

## **Soligenix Receives Orphan Drug Designation from the European Commission for RiVax® for Prevention of Ricin Poisoning**

**Princeton, NJ – March 22, 2018** – 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 the European Commission, acting on the positive recommendation from the European Medicines Agency (EMA) Committee for Orphan Medicinal Products, has granted orphan drug designation to the Company's recombinant modified ricin toxin A-chain subunit (the active pharmaceutical ingredient in RiVax®) for the prevention of ricin poisoning. RiVax® has previously been granted orphan drug designation from the US Food and Drug Administration (FDA).

The European Commission grants orphan designations for medicines that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union (EU) and where no satisfactory treatment is available. In addition to a 10-year period of marketing exclusivity in the EU after product approval, orphan drug designation provides incentives for companies seeking protocol assistance from the EMA during the product development phase, and direct access to the centralized authorization procedure which allows access to all 28 EU member states' markets.

"We are extremely pleased to have received European orphan drug designation for the RiVax® program," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix, Inc. "This EU orphan designation, combined with our US orphan designation, positions this biodefense program for a potentially accelerated global regulatory product development pathway to address this unmet need. RiVax® has shown up to 100% protection against aerosolized ricin exposure in non-human primates and safety in humans and we look forward to further developing our thermostable formulation for human use."

### **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 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 it needs. 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. 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-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 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](#).

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.

The development of RiVax® has been sponsored through a series of grants from both National Institute of Allergy and Infectious Diseases (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 from the FDA and EMA, conferring 7 and 10 years marketing exclusivity, respectively.

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 ranging between \$125 million to \$350 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 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 three months (maximum timepoint tested) have also been demonstrated with other antigens (e.g., human papillomavirus, Ebola and anthrax).

#### **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](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," "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 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. Further, there can be no assurance that RiVax® will qualify for a biodefense PRV or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. 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.

---

<https://ir.soligenix.com/2018-03-22-soligenix-receives-orphan-drug-designation-from-the-european-commission-for-rivax-R-for-prevention-of-ricin-poisoning>