing the number of people receiving sufficient doses of the vaccine to protect them from disease. We are very encouraged by these preliminary results and look forward to our continuing collaboration with Soligenix and HBI to further develop our Ebola and multivalent filovirus vaccines."

"We continue to demonstrate the potential of the ThermoVax® heat stabilization platform," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "These results join other successful endeavors with ricin and anthrax vaccines. We look forward to expanding the use of this proprietary technology, while continuing to develop ThermoVax® using RiVax®, our novel subunit ricin vaccine, under an active NIAID contract award."

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., Ebola and

anthrax).

About JABSOM, UH Mānoa

The John A. Burns School of Medicine (JABSOM) at the University of Hawai‘i Mānoa honors its unique research environment to excel in science-based efforts to eliminate diseases that disproportionately affect people in Hawai‘i and the Pacific region. Annually at JABSOM, more than 500 future physicians are learning medicine, JABSOM researchers secure up to $60 million in grants, and overall economic stimulus to Hawai‘i from the school tops $456 million annually. JABSOM also confers degrees in Clinical Translational Research, Communication Sciences and Disorders, Tropical Medicine, Cell and Molecular Biology, Medical Technology and Developmental and Reproductive Biology.

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 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 ThermoVax® or 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.
