

Soligenix - Advancing to Important Inflection Points With Two Pivotal Phase 3 Clinical Trials

Company provides Q1 2019 update and guidance

Princeton, NJ - April 23, 2019 - 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 an update, as well as to provide some further guidance on our development programs moving forward.

Our focus remains, first and foremost, on the quality execution of our two pivotal Phase 3 clinical trials, including SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma (CTCL) and SGX942 (dusquetide) for the treatment of oral mucositis in head and neck cancer. 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 additional non-dilutive funding to support our rare disease pipeline.

Corporate Highlights

Biotherapeutics Business Segment

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

- We are actively enrolling patients in our pivotal Phase 3 double-blind, placebo-controlled study in CTCL with SGX301 (synthetic hypericin) following the positive recommendation received from the independent Data Monitoring Committee (DMC) in October 2018. Following the DMC's unblinded interim analysis with data from approximately 100 study subjects, including assessment of the study's primary efficacy endpoint, the DMC recommended that approximately 40 additional subjects be randomized into the trial to maintain the rigorous assumption of 90% statistical power for the primary efficacy endpoint. No safety concerns were reported by the DMC based on the interim analysis (access October 15, 2018 press release [here](#)). Although we do not typically give specific enrollment numbers during the active conduct of our clinical trials, I will say that we are well into enrolling the additional subjects required for completion of this pivotal study.

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 35 CTCL centers across the US, representing the major Key Opinion Leaders (KOLs) in this indication, are participating in this pivotal trial, which is targeted to enroll approximately 160 evaluable subjects. 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 having elected to continue into Cycle 3, 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, and anticipate completing study enrollment in the second half of 2019, with final top-line results no later than Q1 2020.

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

- We also are actively enrolling patients in a pivotal Phase 3 multinational, double-blind, placebo-controlled clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer (HNC) receiving chemoradiation therapy (CRT). Since enrolling our first patient in December 2017 in a “controlled roll-out” of the study in the US to assure site adherence with the protocol design, we have expanded enrollment into Europe following the same controlled process. As we recently announced (access April 18, 2019 press release [here](#)), we have completed the approximate 90 subject enrollment necessary to support the interim analysis. We must now wait for the last enrolled subject to reach the study’s primary endpoint measure (consistent with how it was measured in the positive Phase 2 trial), which will occur up to 16 weeks after the subject enters the study due, in large part, to their extended CRT regimen for their HNC. The DMC interim analysis for the trial is currently anticipated to occur in September 2019. Similarly, current estimates have completion of full enrollment in the study on target for the second half of 2019, with final top-line results anticipated in the first half of 2020, pending the DMC recommendation. Rest assured, we take clinical trial execution very seriously and are diligently working to give this important Phase 3 study and the drug candidate every opportunity to be successful, not only for the Company, but for the participating clinicians, and most importantly, for the Soligenix shareholders and the patients suffering from this extremely debilitating disease.

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 median 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. The Phase 2 data demonstrated a significant reduction in the duration of oral mucositis, as well as reduced infection rates, as published in 2016 in the Journal of Biotechnology (available [here](#)). Long-term follow-up data from the Phase 2 trial, published in 2017 in Biotechnology Reports (available [here](#)), 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.

Approximately 50 oncology centers in the US and Europe are actively participating in this pivotal, Phase 3 study, which is targeted to enroll approximately 190 subjects with squamous cell carcinoma of the oral cavity and oropharynx who are scheduled to receive the standard treatment regimen with a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m² every third week.

The oral mucositis development program has received ongoing partial funding of approximately \$1.5 million over two years from an SBIR grant awarded by the NIH’s 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 successfully identified biomarkers for RiVax® testing, as published in the journal Vaccine in 2018 (available [here](#)), 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 anticipate initiating a Phase 2 vaccine immunogenicity and safety study in healthy volunteers utilizing RiVax® in the second half of 2019. In parallel, additional efficacy studies in non-human primates are planned for initiation, enabling a larger database of biomarkers for correlation with human clinical results. 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 in the US, has the potential to qualify for a biodefense Priority Review Voucher (PRV). PRVs are transferable and have been sold for as much as \$350 million. Recent events, including the news of an envelope addressed to President Trump that was thought to contain this potent and potentially lethal toxin, as well as 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. Previous work demonstrating thermostabilization of the univalent vaccine has been recently published in the European Journal of Pharmaceutics and Biopharmaceutics (available [here](#)).

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. In April 2019, we also received approximately \$611,000 in net proceeds for the sale of a tax credit under the New Jersey Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program.

Equity Financing

We started the year with approximately \$9 million in cash. In addition to the non-dilutive funding received and anticipated in 2019, we also filed an updated prospectus supplement to our existing shelf registration statement in October 2018 under which we may sell up to \$9.0 million shares of common stock, in anticipation of future capital needs, such as the execution of certain CTCL pre-commercialization activities to potentially support a new drug application filing with the FDA. 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 2019 as we further advance our development programs. Best wishes!

Dr. Christopher J. Schaber

President and Chief Executive Officer

Soligenix, Inc.

April 23, 2019

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 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 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 (including the outcome of the interim analysis) or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the PRV program or the amount for which a PRV for RiVax® can be sold. 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/2019-04-23-soligenix-advancing-to-important-inflection-points-with-two-pivotal-phase-3-clinical-trials>