Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And First Quarter 2023 Financial Results

PRINCETON, N.J., May 15, 2023 /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, 2023.

"We recently completed a public offering with gross proceeds of approximately $8.5 million, which will allow us to continue to move our rare disease pipeline forward," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Recently we announced positive clinical results from a compatibility study evaluating HyBryte™ (synthetic hypericin sodium) in the treatment of cutaneous T-cell lymphoma (CTCL). The purpose of the study was to establish that any light device capable of producing visible light of an appropriate and consistent wavelength (500 to 650 nm) was suitable for use with HyBryte™ and to extend the pharmacokinetic profile using a recently developed, more sensitive hypericin assay. Additionally, the United States (U.S.) Food and Drug Administration (FDA) has granted our Type A Meeting request to initiate formal discussions regarding the design of a second, confirmatory Phase 3 pivotal study evaluating HyBryte™ in the treatment of early stage CTCL, where it has successfully demonstrated statistically significant results in the first Phase 3 clinical trial. We also continue to evaluate synthetic hypericin (SGX302) in mild-to-moderate psoriasis where we anticipate the clinical study results in the second half of 2023."

Dr. Schaber continued, "From a business strategy perspective, we recently announced two important additions. We entered into an exclusive option agreement with Silk Road Therapeutics, a privately-held company, pursuant to which we have the right to evaluate and acquire a novel topical formulation of Pentoxifylline (PTX), a non-biological anti-TNF-alpha inhibitor, for the treatment of mucocutaneous ulcers in patient's suffering from Behçet's Disease (BD). This has the potential to expand our already robust rare disease pipeline. We also added Timothy R. Coté, MD, to our Board of Directors. Dr. Coté comes with extensive regulatory and orphan drug development expertise, having served as the Director of the FDA Office of Orphan Products Development where he implemented the U.S. Orphan Drug Act and personally signed decisions on more than 1,400 orphan drug designation applications. With approximately $10.3 million in cash at March 31, 2023, not including our non-dilutive government funding and the recent financing, which increases are partially offset by the recent $5.0 repayment under our credit facility, we continue to manage cash burn very carefully to achieve our near-term milestones, as we continue to assess all strategic options, including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On May 11, 2023, the Company announced the U.S. FDA had granted our Type A meeting request to discuss the design of a second, Phase 3 pivotal study evaluating HyBryte™ in the treatment of early stage CTCL. To view this press release, please click here.
- On May 9, 2023, the Company announced the closing of its public offering of 6,538,500 shares of common stock (or common stock equivalents in lieu thereof) and warrants to purchase up to 6,538,500 shares of common stock at a combined public offering price of $1.30 per share and accompanying warrant having a $1.50 per share exercise price for aggregate gross proceeds of approximately $8.5 million, before deducting placement agent fees and other offering expenses. To view this press release, please click here.
- On May 4, 2023, the Company announced positive clinical results from a compatibility study evaluating HyBryte™ in the treatment of CTCL using the commercially ready Daavlin Series 7 visible light device. To view this press release, please click here.
- On May 3, 2023, the Company announced the appointment of Timothy R. Coté, M.D., M.P.H. to its Board of Directors. To view this press release, please click here.
- On May 1, 2023, the Company announced that it had entered into an exclusive option agreement with Silk Road Therapeutics, a privately-held company. To view this press release, please click here.
- On April 14, 2023, the Company announced the outcome of the Type A Meeting with the U.S. FDA to discuss the contents of a refusal to file letter previously issued for its new drug application for HyBryte™ in the treatment of early stage CTCL. To view this press release, please click here.

Financial Results – Quarter Ended March 31, 2023

Soligenix's revenues for the quarter ended March 31, 2023 were $0.3 million as compared to $0.2 million for the quarter ended March 31, 2022. Revenues primarily relate to third party licensing and the government contracts and grants awarded in support of RiVax®, its ricin toxin vaccine candidate; SGX943, its therapeutic candidate for treatment of emerging and/or antibiotic-resistant infectious diseases; and CiVax™, its vaccine candidate for the prevention of COVID-19.

Soligenix's net loss was $1.0 million, or ($0.36) per share, for the quarter ended March 31, 2023, as compared to $4.3 million, or ($1.52) per share, for the quarter ended March 31, 2022. The decrease in net loss was primarily due to a decrease in operating expenses in addition to the recognition of an income tax benefit resulting from the sale of its 2021 net operating loss (NOL) carryforwards during the three months ended March 31, 2023.

Research and development expenses were $0.9 million as compared to $1.7 million for the quarters ended March 31, 2023 and 2022, respectively. The decrease was primarily due to the decrease in costs associated with the Oral Mucositis Phase 3 clinical trial as well as a decrease in manufacturing costs associated with the HyBryte™ NDA filing.

General and administrative expenses were $1.2 million and $2.5 million for the quarters ended March 31, 2023 and 2022, respectively. This decrease in general and administrative expenses is primarily attributable to a reduction in legal and consulting expenses associated with the arbitration against Emergent and certain of its subsidiaries.

As of March 31, 2023, the Company's cash position was approximately $10.3 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 and moving toward potential commercialization of HyBryte™ (SGX301 or synthetic hypericin sodium) 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 expansion of synthetic hypericin (SGX302) into psoriasis, 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).

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 https://www.soligenix.com and follow us on LinkedIn and Twitter at @Soligenix_Inc.

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. The Company cannot offer assurances that the FDA will agree to the proposed design of a second, Phase 3 pivotal study evaluating HyBryte™ (hypericin sodium) in the treatment of early stage cutaneous T-cell lymphoma; that, if accepted, the Company will conduct the trial; or that, if the Company conducts the trial, the trial will be successful. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 1/2 proof-of-concept clinical trial of SGX302 for the treatment of psoriasis, there can be no assurance as to the timing or success of the clinical trials of SGX302 for the treatment of psoriasis. 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. HyBryte™ potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this information. While the Company has determined this potential market size based on assumptions that it believes are reasonable, there are a number of factors that could cause expectations to change or not be realized. 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.

SOURCE Soligenix, Inc.

For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200 | www.soligenix.com

---