Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Year-End 2020 Financial Results

PRINCETON, N.J., March 30, 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, announced today its recent accomplishments and financial results for the year ended December 31, 2020.

"2021 will be another important year for Soligenix on a number of fronts," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With our pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial successfully completed, we are now preparing to begin submission of the rolling new drug application (NDA) in 2Q 2021 for this first-in-class therapy. Compared to the currently approved cutaneous T-cell lymphoma (CTCL) therapies for early disease, the SGX301 treatment response 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. Moreover, patients with more difficult to treat plaque lesions also showed this same treatment benefit, an advantage over some other therapies which primarily work only for patch lesions. Under our Public Health Solutions business segment, we continue to advance multiple therapeutic and vaccine candidiates, with the support of non-dilutive government funding, including our heat stable COVID-19 vaccine, CiVax™, which recently demonstrated rapid-onset, broad-spectrum, neutralizing antibody and cell-mediated immunity using full-length Spike protein antigens in mice. Overall, our thermostabilization platform has now demonstrated compatibility with two different adjuvants, consistently enabling single-vial vaccine presentations with characteristics for ambient shipping and long-term storage. Further, non-human primate data is expected across our vaccine platform later this year."

Dr. Schaber continued, "With over $30 million in cash, not including our non-dilutive funding, we anticipate having sufficient capital to achieve multiple inflection points across our rare disease pipeline, including moving towards NDA and U.S. commercialization of SGX301 in CTCL. As CTCL is a highly specialized orphan market with a discrete prescriber base, it presents a tailor-made market opportunity for us. We estimate peak U.S. annual net sales to exceed $90 million and the total U.S. revenues during the 10-year forecast period to be greater than $700 million. With a total addressable worldwide market projected to be approximately $250 million annually, we continue to have ongoing confidential discussions regarding ex-U.S. partnership opportunities."

Soligenix Recent Accomplishments

- On March 9, 2021, the Company announced that it 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 $865,000 in net proceeds. To view this press release, please click here.
- On March 4, 2021, the Company announced publication of pre-clinical immunogenicity studies for CiVax™ (heat stable COVID-19 vaccine program) demonstrating rapid-onset, broad-spectrum, neutralizing antibody and cell-mediated immunity is confirmed using full-length Spike protein antigens. To view this press release, please click here.
- On February 24, 2021, 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 February 1, 2021, the Company announced that the Hong Kong Registrar of Patents granted a patent for the application titled "Formulations and Methods of Treatment of Skin Conditions" (No. 16102842.8), published on January 29, 2021 under Publication No. 1214771 B. To view the press release, please click here.
- On January 26, 2021, the Company hosted an Investor Webcast Event regarding U.S. commercial planning for SGX301 (synthetic hypericin) in the treatment of CTCL. To listen to the webcast, please click here.
- On January 7, 2021, the Company announced that it signed an exclusive Supply, Distribution and Services Agreement with Daavlin, securing 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. To view the press release, please click here.
- On December 28, 2020, the Company announced that the National Institute of Allergy and Infectious Diseases (NIAID) awarded Soligenix a Direct to Phase II Small Business Innovation Research (SBIR) grant of approximately $1.5 million to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 and Ebola Virus Disease vaccine candidates in conjunction with the CoVaccine HT™ adjuvant. To view the press release, please click here.
- On December 22, 2020, the Company announced preliminary top-line results for its pivotal Phase 3 DOM-INNATE trial evaluating SGX942 in the treatment of severe oral mucositis in patients with head and neck

cancer receiving chemoradiation. To view the press release, please click here.
- On December 16, 2020, the Company announced that it entered into a $20 million convertible debt financing agreement with Pontifax Medison Debt Financing, the healthcare-dedicated venture and debt fund of the Pontifax life science funds. To view the press release, please click here.
- On December 8, 2020, the Company announced that it demonstrated extended protection with its heat stable ricin toxin vaccine, RiVax®. To view the press release, please click here.

Financial Results – Year Ended December 31, 2020

Soligenix's revenues for the year ended December 31, 2020 were $2.4 million as compared to $4.6 million for the year ended December 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 $17.7 million, or ($0.64) per share, for the year ended December 31, 2020, as compared to $9.4 million, or ($0.48) per share, for the year ended December 31, 2019. The increase in net loss is primarily due to increased expenditures incurred to support both the pivotal Phase 3 trial of SGX301 in the treatment of CTCL and the pivotal Phase 3 trial of SGX942 in the treatment of oral mucositis in head and neck cancer, as well as a $5 million success milestone payment in common stock (based upon an effective per share price of $2.56) as a result of SGX301 demonstrating statistically significant treatment response in the pivotal Phase 3 clinical trial.

Research and development expenses were $10.1 million as compared to $8.1 million for the years ended December 31, 2020 and 2019, respectively. The increase in research and development spending for the year ended December 31, 2020 was related to expenditures incurred in the expansion of the Phase 3 clinical trial of SGX942 as well as the ongoing Phase 3 clinical trial of SGX301.

General and administrative expenses were $4.0 million as compared to $3.5 million for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, the Company's cash position was approximately $18.7 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 and moving toward potential commercialization of SGX301 (synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With a successful Phase 3 study completed, regulatory approval is being sought and commercialization activities for this product candidate are 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, and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). 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 Agency (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 its 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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