

Soligenix Issues Corporate Update - Highlights Important Catalysts for Second Half of 2020

PRINCETON, N.J., July 20, 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,

I hope this letter finds you and your families safe and healthy. A great deal has changed in the World since my last update earlier this year. We are now living through a pandemic that is testing all of us both personally and professionally. Like many life science companies, we are confronted with the challenge of trying to predict the impact COVID-19 may have on our operations and public guidance moving forward. As many of you are aware, we had taken a conservative approach with our Phase 3 clinical programs in order to maintain their statistical integrity during these unprecedented times; however, *I am pleased to report that the negative impact of the pandemic on our studies was much less significant than initially anticipated and all timelines remain on-track.* Nonetheless, we will continue to remain vigilant and will report any challenges caused by the COVID-19 pandemic that may have a potential impact on our current guidance.

We continue to execute on our strategy with a number of positive accomplishments. In March, we announced positive data in our pivotal Phase 3 FLASH ("Fluorescent Light Activated Synthetic Hypericin") study with SGX301 (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL). In the double-blind, placebo-controlled portion of the study (Cycle 1), a statistically significant treatment response ($p=0.04$) was achieved in the primary endpoint after 6 weeks of therapy (press release available [here](#)). This positive treatment response continued to dramatically improve with extended SGX301 treatment in the open-label treatment cycle, referred to as Cycle 2, with an additional 6 weeks of therapy ($p<0.0001$ compared to placebo and $p<0.0001$ compared to 6-weeks treatment; press release available [here](#)). Next up will be the extended safety results from the optional, compassionate-use, treatment cycle (Cycle 3) and the subsequent 6-month follow-up expected in the fourth quarter of 2020. In Cycle 3, subjects that completed Cycles 1 and 2 had the option of continuing SGX301 treatment of up to all of their lesions for another 6 weeks. I am happy to report that the majority of patients enrolled have elected to continue with this optional cycle of the study – a clear indication of their satisfaction. This clinical trial success was a tremendous accomplishment for the company, and we are eagerly anticipating other important milestones during the remainder of 2020.

Our other pivotal Phase 3 clinical trial with SGX942 (dusquetide), referred to as the DOM-INNATE ("Dusquetide treatment in Oral Mucositis – by modulating INNATE Immunity") study, treating oral mucositis in patients with head and neck cancer, completed patient enrollment in June (press release available [here](#)). The study successfully enrolled 268 subjects, following positive interim analysis, which included a prospectively defined, unblinded assessment of the study's primary efficacy endpoint by an independent Data Monitoring Committee (DMC). As you may recall, the study enrollment was temporarily extended as we assessed the potential impact of COVID-19 on the study (e.g., patient treatment compliance and completion of necessary assessments). With extra efforts by participating patients, physicians and clinical staff, we successfully reported that the negative impact of the pandemic on the overall study was much less than initially anticipated. **With enrollment now completed, top-line results are expected in the fourth quarter of 2020.**

Under our Public Health Solutions business segment, we continue to advance our work with the University of Hawai'i at Mānoa (UH Mānoa) and Hawaii Biotech Inc. (HBI) on filovirus vaccines (protecting against viruses such as Ebola and Marburg). We also extended this program to the development of vaccines to potentially combat coronaviruses, including SARS-CoV-2, the cause of COVID-19 (recent conference presentation available [here](#)). We continue to support our FDA Fast Tracked (press release available [here](#)) heat stable ricin vaccine, RiVax[®], with a National Institute of Allergy and Infectious Disease contract award of \$21.2 million.

With approximately \$9 million in cash, not including our non-dilutive government funding, along with the at-the-market (ATM) sales issuance agreement with B. Riley FBR, Inc. to judiciously supplement our cash runway as needed, we anticipate having sufficient capital to achieve multiple inflection points across our rare disease pipeline, including top-line results in our SGX942 Phase 3 clinical trial in oral mucositis.

Corporate Highlights

Since our last update in January, we have continued to focus on the quality execution of our multiple development programs in our rare disease pipeline, *where we currently anticipate achieving multiple important milestones in the second half of 2020.*

Specialized Biotherapeutics Business Segment

We continue to advance our two pivotal Phase 3 clinical programs.

1. On March 19, 2020, we announced positive preliminary top-line results for our pivotal Phase 3 FLASH trial evaluating SGX301 in the treatment of Stages IA, IB and IIA CTCL. The study enrolled 169 patients randomized 2:1 to receive either SGX301 or placebo, demonstrating a statistically significant treatment response ($p=0.04$) in the Composite Assessment of Index Lesion Score (CAILS) primary endpoint assessment at 8 weeks for Cycle 1.

As Ellen Kim, MD, Director of the Dermatology Clinic, Perelman Center for Advanced Medicine and Lead Investigator of the FLASH study stated in the announcement, "This is an important outcome for patients suffering from CTCL. SGX301 has successfully demonstrated efficacy in this challenging chronic cancer, with no safety concerns, making it a potentially preferred first-line option for the treatment of early stage CTCL, which is the large majority of patients suffering from this disease. This successfully proves that the drug has biologic activity in combating this disease in a relatively short time window, with preliminary data suggesting that the improvement continues to increase with extended treatment. In addition to the efficacy demonstrated, SGX301 was well-tolerated and its mechanism of action is not associated with DNA damage like other currently available therapies."

On April 30, 2020, we announced that continued treatment with SGX301 (synthetic hypericin) twice weekly for 12 weeks increased the positive response rate to 40% ($p<0.0001$ compared to placebo and $p<0.0001$ compared to 6-weeks treatment) in the open-label treatment cycle (referred to as Cycle 2) of the pivotal Phase 3 study for the treatment of early-stage CTCL. These highly statistically significant results confirm the benefit of continued SGX301 treatment in CTCL patients.

As Ms. Susan Thornton, Chief Executive Officer of the Cutaneous Lymphoma Foundation, the largest patient advocacy organization for CTCL, noted in the announcement, "The availability of a safe, rapid-acting, treatment for CTCL is extremely important to patients. From the patient perspective, you want a treatment that is safe and effective with the least amount of side effects. Many of the therapies available today either don't work for all patients, don't work for long-periods of time, can't be used by some because of their concerning side effects, or are used off-label creating access issues. As the leader of the patient organization and a patient myself, I know first-hand the importance of developing more therapies and options to support people living with this rare cancer."

We are now awaiting the safety data from the optional (compassionate use) treatment cycle (Cycle 3) of the trial, in which patients could receive SGX301 treatment of up to all their lesions, as well as the 6-month safety follow-up once all treatment has ended. Of note is that not only have the majority of patients enrolled elected to continue with this optional cycle of the study, but in an analysis of a subset of patients in Cycle 3, it was demonstrated that SGX301 is not systemically available, consistent with the general safety observed with this topical product to date. **Results from Cycle 3 and the subsequent 6-month follow-up are expected in the fourth quarter of 2020.**

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).

2. On June 24, 2020, we announced that we completed full enrollment of 268 patients randomized into the 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). With the positive interim analysis previously reported (press release available [here](#)), **we look forward to final top-line results for the DOM-INNATE study in the fourth quarter of 2020.**

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.

Public Health Solutions Business Segment

We most recently announced exciting developments in the area of emerging infectious diseases. In collaboration with UH Mānoa and HBI, we continue to advance development of filovirus vaccines (protecting against viruses such as Ebola and Marburg). Working with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), UH Mānoa, we have demonstrated the feasibility of developing heat stable subunit filovirus vaccines, including Ebola virus disease as well as Marburg virus disease, with both monovalent and bivalent vaccine combinations. Formulation conditions have been identified to enable heat stabilization of each antigen, alone or in combination, for at least 12 weeks at 40 degrees Celsius (104 degrees Fahrenheit).

Formulation development work with the UH Mānoa on a trivalent thermostabilized Ebola vaccine is currently supported by a \$700,000 sub-award over five years from NIAID. The subunit vaccine offers broader coverage for differing filoviruses, including Ebola, Marburg and Sudan, and offers the potential for a simpler supply chain 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](#)).

Expanding on our glycoprotein vaccine platform with UH Mānoa, we have also recently announced efforts to develop a safe, broadly applicable, subunit vaccine for treatment of COVID-19. Our COVID-19 vaccine candidate, CiVax™, utilizes a novel adjuvant, CoVaccine HT™, which we have exclusively licensed from BTG Specialty Pharmaceuticals ("BTG"), a division of Boston Scientific Corporation (NYSE: BSX), in the fields of coronavirus and pandemic flu (press release available [here](#)). Proof of concept studies in mice with the platform have already demonstrated strong potential COVID-19 immunogenicity. There are two components to the immune response - the antibody response and the cell-mediated response (involving T-cells); both of which can be activated by vaccines. Typically, vaccines are characterized by their ability to generate antibodies and particularly neutralizing antibodies (that is, antibodies that can prevent virus binding and entry, as well as marking the virus for destruction). **Prototype studies with the CoVaccine adjuvant with a SARS-CoV-2 antigen has indicated that both types of immunity can be significantly enhanced.** Some of these results are available in a recent conference presentation (available [here](#)). We will look to disclose more data as it becomes available.

We continue to progress our heat stable ricin vaccine, RiVax®[®], with the support of up to \$21.2 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](#) and more recently [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.

RiVax®[®] has received Orphan Drug designation as well as Fast Track designation from the FDA, 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.

Additionally, RiVax®[®] was granted Orphan Drug designation from the EMA. 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.

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 government grant and contract awards of up to \$22.5 million in our Public Health Solutions business segment to support RiVax®[®] development, our collaboration with the UH Mānoa and HBI 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 to date has provided a meaningful offset to our development expenses while better positioning us to effectively manage our overall cash burn.

Balance Sheet and Capital

As of June, we had approximately \$9 million in cash. In addition to the non-dilutive funding received to date, we also have an 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 a solid balance sheet and the available resources, we currently do not contemplate a larger capital raise until after final top-line oral mucositis results are disclosed. We also continue to have ongoing confidential 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.

One last note is our recent membership into the Russell Microcap[®] Index, which remains in place for one year and means automatic inclusion in the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. Approximately \$9 trillion in assets are benchmarked against Russell's US indexes. For more information on the Russell Microcap[®] Index, go to the "Russell Reconstitution" section on the FTSE Russell website [here](#).

In closing, thank you for your interest and your ongoing support of Soligenix. It continues to be a very exciting time in our life cycle and late stage pipeline. We look forward to the second half of 2020 being as productive as the first half, with the potential for multiple near-term catalysts on the horizon as we further advance our development programs towards commercialization. Best wishes!

Dr. Christopher J. Schaber
President and Chief Executive Officer
Soligenix, Inc.
July 20, 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, SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and our research programs to identify and develop novel vaccine candidates targeting viral infection including Ebola, Marburg and SARS-CoV-2 (the cause of COVID-19). 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, such as experienced with the COVID-19 outbreak. 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 the 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 any of our other clinical/preclinical trials. Despite the statistically significant result achieved in the SGX301 Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that a marketing authorization from the FDA or EMA will be successful. 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®. Also, no assurance can be provided that the Company will receive or continue to receive non-dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. 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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