

## **Soligenix Announces Presentation and Poster at the 2017 Chemical and Biological Defense Science and Technology Conference in Long Beach, CA**

**Princeton, NJ – November 27, 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 Dr. Oreola Donini, Chief Scientific Officer, will be presenting preclinical data from two of its biodefense development programs at the upcoming Chemical and Biological Defense Science and Technology Conference on November 28-30, 2017 to be held at the Long Beach Convention Center, Long Beach, CA.

### **Oral Presentation:**

***Innate Defense Regulators – Supercharging Antibiotic Treatment for Resistant or Unknown Infectious Disease*** presented by Dr. Oreola Donini, Chief Scientific Officer, Soligenix, Inc., on November 28, 2017 from 2:30-3:00 PM Pacific Standard Time (PST), Room 104A. The abstract is available [here](#).

### **Poster Presentations:**

***Using Monoclonal Antibodies as Immune Correlates of Protection: Thermostable Ricin Toxin Vaccine Development*** attended by Dr. Oreola Donini, Chief Scientific Officer, Soligenix, Inc., on November 28, 2017 from 6:00-8:00 PM PST, Exhibit Hall B. The abstract is available [here](#).

The presented results will address recent preclinical efficacy findings in two programs funded by the National Institute of Allergy and Infectious Diseases (NIAID), including:

- SGX943 (dusquetide) in the treatment of antibiotic resistant infections including melioidosis, and
- RiVax®, a proprietary thermostable ricin toxin vaccine, in an inhalational model of ricin intoxication.

Dusquetide is an Innate Defense Regulator (IDR), which enhances the anti-infective activity of the innate immune system while down-modulating inflammation. Since IDRs do not directly target the bacteria, it is unlikely to engender resistance and is complementary with current antibiotic regimens. Soligenix has recently reported the results of a Phase 2 clinical study using dusquetide in the treatment of oral mucositis in head and neck cancer patients undergoing chemoradiation therapy. In addition to demonstrating a reduction in the duration of oral mucositis in these patients, dusquetide treatment was also associated with a reduced incidence of reported infections.

RiVax® is the Company's candidate vaccine for the prevention of death following exposure to ricin toxin using a unique antigen that is completely devoid of the toxic activity of ricin. When formulated using Soligenix's proprietary ThermoVax® technology, RiVax® has demonstrated significantly enhanced thermostability and 100% protection in preclinical aerosol challenge models. Moreover, potential correlates of immune protection have been identified, which is a requirement of the "Animal Rule" to pursue approval of RiVax®.

Preclinical studies for SGX943 (grant #1R43 AI108175-01A1) and RiVax® (contract #HHSN272201400039C) were supported by awards from NIAID.

### **About Chemical and Biological Defense Science and Technology (CBD S&T) Conference**

The CBD S&T Research Conference is a forum for discussion between individuals conducting research to defend against bioterrorism and with the Defense Threat Reduction Agency (DTRA). The conference

focuses on the latest developments in the medical and physical science disciplines of chemical and biological defense. The conference offers business, learning and networking opportunities in the biodefense arena with over 1500 planned attendees.

For more information about the 2017 CBD S&T conference, please refer to the conference website at <https://www.cbdstconference.com/>.

## **About Dusquetide**

Dusquetide (the active ingredient in both SGX942 and SGX943) is an IDR, a new class of short, synthetic peptides. It has a novel mechanism of action whereby it modulates the body's reaction to both injury and infection towards an anti-inflammatory and an anti-infective response. IDRs have no direct antibiotic activity but, by modulating the host's innate immune system responses, increase survival after infections caused by a broad range of bacterial Gram-negative and Gram-positive pathogens. It also accelerates resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- and/or radiation therapy. Preclinical efficacy and safety has been demonstrated in numerous animal disease models including mucositis, colitis, melioidosis, macrophage activation syndrome (MAS) and other bacterial infections. Some of these preclinical findings have been published in an article entitled "A novel approach for emerging and antibiotic resistant infections: Innate defense regulators as an agnostic therapy," available at the following link: <http://dx.doi.org/10.1016/j.jbiotec.2016.03.032>.

Dusquetide has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers and positive results in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation therapy (CRT) for head and neck cancer (HNC). The study results are reviewed in "Dusquetide: A Novel Innate Defense Regulator Demonstrating a Significant and Consistent Reduction in the Duration of Oral Mucositis in Preclinical Data and a Randomized, Placebo-Controlled Phase 2 Clinical Study," published online in the *Journal of Biotechnology* and available at the following link: <http://dx.doi.org/10.1016/j.jbiotec.2016.10.010>.

Long-term (12 month) follow-up data from the Phase 2 study further indicated the safety and tolerability of dusquetide treatment. The long-term follow-up results are reviewed in, "Dusquetide: Reduction in Oral Mucositis associated with Enduring Ancillary Benefits in Tumor Resolution and Decreased Mortality in Head and Neck Cancer Patients", published online in *Biotechnology Reports* and available at the following link: <https://doi.org/10.1016/j.btre.2017.05.002>.

Drug products containing dusquetide have also received Fast Track Designations from the FDA for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in HNC patients, and as an adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis. Orphan Drug Designations for use of dusquetide in the treatment of MAS as well as for the treatment of acute radiation syndrome have also been granted. In addition, dusquetide has been granted Promising Innovative Medicine designation in the United Kingdom by the Medicines and Healthcare Products Regulatory Agency for the treatment of severe oral mucositis in HNC patients receiving CRT.

Soligenix has a strong intellectual property position in the IDR technology platform, including composition of matter for dusquetide and related analogs. Dusquetide was developed pursuant to discoveries made by Professors B. Brett Finlay, PhD and Robert Hancock, PhD of the University of British Columbia, Canada.

## **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 in rapid deployment scenarios 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 (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 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 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.

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 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 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 Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. 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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<http://ir.soligenix.com/2017-11-27-soligenix-announces-presentation-and-poster-at-the-2017-chemical-and-biological-defense-science-and-technology-conference-in-long-beach-ca>