Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Year-End 2019 Financial Results

PRINCETON, N.J., March 30, 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 year ended December 31, 2019.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We are extremely pleased to have achieved positive top-line results in our pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial that demonstrates SGX301's potential to be an important new treatment for early stage cutaneous T-cell Lymphoma (CTCL). Having demonstrated statistical significance in the study's primary endpoint, we will now look to report results from the extended treatment portion of the trial, which we anticipate announcing in June 2020. Following the positive recommendation received from the independent Data Monitoring Committee, we have successfully achieved our target of 260 patients randomized into the 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; however, due to the uncertainty surrounding the coronavirus pandemic, we have decided to enroll approximately 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 evaluation. Therefore, the study target to complete enrollment and provide top-line results is being revised from the second quarter of 2020 to the fourth quarter 2020; however, this will 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 progress our heat stable ricin vaccine, RiVax®, with the support of a National Institute of Allergy and Infectious Disease contract award of up to $24.7 million. We are also excited to advance our work with University of Hawai‘i at Mānoa (UH Mānoa) beyond filovirus vaccines (protecting against viruses such as Ebola and Marburg) to the development of vaccines to potentially combat coronaviruses, including SARS-CoV-2, the cause of COVID-19. With over $7.5M in cash, not including our State and Federal funding, we anticipate having the cash resources sufficient 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 March 23, 2020, the Company announced that it expanded its research collaboration with UH Mānoa to investigate potential coronavirus vaccines. The Company and UH Mānoa are expanding the technology platform, developed as part of their filovirus program, to assess compatibility with coronaviruses including SARS-CoV-2, the cause of COVID-19. The resulting vaccines have the potential to be broadly applicable, including to individuals often excluded from common viral vector vaccine approaches such as children, the elderly and the immunocompromised. To view this press release, please click here.

- On March 19, 2020, the Company announced positive preliminary top-line results for its pivotal Phase 3 FLASH trial evaluating SGX301 (synthetic hypericin) in the treatment of CTCL. The study enrolled 169 patients randomized 2:1 to receive either SGX301 or placebo, demonstrating 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. To view this press release, please click here.

- On February 13, 2020, the Company announced that its RiVax® (heat stable ricin toxin vaccine) development program for prevention of ricin intoxication had received "Fast Track" designation from the FDA. To view this press release, please click here.

- On February 3, 2020, the Company announced that its ongoing collaboration with the UH Mānoa and Hawaii Biotech Inc. had resulted in what the Company believes is a significant milestone in the development of heat stable filovirus vaccines, in which the platform has demonstrated feasible thermostable formulations and protection in non-human primate models with both monovalent and bivalent vaccine candidates in the three most deadly human pathogenic filoviruses (Ebola virus, Sudan virus and Marburg virus). To view this press release, please click here.

- On February 3, 2020, the Company announced that the Japanese Patent Office had granted the patent titled "Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis." This allowance builds on similar intellectual property in the US, New Zealand, Australia and Singapore and patent applications

pending in other jurisdictions worldwide. The new claims cover therapeutic use of dusquetide (active ingredient in SGX942) and related innate defense regulator (IDR) analogs, and add to composition of matter claims for dusquetide and related analogs that have been granted in the US and worldwide. To view this press release, please click here.

- On January 14, 2020, the Company issued an update letter from its President and Chief Executive Officer, Dr. Christopher J. Schaber. To view this press release, please click here.

- On December 18, 2019, the Company announced that it had received preliminary approval for a tax credit from the New Jersey Economic Development Authority's (NJEDA) New Jersey Technology Business Tax Certificate Transfer program. As a result, the Company anticipates being able to transfer this credit and receive approximately $850,000 in net proceeds. To view this press release, please click here.

- On December 3, 2019, the Company announced it had completed patient enrollment in its Phase 3 FLASH study for SGX301 in the treatment of CTCL. The study successfully enrolled 169 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. To view this press release, please click here.

Financial Results – Year Ended December 31, 2019

Soligenix's revenues for the year ended December 31, 2019 were $4.6 million as compared to $5.2 million for the year ended December 31, 2018. Revenues included payments on a contract in support of RiVax®, in addition to the grants received to support the development of SGX301 for the treatment of CTCL and SGX942 for the treatment of oral mucositis in HNC.

Soligenix's basic net loss was $9.4 million, or ($0.48) per share, for the year ended December 31, 2019, as compared to $8.9 million, or ($0.68) per share, for the year ended December 31, 2018.

Research and development expenses were $8.1 million as compared to $6.8 million for the years ended December 31, 2019 and 2018, respectively. The increase in research and development spending for the year ended December 31, 2019 was primarily attributable to the expansion of the Phase 3 clinical trial of SGX942 as well as the ongoing Phase 3 clinical trial of SGX301, compared to the same period in 2018.

General and administrative expenses were $3.4 million as compared to $3.0 million for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, the Company's cash position was approximately $5.4 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. 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 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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