Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Second Quarter 2020 Financial Results

PRINCETON, N.J., Aug. 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, announced today its recent accomplishments and financial results for the quarter ended June 30, 2020.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We continue to execute on our strategy with a number of positive accomplishments. 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). The optional, compassionate-use, treatment cycle (Cycle 3) and the subsequent 6-month follow-up is expected in the fourth quarter of 2020, with the majority of patients enrolled having elected to continue with this optional cycle of the study – a clear indication of their satisfaction. We also continue to advance our pivotal Phase 3 clinical trial of SGX942 (dusquetide), referred to as the DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE Immunity) study, 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 (DMC) and after taking a conservative approach to assessing the potential impact of COVID-19 on the study, we have successfully enrolled 268 subjects. With enrollment completed, top-line results continue to be expected in the fourth quarter 2020."

Dr. Schaber continued, "Under our Public Health Solutions business segment, we continue to advance our work with the University of Hawai'i at Mānoa (UHM) and Hawaii Biotech Inc. 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 recently announced publication of positive pre-clinical data from immunogenicity studies with CiVax™ (heat stable COVID-19 vaccine candidate), demonstrating immunity of both broad-spectrum antibody and cell-mediated, rapid onset immunity is possible using the CoVaccine HT™ adjuvant. Our heat stable ricin vaccine, RiVax®, continues to be supported with a National Institute of Allergy and Infectious Disease contract award of $21.2 million. With over $11M 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 final top-line results in our SGX942 Phase 3 clinical trial in oral mucositis."

Soligenix Recent Accomplishments

- On July 28, 2020, the Company announced publication of pre-clinical immunogenicity studies for its CiVax™ program (heat stable COVID-19 vaccine candidate), demonstrating immunity of both broad-spectrum antibody and cell-mediated, rapid onset immunity is possible using the CoVaccine adjuvant. The article, authored by collaborators at the UHM, is titled, "CoVaccine HT™ adjuvant potentiates robust immune responses to recombinant SARS-CoV-2 spike-S1 immunization," and has been submitted for peer-review to the journal *npj Vaccines*. An accelerated preprint of the manuscript has been made available here. To view this press release, please click here.
- On July 20, 2020, the Company announced that it had issued an update letter from its President and Chief Executive Officer, Dr. Christopher J. Schaber, highlighting important catalysts for the second half of 2020. To view this press release and letter, please click here.
- On June 24, 2020, the Company announced that it had completed patient enrollment in its Phase 3 DOM-INNATE study for SGX942 (dusquetide) in the treatment of oral mucositis in HNC patients. 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 DMC. To view this press release, please click here.
- On June 22, 2020, the Company announced that it would join the Russell Microcap® Index at the conclusion of the 2020 Russell indexes annual reconstitution, effective after the US market opens on June 29th, according to a final list of additions posted June 15th. To view this press release, please click here.

Financial Results – Quarter Ended June 30, 2020

Soligenix's revenues for the quarter ended June 30, 2020 were $0.5 million as compared to $1.4 million for the quarter ended June 30, 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 $2.8 million, or ($0.10) per share, for the quarter ended June 30, 2020, as compared to $2.1 million, or ($0.12) per share, for the quarter ended June 30, 2019. This increase in net loss was primarily the result of increased research and development spending primarily attributable to higher clinical trial site and patient fees for the pivotal Phase 3 clinical trials of SGX301 and SGX942.

Research and development expenses were $2.2 million as compared to $1.9 million for the quarters ended June 30, 2020 and 2019, respectively. The increase in research and development spending for the quarter ended June 30, 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 $0.8 million for both the three months ended June 30, 2020 and 2019.

As of June 30, 2020, the Company's cash position was approximately $11.2 million.

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 vaccine programs targeting both filoviruses (such as Marburg and Ebola) and coronaviruses. 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 Biomedical Advanced Research and Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA).

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. The Company cannot offer assurance as to any result from the arbitration against, or that it will recover any damages from, Emergent BioSolutions, Inc., Emergent Product Development Gaithersburg, Inc. and Emergent Manufacturing Operations Baltimore LLC. 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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