

Soligenix - Driving Towards Key Inflection Points with Two Pivotal Phase 3 Clinical Trials

Company provides 2017 highlights and 2018 development program guidance

Princeton, NJ - January 25, 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, today issued an update letter from its President and Chief Executive Officer, Dr. Christopher J. Schaber. The content of this letter is provided below.

Dear Friends and Shareholders,

Now that we have concluded 2017, I wanted to take this opportunity to provide a summary of our progress and highlight our accomplishments made during the year, as well as to provide some further guidance on our development programs as we begin 2018.

Our focus this coming year remains, first and foremost, the quality execution of our two pivotal Phase 3 clinical trials, including SGX942 (dusquetide) for the treatment of oral mucositis in head and neck cancer and SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma (CTCL). In addition, we are continuing to advance development of our heat stable ricin toxin vaccine (RiVax®) with the financial support of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), while we also continue to actively pursue non-dilutive funding to support our rare disease pipeline.

Corporate Highlights

Non-Dilutive Funding

Throughout the year, we were awarded in excess of \$8.6 million in non-dilutive funding from various government sources across our entire biodefense and biotherapeutics pipeline in order to advance multiple development programs, which support we greatly appreciate. As part of this funding, we received approval for a tax credit from the New Jersey Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program and received approximately \$417,000 in net proceeds from the transfer of this credit.

During the third quarter, we received two Small Business Innovative Research (SBIR) grant awards totaling approximately \$3 million over two years by the NIH National Cancer Institute (NCI) and the National Institute of Dental and Craniofacial Research (NIDCR) for two of our biotherapeutics development programs. The award from the NCI is to support the conduct of our ongoing pivotal Phase 3 trial of SGX301 as a treatment for CTCL, and the award from the NIDCR is to support the conduct of our ongoing pivotal Phase 3 trial of SGX942 as a treatment for severe oral mucositis in patients with head and neck cancer receiving chemoradiation therapy (CRT).

During the year, we also received over \$5 million of non-dilutive funding in our biodefense business segment. NIAID exercised a \$2.5 million option to fund good manufacturing practice compliant RiVax® bulk drug substance and finished drug product manufacturing and a \$2 million option to fund additional RiVax® animal efficacy studies. The overall objective of the contract, totaling up to \$24.7 million over six years, is to advance the development of our thermostabilization technology, ThermoVax®, in combination with RiVax®, our ricin toxin vaccine, as a countermeasure to prevent the effects of ricin exposure. Additionally, we were awarded funding of approximately \$700,000 over five years, as collaborators in a NIAID Research Project grant awarded to the University of Hawai'i at Manoa for the development of a trivalent thermostabilized Ebola vaccine.

Equity Financing

In addition to the non-dilutive funding received, we completed a registered direct offering of 1,575,500 shares of common stock and a concurrent private placement of 982,000 shares of common stock at an above the market purchase price of \$2.00 per share. Our gross proceeds from these offerings were \$5,115,000 before deducting offering expenses. The lead investors in the financing included Knoll Capital Management, LP and ACT Capital Management, LLLP, two fundamental life science investors, and two of our largest existing shareholders.

We begin 2018 with approximately \$8 million in cash, not including our non-dilutive NIH funding.

Biotherapeutics Business Segment

During the year, we made good progress in advancing our clinical development programs. We continue to actively enroll patients in our pivotal Phase 3 study in CTCL with SGX301 (synthetic hypericin) and are

encouraged by this development program as a potential front line treatment where there is currently an unmet medical need. This trial, referred to as the “FLASH” study (Fluorescent Light Activated Synthetic Hypericin), aims to evaluate the response to SGX301 as a skin directed therapy to treat early stage CTCL. SGX301 has received Orphan Drug designation as well as Fast Track designation from the United States (US) Food and Drug Administration (FDA). Additionally, SGX301 was granted Orphan Drug designation from the European Medicines Agency (EMA) and Promising Innovative Medicine (PIM) designation from the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK).

Approximately thirty CTCL centers across the US are participating in this pivotal trial. Although the trial begins with a double-blind, placebo-controlled portion (referred to as Cycle 1), all participants in the trial eventually receive active study drug (referred to as Cycle 2) and an optional portion of the trial is available to them to continue with SGX301 treatment (referred to as Cycle 3). We remain encouraged by the response to this trial and by the majority of patients that have elected to continue into the optional open-label portion of the study. We continue to work closely with the Cutaneous Lymphoma Foundation, as well as the National Organization for Rare Disorders. As CTCL is a chronic disease that patients can potentially live with for many years, if closely managed, study enrollment can ebb and flow with the summer vacation and winter holiday seasons, as some patients tend to not start new treatments that may interfere with important family events; therefore, we continue to take a conservative approach to estimating study completion and availability of top-line data. As a result, we have adjusted our trial guidance, with the prospectively defined, blinded interim analysis taking place in the second half of 2018 and top-line final study results potentially moving into the first half of 2019. Rest assured, we take development timelines very seriously. To this end, quality enrollment and completion of this pivotal Phase 3 CTCL study continues to be our top priority.

During the third quarter, we initiated a pivotal double-blind, placebo-controlled Phase 3 clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer receiving CRT. This trial, referred to as the “DOM-INNATE” study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity), aims to evaluate the response of SGX942 in reducing the duration of severe oral mucositis, in addition to other clinically meaningful measures, and incorporates feedback from the FDA as well as the EMA via the Scientific Advice process. The Scientific Advice from the EMA indicated that a single, double-blind, placebo-controlled Phase 3 study, if successful, in conjunction with the positive results from the Phase 2 dose-ranging study, generally will be sufficient to support a marketing authorization application for potential licensure in Europe. SGX942 is the first Innate Defense Regulator in development for oral mucositis and has previously demonstrated positive results in a Phase 2 clinical trial.

Dusquetide is a new chemical entity with 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. It also accelerates resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo-and/or radiation therapy. Long-term follow-up data from the Phase 2 trial, published in the second quarter of 2017, further indicated the safety and tolerability of SGX942 treatment, with a sustained trend towards reduced mortality and increased tumor resolution compared to placebo. SGX942 has received Fast Track designation from the FDA for the treatment of oral mucositis as a result of CRT in head and neck cancer patients as well as PIM designation from the MHRA in the UK. In addition, the US Patent Office has granted the patent entitled “Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis”. The newly issued patent claims therapeutic use of dusquetide and related IDR analogs, and adds to composition of matter claims for dusquetide and related analogs that have been granted in the US and worldwide.

We anticipate that approximately fifty US and European oncology centers will be participating in this pivotal Phase 3 study. Currently, the study is actively enrolling in the US, which includes a number of centers that had previously participated in the Phase 2 study, with expansion into Europe occurring later this year. Current guidance on timing of study completion continues to be 2019, with a prospectively defined, blinded interim analysis for the trial occurring in the first half of 2019.

BioDefense/Vaccine Business Segment

In addition to the ongoing funding of up to \$24.7 million awarded by NIAID for the development of our ricin toxin vaccine, RiVax®, we announced that biomarkers for RiVax® testing have been successfully identified, facilitating potential approval under the FDA Animal Rule. The FDA Animal Rule is applied to products where testing in human clinical trials would be unethical, and in the case of ricin toxin, fatal. The Animal Rule combines safety studies in humans and efficacy testing in animals to facilitate approval. Key to the application of the Animal Rule is the requirement to establish a correlation between the immune response observed in clinical trials in healthy volunteers with the immune response demonstrated in animal efficacy studies.

In 2018, we intend to initiate a Phase 1/2 vaccine safety and immunogenicity study utilizing RiVax®. In parallel, efficacy studies in non-human primates are also planned in 2018, with initial results currently anticipated for late 2018. Identification of a biomarker to facilitate demonstrating the correlation between animal and human

studies is a significant accomplishment in the RiVax® development program. In addition to being protective and thermostable, RiVax® has demonstrated that a reduced number of vaccinations may be required to establish protection, potentially utilizing only two doses instead of three. RiVax® has received Orphan Drug designation from the FDA and as a new chemical entity, upon approval, has the potential to qualify for a biodefense Priority Review Voucher (PRV). PRVs are transferable and can be sold, with sales in recent years of up to \$350 million.

In closing, thank you for your interest and your continued support of Soligenix. We look forward to another productive year as we further advance our development programs, and will strive to provide similar updates on a quarterly basis moving forward. Best wishes to you and your families for a happy, healthy and prosperous 2018!

Dr. Christopher J. Schaber
President and Chief Executive Officer
Soligenix, Inc.
January 25, 2018

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.

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 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®. 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/2018-01-25-soligenix-driving-towards-key-inflection-points-with-two-pivotal-phase-3-clinical-trials>