Soligenix Investor Relations

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

Company provides mid-year update and guidance

Princeton, NJ – July 19, 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,

I wanted to take this opportunity to provide a mid-year update, as well as to provide some further guidance on our development programs.

Our focus remains, first and foremost, on 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 continue to advance the 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

Biotherapeutics Business Segment

We continue to make good progress in advancing our two (2) pivotal Phase 3 clinical programs.

2. We are actively enrolling patients in our pivotal Phase 3 study in CTCL with SGX301 (synthetic hypericin) with interim results still anticipated in the October timeframe and final topline results targeted for the first half of 2019. We remain encouraged by this development program as a potential front line treatment where there is currently an unmet medical need. You may recall that 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, which is targeted to enroll approximately 120 patients. 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.

The CTCL development program has partial funding of approximately $1.5 million over two years from a Small Business Innovative Research (SBIR) grant awarded by the NIH National Cancer Institute (NCI).

2. We are also actively enrolling patients in 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 chemoradiation therapy (CRT). Current guidance on timing of study completion continues to be 2019, with the interim analysis for the trial occurring in the first half of 2019 and final topline results targeted for the second half of 2019.

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. 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 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.

We anticipate that approximately fifty US and European oncology centers will be participating in this pivotal Phase 3 study, which is targeted to enroll approximately 190 patients. Currently, the study is enrolling in the US, which includes a number of centers that had previously participated in the Phase 2 study, with expansion into Europe anticipated to occur in the next several weeks.

The oral mucositis development program has partial funding of approximately $1.5 million over two years from a SBIR grant awarded by the NIH National Institute of Dental and Craniofacial Research (NIDCR).

BioDefense/Vaccine Business Segment

We are advancing the development of our thermostabilized ricin toxin vaccine, RiVax®, with the support of up to $24.7 million over six years awarded by NIAID, where we have 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.

We will continue to provide preclinical findings, as they become available, later this year. We also anticipate initiating a Phase 2 vaccine immunogenicity and safety study in healthy volunteers utilizing RiVax®. In parallel, additional efficacy studies in non-human primates are planned for initiation, enabling a larger

database of biomarker correlates for correlation with human clinical results. Identification of biomarkers that correlate protection 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, and both vaccine regimens are planned to be tested in the Phase 2 study planned to begin this year.

RiVax® has received Orphan Drug designations from both the FDA and EMA, 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. Recent events, including a foiled bioattack with ricin in Germany, suggest that the RiVax® vaccine may be of increasing interest to multiple countries.

Formulation development work with the University of Hawai'i on a trivalent thermostabilized Ebola vaccine continues as planned with the support of a $700,000 sub-award over five years from NIAID. The subunit vaccine offers broader coverage to different strains of Ebola, as well as Marburg virus, and offers the potential for a simpler chain of custody with no refrigerated conditions required.

Non-Dilutive Funding

As noted above, we aggressively pursue non-dilutive funding sources to support our rare disease pipeline. We have received two NIH SBIR grant awards totaling approximately $3 million for two of our biotherapeutics development programs. We are also operating under NIAID grant and contract awards of up to $25.4 million to support RiVax® development and our collaboration with the University of Hawai'i at Manoa for the development of a trivalent thermostabilized Ebola vaccine in our BioDefense business segment. This non-dilutive funding continues to provide a meaningful offset to our development expenses while better positioning us to more effectively manage our overall cash burn.

Equity Financing

In addition to the non-dilutive funding received, we recently completed an at the market registered direct offering of 8,932,038 shares of common stock at $1.03 together with warrants to purchase up to 3,572,815 shares of our common stock with an exercise price of $2.25 per share. Our gross proceeds from these offerings, which include the exercise of the underwriter's over-allotment option to purchase additional shares of common stock and warrants, were approximately $9.2 million before deducting offering expenses. The lead investor was Altamont Pharmaceutical Holdings, LLC, a long, fundamental life science investor, and currently our largest existing shareholder at approximately 13%.

We believe that, given current development assumptions, the approximate $8.4 million in net proceeds coupled with our existing cash on hand, which at the end of March 2018 was $6.4 million, and including our non-dilutive government funding, provides a cash runway of at least 12 months. With this available funding, we are now positioned to achieve multiple potential key milestones across our rare disease pipeline.

In closing, thank you for your interest and your continued support of Soligenix. We look forward to a productive second half of 2018 as we further advance our development programs, and will strive to provide similar updates on a periodic basis moving forward. Best wishes to you and your families for a happy and safe remainder of the summer!

Dr. Christopher J. Schaber

President and Chief Executive Officer

Soligenix, Inc.

July 19, 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.

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http://ir.soligenix.com/2018-07-19-soligenix-driving-towards-key-inflection-points-with-two-pivotal-phase-3-clinical-trials