Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And First Quarter 2020 Financial Results

PRINCETON, N.J., May 15, 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, announced today its recent accomplishments and financial results for the quarter ended March 31, 2020.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "This has been a very rewarding year for us thus far. Our pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial continues to demonstrate SGX301's potential to be an important new treatment for early-stage cutaneous T-cell lymphoma (CTCL). In the double-blind, placebo controlled Cycle 1 portion of the study, a statistically significant treatment response ($p=0.04$) was achieved in the primary endpoint after 6 weeks of therapy. This positive treatment response continued to significantly 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). We also continue to advance our pivotal Phase 3 clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer (HNC) receiving chemoradiation therapy. Following the positive recommendation received from the independent Data Monitoring Committee, we have successfully achieved our target of 260 patients randomized into the study; however, due to the uncertainty surrounding the coronavirus pandemic, we decided to enroll up to 25 additional patients into the study. We are taking this cautious approach in order to maintain the statistical integrity of the trial, by accounting for patients that may potentially drop out of the study before completing their protocol required study treatment and evaluations. Therefore, the study target to complete enrollment and provide top-line results has been revised to the fourth quarter 2020; however, this will continue to remain dependent on the medical and logistical challenges caused by the coronavirus showing a reasonable level of improvement in the relative near-term."

Dr. Schaber continued, "Under our Public Health Solutions business segment, we continue to advance our work with University of Hawai'i at Mānoa (UH Mānoa) on filovirus vaccines (protecting against viruses such as Ebola and Marburg) and the development of vaccines to potentially combat coronaviruses, including SARS-CoV-2, the cause of COVID-19. We continue to support our heat stable ricin vaccine, RiVax®, with a National Institute of Allergy and Infectious Disease contract award of $21.2 million. With over $8M in cash, not including our non-dilutive government funding, along with the at-the-market 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."

Soligenix Recent Accomplishments

- On May 11, 2020, the Company announced publication of immunogenicity studies for RiVax® identifying novel correlates of immune protection to facilitate potential approval under the United States Food and Drug Administration (FDA) "Animal Rule." The article, titled "A Multivariate Model Combining Endpoint and Epitope-specific Antibody Responses as a Correlate of Protection to Ricin Toxin," has been submitted to the peer-reviewed medical journal Vaccine and a preprint is available here. To view this press release, please click here.
- On May 7, 2020, the Company announced that it had received approximately $840,000, net of transaction costs, in non-dilutive financing via the State of New Jersey's Technology Business Tax Certificate Transfer Program. To view this press release, please click here.
- On April 30, 2020, the Company announced that continued treatment with SGX301 (synthetic hypericin) twice weekly for 12 weeks increased the positive response rate to 40% ($p<0.0001$ compared to placebo and $p<0.0001$ compared to 6-weeks treatment) in Cycle 2 of its pivotal Phase 3 FLASH study for the treatment of early-stage CTCL. These highly statistically significant results confirm the benefit of continued SGX301 treatment in CTCL patients. To view this press release, please click here.
- On April 16, 2020, the Company announced it had executed an agreement for the exclusive worldwide license of CoVaccine HT™, a novel vaccine adjuvant, from BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation (NYSE: BSX), for the fields of pandemic flu and coronaviruses, including SARS-CoV-2, the cause of COVID-19. To view this press release, please click here. This collaboration further builds on the recently announced collaboration between the UH Mānoa and Soligenix to develop a SARS-CoV-2 vaccine (available here).
- On April 6, 2020, the Company announced that the European patent office has granted the divisional patent application titled "Formulations and Methods of Treatment of Skin Conditions" (No. 2932973). The granted claims are directed to the therapeutic use of synthetic hypericin in the treatment of CTCL. To view

this press release, please click here.

Financial Results – Quarter Ended March 31, 2020

Soligenix's revenues for the quarter ended March 31, 2020 were $0.9 million as compared to $1.1 million for the quarter ended March 31, 2019. Revenues included payments on a contract in support of RiVax®, our ricin toxin vaccine candidate, grants received to support the development of SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases, ThermoVax®, our thermostabilization technology, and the assessment of SGX942 safety in juvenile animals.

Soligenix's basic net loss was $7.6 million, or ($0.32) per share, for the quarter ended March 31, 2020, as compared to $1.6 million, or ($0.09) per share, for the quarter ended March 31, 2019. This increase in net loss was primarily the result of the issuance of $5 million of common stock as a milestone payment triggered by the successful Phase 3 clinical trial of SGX301 for the treatment of CTCL and increased research and development spending. The number of shares of common stock issued as a milestone payment was calculated using an effective price of $2.56 per share, based upon a formula set forth in the applicable agreement.

Research and development expenses were $2.7 million as compared to $1.6 million for the quarters ended March 31, 2020 and 2019, respectively. The increase in research and development spending for the quarter ended March 31, 2020 was primarily attributable to the site and patient fees for the pivotal Phase 3 clinical trials of SGX301 and SGX942, compared to the same period in 2019.

General and administrative expenses were $0.9 million for both the three months ended March 31, 2020 and 2019.

As of March 31, 2020, the Company's cash position was approximately $7.2 million, not including the approximate $840,000 recently received from the State of New Jersey's Technology Business Tax Certificate Transfer Program.

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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