

Soligenix - Advancing to Important Inflection Points With Two Pivotal Phase 3 Clinical Trials Company provides corporate update and guidance

PRINCETON, N.J., Jan. 14, 2020 /PRNewswire/ -- 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,

Let me start by wishing you a Healthy and Happy New Year! I wanted to take this opportunity to provide a corporate update, as well as some further guidance on our development programs moving forward.

It is truly an exciting time for the Company. As many of you are aware, we have a number of significant and potentially transformational events ahead of us this quarter and over the next six months. Most notably, top-line final results are imminent from two pivotal Phase 3 clinical trials:

- SGX301 (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL), where we have completed enrollment and expect [top-line results in Q1 2020](#); and
- SGX942 (dusquetide) for the treatment of oral mucositis in head and neck cancer, where we expect to complete enrollment in Q1 2020 and report [top-line results in Q2 2020](#).

In addition, we continue to advance the development of our heat stable ricin toxin vaccine (RiVa[®]) 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 actively pursue additional non-dilutive funding to support our rare disease pipeline.

Corporate Highlights

This past year we strengthened our commercial and business expertise, both at the Board level and with our senior management team, so that we may begin to position the company for the potential success of our Phase 3 clinical trials.

In July 2019, we announced the addition of Ms. Diane Parks to our Board of Directors (access press release [here](#)). Ms. Parks is an accomplished businesswoman and commercial executive with an extensive record of driving profitable growth for large pharmaceutical and biotech companies. With a successful career spanning more than 30 years, she served as Senior Vice President and Head of US Commercial for Kite Pharma, Inc. (acquired by Gilead Sciences, Inc. for \$11.9B), as Vice President and Head of Global Marketing for Pharmacyclics, Inc. (acquired by Abbvie, Inc. for \$21B), as Vice President of Sales for Amgen Inc., and as Senior Vice President, Specialty Biotherapeutics for Genentech, Inc. (acquired by Roche Holdings AG for \$46.8B). As we look forward to potential product approval, we intend to leverage Ms. Park's extensive business and commercialization experience in launching novel drug therapies in orphan diseases and areas of high unmet medical need. We believe her expertise adds significantly to our already diverse and experienced Board of Directors and management team.

In September 2019, we announced the additions of Jonathan Guarino, CPA, as Senior Vice President and Chief Financial Officer (access press release [here](#)) and Daniel Ring, as Vice President, Business Development and Strategic Planning (access press release [here](#)). Both Jonathan and Dan come with extensive backgrounds in their respective disciplines, while also having experience working for commercial life science companies.

As we look forward to 2020, we continue to evaluate with prospective partners a number of strategic alternatives including, but not limited to, merger, acquisition, partnership, alliance, co-development and/or co-commercialization licensing agreements.

Specialized Biotherapeutics Business Segment

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

- We completed patient enrollment in our pivotal Phase 3 double-blind, placebo-controlled study in CTCL with SGX301 (synthetic hypericin) in December (access press release [here](#)) following the positive recommendation received from the independent Data Monitoring Committee (DMC) in October 2018 (access press release [here](#)). Everything remains on track and our focus is now to complete the treatments for all patients and to lock the study database shortly thereafter, facilitating top-line results in Q1 2020.

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 enrolled 169 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 that the majority of patients have elected to continue with Cycle 3, the optional open-label portion of the study. We also continue to work closely with patient advocacy groups, such as the Cutaneous Lymphoma Foundation and the National Organization for Rare Disorders.

The CTCL development program has received 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 continue to actively enroll 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 announced in August 2019 (access press release [here](#)), the DMC conducted an unblinded interim analysis with data from approximately 90 study subjects, including assessment of the study's primary efficacy endpoint. The DMC recommended that 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. Although we do not typically give specific enrollment numbers during the active conduct of our clinical trials, I am happy to say that we currently have over 220 of the 260 subjects required to complete enrollment in this study. Consistent with our public guidance, we currently expect to complete enrollment in Q1 2020, with final topline results in Q2 2020.

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 HNC 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 260 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 and concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m² every third week.

The oral mucositis development program has received 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).

Public Health Solutions 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 recently initiated a third Phase 1C vaccine immunogenicity and safety study in healthy volunteers utilizing RiVax[®] (access press release [here](#)). This study is building upon the safety already demonstrated with the RiVax[®] antigen from the two previous Phase 1 clinical trials, but will look to test the product formulated with our proprietary heat stabilization technology (ThermoVax[®]). In parallel, additional efficacy studies in non-human primates are planned, 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 future studies.

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 can be sold, with sales in recent years of approximately \$100 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](#)).

Additional funding for dusquetide (active ingredient in SGX942) has also been obtained through a Defense Threat Reduction Agency (DTRA) subaward of approximately \$600,000 over 3 years (access press release [here](#)). These studies will further elucidate the therapeutic anti-infective action of dusquetide in animal models of biodefense-related infectious agents.

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 in our Public Health Solutions business segment to support RiVax[®] development, our collaboration with the University of Hawai'i at Manoa for the development of a trivalent thermostabilized Ebola vaccine and the evaluation of dusquetide as a broad spectrum therapeutic for the treatment of bacterial infectious disease. This non-dilutive funding continues to provide a meaningful offset to our development expenses while better positioning us to effectively manage our overall cash burn. Recently, we also received preliminary approval of a tax credit under the New Jersey Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program, which we anticipate being able to sell for approximately \$850,000 in net proceeds (access press release [here](#)).

Balance Sheet and Capital

As of January, we have over \$6 million in cash. In addition to the non-dilutive funding received and anticipated in 2019, we also have an At-The-Market (ATM) instrument in place with B. Riley FBR, Inc. to judiciously supplement cash if/when the need arises and stock volume and price permit, such as to support the execution of certain CTCL pre-commercialization activities to potentially support a new drug application filing with the FDA. With this available funding, we currently do not contemplate a larger capital raise, until at the earliest, after final top-line CTCL results are disclosed. We also continue to have ongoing business development discussions, which may lead to more favorable capital inflows, including the potential to receive additional non-dilutive funding. Overall, we are mindful of dilution and will look at all future capital inflow initiatives in the most efficient and shareholder friendly manner as possible.

In closing, thank you for your interest and your continued support of Soligenix. It is a very exciting time in our life cycle. We look forward to a productive 2020 as we further advance our development programs towards potential commercialization. Best wishes!

Dr. Christopher J. Schaber
President and Chief Executive Officer
Soligenix, Inc.
January 14, 2020

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 Specialized 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 Public Health Solutions 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), the Defense Threat Reduction Agents (DTRA) 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 (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. 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.

SOURCE Soligenix, Inc.

For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200 | www.soligenix.com, Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540

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