Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And First Quarter 2021 Financial Results

PRINCETON, N.J., May 17, 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 quarter ended March 31, 2021.

"This year continues to be an exciting year of progress for Soligenix," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We recently announced presentation of clinical data from our successful pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) clinical trial for HyBryte™ (SGX301) in the treatment of cutaneous T-cell lymphoma (CTCL) at both the American Academy of Dermatology, where HyBryte™ was designated "Top 12 late-breaking research," and the Society for Investigative Dermatology. We also received U.S. Food and Drug Administration (FDA) conditional acceptance of HyBryte™ as the proposed brand name for SGX301 (synthetic hypericin), as we continue to prepare for a new drug application (NDA) submission and U.S. commercialization for this novel first-in-class photodynamic therapy for treatment of early stage CTCL. Under our Public Health Solutions business segment, supported by non-dilutive government funding, we continue to advance multiple therapeutic and vaccine candidates. CiVax™, our heat stable COVID-19 vaccine, recently demonstrated that the proprietary subunit protein antigen, locked into its receptor-binding configuration, was immunogenic in both mice and non-human primates, which is an important step in advancing CiVax™ towards human clinical trials."

Dr. Schaber continued, "With approximately $30 million in cash, not including our non-dilutive government funding, we anticipate having sufficient capital to achieve multiple inflection points as we advance our rare disease pipeline, including NDA filing and U.S. commercialization of HyBryte™ in CTCL, where 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."

Soligenix Recent Accomplishments

- On May 10, 2021, the Company announced that HyBryte™ (hypericin) was awarded an "Innovation Passport" for the treatment of early stage CTCL in adults under the United Kingdom's (UK's) Innovative Licensing and Access Pathway (ILAP). To view this press release, please click here.
- On April 28, 2021, the Company announced that its Senior Vice President and Chief Scientific Officer, Oreola Donini, PhD, delivered a presentation demonstrating the potency of the CiVax™ (COVID-19 vaccine) development program in mice and non-human primates (NHPs), at the Annual Conference on Vaccinology Research, held April 26-27, 2021. To view this press release, please click here.
- On April 26, 2021, the Company announced that Ellen Kim, MD, Medical Director, Dermatology Clinic, Perelman Center for Advanced Medicine, Professor of Dermatology at the Hospital of the University of Pennsylvania, and the Lead Principal Investigator for the Phase 3 FLASH study, delivered a presentation at the American Academy of Dermatology Association Virtual Meeting Experience, held April 23-25, 2021, expanding on data related to the efficacy and safety of HyBryte™ in the treatment of CTCL. To view this press release, please click here.
- On April 7, 2021, the Company announced that the FDA had conditionally accepted HyBryte™ as the proposed brand name for SGX301 (synthetic hypericin), the Company's novel first-in-class photodynamic therapy for first-line treatment of early stage CTCL. To view this press release, please click here.
- On March 30, 2021, the Company announced its recent accomplishments and financial results for the year ended December 31, 2020. To view this press release, please click here.

Financial Results – Quarter Ended March 31, 2021

Soligenix's revenues for the quarter ended March 31, 2021 were $0.1 million as compared to $0.9 million for the quarter ended March 31, 2020. Revenues included payments on a contract in support of RiVax®, our ricin toxin vaccine candidate, and grants received to support the development of: SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases; ThermoVax®, our thermostabilization technology; and CiVax™, our vaccine candidate for the prevention of COVID-19.

Soligenix's basic net loss was $2.4 million, or ($0.06) per share, for the quarter ended March 31, 2021, as compared to $7.6 million, or ($0.32) per share, for the quarter ended March 31, 2020. This decrease in net loss was primarily due to a $5.0 million success milestone due to Hy Biopharma that was paid 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 Inc. during the three months ended March 31, 2020.

Research and development expenses were $1.4 million as compared to $2.7 million for the quarters ended March 31, 2021 and 2020, respectively. The decrease in research and development spending for the quarter ended March 31, 2021 was primarily attributable to the reduction in expense due to the completion of the HyBryte™ and SGX942 clinical trials.

General and administrative expenses were $0.9 million for both the three months ended March 31, 2021 and 2020.

As of March 31, 2021, the Company's cash position was approximately $30.5 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 HyBryte™ (SGX301 or 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 HyBryte™ (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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