

## **Soligenix Receives Additional NIAID Funding to Advance Development of Heat Stable Ricin Vaccine**

### **Awarded \$4.3M to Support Manufacturing Activities**

**Princeton, NJ – May 5, 2016** – Soligenix, Inc. (OTCQB: 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 the National Institute of Allergy and Infectious Diseases (NIAID) has exercised an option for RiVax™ bulk drug substance and finished drug product process scale-up and technology transfer that will support preclinical studies and manufacturing in accordance with current good manufacturing practices (cGMPs). The overall objectives of the contract are to advance the development of Soligenix's thermostabilization technology, ThermoVax®, combined with the company's ricin toxin vaccine, RiVax™, as a medical countermeasure to prevent the effects of ricin exposure.

The exercised option for contract #HHSN272201400039C will provide Soligenix with an additional \$4.3M in funding (total awarded to date under this contract: \$13.5M). If all contract options are exercised, the total award of up to \$24.7 million will support the preclinical, manufacturing and clinical development activities necessary to advance heat stable RiVax™ with the FDA.

"The exercise of this option validates Soligenix's success on contractual work completed to date and reflects NIAID's ongoing commitment to advance development of viable thermostabilization technologies that can be applied to important vaccine preparations," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "It also highlights the government's commitment to identification and development of countermeasures to protect both the public and, more likely, first responders, in the event of ricin exposure. We thank NIAID for its past and present support and look forward to advancing RiVax™ development toward potential FDA licensure and government procurement."

### **About Ricin Toxin**

Ricin toxin is a plant toxin and potential biological weapon because of its stability, high potency, and availability as a by-product of castor oil production. Ricin comes in many forms like powder, mist, or pellet. Ricin can also be dissolved in water and other liquids. The US Centers for Disease Control and Prevention (CDC) estimates 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 getting inside the cells of the body and preventing the cells from making the proteins it needs. Without the proteins, cells die, which is eventually harmful to the whole 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 in rapid deployment scenarios in the event of a biological attack.

### **About RiVax™**

RiVax™ is Soligenix's proprietary 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 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 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 preclinical animal studies, the Alum formulation of RiVax™ also induced higher titers and longer lasting antibodies than the adjuvant-free vaccine. Vaccination with the 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.

The development of RiVax™ has been sponsored through a series of grants from both NIAID and the FDA, which were granted to Soligenix and to the University of Texas Southwestern (UTSW) where the vaccine originated. To

date, Soligenix and Dr. Ellen Vitetta and colleagues at UTSW have collectively received approximately \$25 million in grant funding from NIAID for development of RiVax™ and related vaccine technologies. RiVax™ would potentially be added to the Strategic National Stockpile and dispensed in the event of a terrorist attack.

### **About ThermoVax®**

ThermoVax® is a technology that is designed to eliminate the standard cold chain production, distribution and storage logistics required for most vaccines. Cold chain requirements add considerable cost to the production and storage of current conventional vaccines. According to the Biopharma Cold Chain Sourcebook of 2010, 98% of all vaccines (with a total value of \$20.6 billion) require shipment through cold chain. 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. Further, the World Health Organization (WHO) reports that 50% of all global vaccine doses are wasted because they are not kept within required temperature ranges. NIAID has also highlighted the priority of technologies for biodefense vaccines that focus on broad spectrum approaches including vaccine adjuvants and temperature stabilization for long shelf life, rapid onset of immunity, and surge capacity for production. 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 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. RiVax™ is extremely labile in liquid form requiring careful management under refrigerated conditions at 4 degrees Celsius (39 degrees Fahrenheit). By employing ThermoVax® during their final formulation, it is possible to produce stable and potent vaccines that are capable of withstanding temperatures at least as high as 40 degrees Celsius (104 degrees Fahrenheit) for up to one year.

The underlying technology has been developed by Drs. John Carpenter and Theodore Randolph at the University of Colorado. The vaccine technology has been developed to date in collaboration with SRI International, the University of Kansas, the Wadsworth Center of the New York State Department of Health, and the Tulane National Primate Research Center under the sponsorship of the cooperative grant from NIAID.

### **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 first-in-class photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, 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), and our novel innate defense regulator technology (SGX942) for the treatment of oral mucositis.

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 melioidosis therapeutic candidate. The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. Currently, this business segment is supported with up to \$57 million in 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](http://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," "intends," "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, including SGX942, particularly in light of the significant uncertainty inherent in developing vaccines against bioterror threats conducting preclinical and clinical trials of vaccines, obtaining regulatory approvals and manufacturing 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. Positive results from the Phase 2 study evaluating SGX942 does not ensure that the follow-on Phase 2/3 clinical study will be successful. 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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