

Soligenix Provides Important Highlights and Upcoming Catalysts in Corporate Update Letter

PRINCETON, N.J., Feb. 24, 2021 /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 would like to start by thanking you for your continued support, and hope that you and your families are all healthy and well. As 2020 recedes in the rearview mirror, we seem to be turning a corner on the challenges the COVID-19 pandemic has imposed on our everyday lives with promising coronavirus vaccines and a hope to return to a more normal existence in the not too distant future. Hope and recovery appear to be the early theme of 2021, and we are energized by the promise of the coming year. Last year posed a number of challenges and some disappointment for Soligenix, but more importantly a number of successes. Most notably, our positive Phase 3 study of SGX301 (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL), allowing us to advance toward a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for marketing authorization in the not too distant future. We also debuted new opportunities in our robust pipeline, such as our novel heat stable COVID-19 vaccine candidate, CiVax™, where we announced positive preclinical results and expect more data to follow shortly. Additionally, we have followed through on our efficient and shareholder-friendly financing strategies, providing us with sufficient capital and cash runway to meet our goals through 2022 as we move towards U.S. commercialization of SGX301 in CTCL. We expect peak annual net sales of SGX301 in the U.S. to exceed \$90 million, with the total addressable worldwide market estimated at approximately \$250 million annually. Overall, we are excited about our near-term and future upcoming catalytic milestones.

Corporate Highlights

Since our last update, we have continued to advance our development programs across both the Specialized BioTherapeutics and Public Health Solutions business segments of our rare disease pipeline, *where we currently anticipate achieving multiple important milestones in 2021 and 2022.*

Specialized Biotherapeutics Business Segment

In late October, we were very happy to announce completion of our pivotal Phase 3 FLASH ("Fluorescent Light Activated Synthetic Hypericin") study with SGX301 and share the continued positive benefits for our CTCL patients. Compared to the currently approved CTCL therapies for early disease, the treatment response to SGX301 was very rapid, being detected in as little as 6 weeks of treatment ([Cycle 1](#), $p=0.0416$). Responses continued to improve through 12 weeks of treatment ([Cycle 2](#), $p<0.0001$ vs end Cycle 1) and 18 weeks of treatment ([Cycle 3](#), $p<0.0001$ vs end Cycle 1), ultimately enabling nearly half of patients who continued treatment to see sustained and significant improvement in their response rates. SGX301 also demonstrated statistically significant responses in both patch (Cycle 2 response 37%, $p=0.0009$) and plaque (Cycle 2 response 42%, $p<0.0001$) lesions, highlighting the unique benefits of the more deeply penetrating visible light activation of hypericin. Unlike other second line and off-label therapies for CTCL, SGX301 was both better tolerated with a reduced dropout rate and more broadly effective, with equal efficacy against both plaque and patch lesions. Further, no synthetic hypericin was detected in the bloodstream of patients, minimizing safety concerns of drug effects outside of the tumor area.

As Brian Poligone, MD, PhD, Lead Enrolling Investigator in the FLASH study and Director of the Rochester Skin Lymphoma Medical Group, Fairport, NY, USA stated in the announcement, "Along with SGX301's rapid response time and safety profile, the patch and plaque data from the study are extremely compelling. Current treatments for CTCL are generally less effective against plaques and deeper lesions, very similar to the problem observed in psoriasis. The ability of SGX301 to target both patches and thicker plaques in CTCL is an important feature for this therapy and, if approved, will be of benefit to patients, regardless of their presentation. These results are consistent with the positive findings highlighted in a [recently reported case study](#) of folliculotropic mycosis fungoides, a hard to treat variant of CTCL where lesions are associated with the hair follicles deep in the skin and more resistant to phototherapy."

With the study complete, we are now preparing to begin submission of the rolling NDA in 2Q 2021 for this first-in-class therapy. SGX301 has received Orphan Drug and Fast Track designations from the FDA. Additionally, SGX301 was granted Orphan Drug designation from the European Medicines Agency (EMA) and Promising Innovative Medicine designation from the Medicines and Healthcare products Regulatory Agency in the United Kingdom.

January 2021 was a busy month for us. We announced a strategic partnership with Daavlin, a leading manufacturer of phototherapy products used worldwide by dermatologists and patients, for supply and distribution of our SGX301 companion light device. This exclusive supply, distribution and services agreement with Daavlin will secure long-term supply and distribution of a commercially ready light device that is an integral component of the regulatory and

commercial strategy for SGX301 for the treatment of CTCL. We also held an investor webcast event to discuss the unique U.S. commercialization opportunity for SGX301 in the treatment of CTCL. During the webcast, we reviewed in some detail the disease, competitive landscape, and our intent to commercialize SGX301 ourselves in a cost efficient and most profitable manner. As CTCL is a highly specialized orphan market with a discrete prescriber base, it presents a tailor-made market opportunity for us, where peak annual net sales in the U.S. are expected to exceed \$90 million, with total U.S. revenues during the 10-year forecast period projected to be greater than \$700 million.

As Michael Young our acting Chief Marketing Officer and Principal, biomedwoRx: Life Sciences Consulting and a Board member of the Cutaneous Lymphoma Foundation stated, "The value proposition for SGX301 is designed around maximizing the opportunity while minimizing the needed commercial investment, and represents a significant therapeutic opportunity in changing the landscape for treatment of early stage CTCL disease."

During this webcast, we also discussed at a high level the analysis that went into our determination to ultimately commercialize in the U.S. versus partnership. This decision was, in large part, based on maintaining 100% of SGX301's value with a very reasonable commercial build and launch expense of approximately \$7 million compared to us retaining less than half of its value with partnering. I would urge all those that want to better understand what a unique value proposition SGX301 in CTCL represents to listen to the full webcast [here](#).

We remain steadfast in our plans for partnership in the ex-U.S. markets and are in a number of active discussions with potential partners with similar reputation and expertise in this therapeutic area. We anticipate receiving marketing approval in the U.S. first, and with this approval in hand we will aggressively pursue marketing authorizations in other key markets worldwide. Given SGX301's success in CTCL, we are now evaluating other potential cutaneous oncology indications that might similarly benefit from the use of our first-in-class synthetic hypericin.

As many of you know, in December, we announced preliminary [top-line results](#) for our pivotal Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE Immunity) trial evaluating SGX942 (dusquetide) in the treatment of severe oral mucositis (SOM) in patients with head and neck cancer (HNC) receiving chemoradiation. The study enrolled 268 patients randomized 1:1 to receive either SGX942 or placebo. The primary endpoint of median duration of SOM did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was clearly observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group. Other secondary endpoints supported the biological activity of dusquetide as well, including a statistically significant 50% reduction in the duration of SOM in the per-protocol population, which decreased from 18 days in the placebo group to 9 days in the SGX942 treatment group ($p=0.049$), consistent with the findings in the Phase 2 trial.

As I noted during our [investor call](#), we are very disappointed with this unanticipated outcome of the study. Despite the fact that SGX942 demonstrated clinically meaningful reductions in oral mucositis consistent with the previous Phase 2 study, the Phase 3 trial did not achieve the statistically significant benefit we expected. We are continuing to analyze the full dataset to better understand why the study did not meet expectations. Any clarity gained from further analysis of the dataset, especially with respect to specific subsets of patients that may benefit from SGX942 therapy, will be communicated to and discussed with the FDA and the EMA.

Public Health Solutions Business Segment

We most recently announced a number of exciting developments in the area of emerging infectious diseases. We were [awarded](#) a Direct to Phase II Small Business Innovation Research grant of approximately \$1.5 million from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 (Coronavirus Disease 2019) and Ebola Virus Disease vaccine candidates in conjunction with our CoVaccine HT™ (CoVaccine) adjuvant. This award also will support immune characterization of this novel, emulsified adjuvant that has unique potency and compatibility with lyophilization strategies to enable thermostabilization of subunit vaccines.

Ongoing collaborations with Axel Lehrer, PhD, Associate Professor (Vaccinology) in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), University of Hawai'i at Mānoa (UHM), have demonstrated the feasibility of developing a [highly immunogenic vaccine for COVID-19](#), the infection caused by SARS-CoV-2. This heat stable subunit vaccine program, we call CiVax™, demonstrated immunity of both broad-spectrum antibody and cell-mediated, rapid onset immunity using the [CoVaccine](#) adjuvant in-licensed from BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation. With significant research dedicated worldwide to the generation of COVID-19 vaccines, it is noteworthy that the essential attributes of a vaccine successful in controlling the ongoing pandemic are believed to include the ability to rapidly stimulate a Th1/Th2 balanced antibody response, raising significant virus neutralizing antibodies, as well as induce potent cell-mediated immunity. Previous work with the CoVaccine adjuvant has indicated that it has these critical characteristics. In addition, unlike other vaccines that have logistical challenges due to cold chain requirements (in some cases requiring maintenance of temperatures less than -70 degrees Celsius), the underlying technology platform has demonstrated the ability to produce single vial vaccines which are stable up to temperatures at least as high as 40 degrees Celsius (104 degrees

Fahrenheit). We expect to have proof of concept data in non-human primates (NHPs) no later than the end of Q2 this year.

We followed this up with an [announcement](#) that we had demonstrated feasibility of developing heat stable subunit protein vaccine formulations for filovirus vaccines, including Ebola virus, Sudan virus, and Marburg virus. Protective efficacy has been demonstrated in NHPs, the gold standard animal model, against infection with Ebola virus, Sudan virus, and Marburg virus. 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. These most recent results demonstrate the thermostabilization of three virus glycoproteins (from *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg marburgvirus*), and the identification of key stability-indicating assays to further support mono-, bi- and tri-valent vaccine formulations.

In December, we demonstrated extended protection with our heat stable ricin toxin vaccine candidate, RiVax[®]. Mice, vaccinated twice on Days 1 and 21 were protected for at least 365 days against subsequent ricin challenge. These [results](#) demonstrate that the thermostabilized vaccine formulation is capable of eliciting enduring protection in mice. Coupled with previous demonstration of efficacy in mice and NHPs as well as long-term thermostability (at least 1 year at 40 degrees Celsius or 104 degrees Fahrenheit), these results reinforce the practicality of stockpiling and potentially utilizing the RiVax[®] vaccine in warfighters and civilian first responders without the complexities that arise for vaccines that require cold chain handling. This same thermostabilization approach is also being advanced in the development of Soligenix's CiVax[™] vaccine for COVID-19.

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 bio attack with ricin in Germany, suggest that the RiVax[®] vaccine may be of increasing interest to multiple countries.

Balance Sheet and Capital

With more than \$30 million in cash as of February 2021, not including our non-dilutive government funding, we are now sufficiently capitalized to achieve multiple key inflection points across our rare disease pipeline, including moving towards NDA and commercialization of SGX301. This increase in capital was due to two important events.

- A \$20 million [strategic partnership](#) with Pontifax Medison, the healthcare-dedicated venture and debt fund of the Pontifax life science funds, in December. Under the terms of the partnership with Pontifax, Soligenix will have access to up to \$20 million in convertible debt financing in three tranches, which will mature over a four-and-a-half-year period and have an interest-only period for the first two years. Upon the closing of this transaction, we accessed the first tranche of \$10 million, and have the option to draw the second tranche of \$5 million at any time over the next 12 months and the third tranche of \$5 million upon filing of the SGX301 NDA, subject to certain conditions. Pontifax may elect to convert the outstanding loan drawn under the first two tranches into shares of Soligenix's common stock at any time prior to repayment at a conversion price of \$4.10 per share. We also have the ability to force the conversion of the loan into shares of our common stock at a conversion price of \$4.92 per share, subject to certain conditions.
- The use of our at-the-market (ATM) sales issuance agreement with B. Riley Securities, Inc. over the last two months to supplement our cash runway. Given the significant increase in both stock price and volume, with more than 186 million shares traded so far during 2021, we were able to add capital to our balance sheet judiciously while limiting sales to an extremely small percentage (approximately 4.6%) of the overall volume.

The combination of these two facilities provides significant cash runway through 2022. With a solid balance sheet and other available resources at our disposal, such as non-dilutive government funding, we are well positioned to aggressively advance and expand our pipeline. 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 capital. Overall, we continue to remain 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 ongoing support of Soligenix. It continues to be a very exciting time in our life cycle and late stage pipeline. We look forward to 2021 being even more productive than 2020, 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.
February 24, 2021

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 and commercializing SGX301 (synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma. With a successful Phase 3 study completed, regulatory approval and commercialization for this product is being advanced initially in the U.S. Development programs in this business segment also include our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including 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 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 the timing or success of any of our 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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