Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Third Quarter 2020 Financial Results

PRINCETON, N.J., Nov. 12, 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 September 30, 2020.

"We continue to look to the future with our Specialized BioTherapeutics business segment," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With the recent successful completion of our pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial, SGX301 has demonstrated the potential to be a significant 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 just 6 weeks of therapy. This positive treatment response continued to significantly improve with extended SGX301 treatment in the open-label treatment cycles at 12 weeks (Cycle 2) and 18 weeks (Cycle 3), reinforcing the positive SGX301 primary endpoint treatment response demonstrated in Cycle 1. With the study now concluded, we will begin preparing our new drug application for submission to the FDA. We also continue to progress our pivotal Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE Immunity) study for SGX942 (dusquetide), for the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. With enrollment of 268 subjects completed, top-line final results continue to be expected before the end of the year."

Dr. Schaber continued, "Under our Public Health Solutions business segment, supported by non-dilutive government funding, 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 novel CoVaccine HT™ adjuvant in-licensed from BTG Specialty Pharmaceuticals (a division of Boston Scientific Corporation). Our heat stable ricin vaccine, RiVax®, continues to be supported with a National Institute of Allergy and Infectious Disease contract award. 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 October 22, 2020, the Company announced the continued optional treatment with SGX301 (synthetic hypericin) across all lesions during the compassionate use, safety portion of the trial (Cycle 3), for a total of 6 months in the study, continued to significantly improve responses and remained safe and well-tolerated in its FLASH study. This data reinforces the positive SGX301 primary endpoint treatment response demonstrated in Cycle 1. SGX30l treatment in Cycle 3 further improved response rates, with 49% of patients electing to receive SGX301 for a total of 18 weeks demonstrating a 50% or greater reduction in their combined CAILS (Composite Assessment of Index Lesion Score) lesion score compared to 40% of patients demonstrating such a reduction after completing 12 weeks of SGX301 treatment in Cycle 2 (p=0.046). In addition, continued analysis of results has revealed that 12 weeks of SGX301 treatment (Cycle 2) is equally effective on both patch (response 37%, p=0.0009) and plaque (response 42%, p<0.0001) lesions of CTCL when compared to Cycle 1 placebo lesion responses. SGX301 continued to be very well tolerated, benefiting from the lack of hypericin circulation in the blood stream after targeted topical application to the lesions, as well as the use of visible light. To view this press release, please click here.

- On September 15, 2020, the Company announced the publication of nonclinical results characterizing filovirus protein antigens (including for Ebola and Marburg viruses) and their thermostabilization. The article, authored by collaborators at the University of Colorado, University of Hawai'i at Mānoa (UHM) and Soligenix, is titled, "Preservation of Quaternary Structure in Thermostable, Lyophilized Filovirus Glycoprotein Vaccines: A Search for Stability-Indicating Assays" and has been accepted for publication in the Journal of Pharmaceutical Sciences. A copy of manuscript has been made available here. To view this press release, please click here.

- On September 10, 2020, the Company conducted an Investor Webcast presentation on the use of its

thermostabilized glycoprotein vaccine platform for the development of a COVID-19 vaccine, called CiVax™. To listen to this Webcast Event, please click here and to view the press release, please click here.

Financial Results – Quarter Ended September 30, 2020

Soligenix's revenues for the quarter ended September 30, 2020 were $0.6 million as compared to $1.3 million for the quarter ended September 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 $1.8 million, or ($0.06) per share, for the quarter ended September 30, 2020, as compared to $2.7 million, or ($0.14) per share, for the quarter ended September 30, 2019. This decrease in net loss was primarily the result of decreased research and development spending due to the completion of the CTCL trial.

Research and development expenses were $1.3 million as compared to $2.3 million for the quarters ended September 30, 2020 and 2019, respectively. The decrease in research and development spending for the quarter ended September 30, 2020 was primarily attributable to the reduction in expense due to the completion of the CTCL trial.

General and administrative expenses were $0.8 million for both the three months ended September 30, 2020 and 2019.

As of September 30, 2020, the Company's cash position was approximately $11.3 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 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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