Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Third Quarter 2023 Financial Results

PRINCETON, N.J., Nov. 13, 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 September 30, 2023.

"We continue our collaborative discussions with the U.S. Food and Drug Administration (FDA) regarding the design of a second, confirmatory Phase 3 pivotal study evaluating HyBryte™ (synthetic hypericin sodium) in the treatment of cutaneous T-cell lymphoma (CTCL), where we successfully demonstrated statistically significant results in the first Phase 3 clinical trial," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We continue to actively enroll patients in the Phase 2a trial of SGX302 (synthetic hypericin sodium) for the treatment of mild-to-moderate psoriasis after demonstration of a clear biological signal in all five of the initial patients, with the majority recording an improvement in their PASI (psoriasis area and severity index) score. Under our Public Health Solutions business segment, we continue to advance our heat stable vaccine platform technology, ThermoVax®. Most recently, we successfully demonstrated two year stability of thermostabilized bivalent and trivalent filovirus vaccine candidates at temperatures of 40 degrees Celsius (104 degrees Fahrenheit) when formulated in a single vial, needing reconstitution only with sterile water immediately prior to use. This follows the previous successful demonstration of 100% protection of non-human primates against lethal Sudan ebolavirus and Marburg marburgvirus challenge with the bivalent vaccine."

Dr. Schaber continued, "With approximately $10.3 million in cash at September 30, 2023, not including our non-dilutive government funding, we are managing cash burn very carefully in order to achieve our near-term milestones. We continue to evaluate a number of strategic options, including but not limited to, partnership and merger and acquisition opportunities."

Financial Results – Quarter Ended September 30, 2023

Soligenix's revenues for the quarters ended September 30, 2023 were $0.1 million as compared to $0.2 million for the quarter ended September 30, 2022. Revenues primarily relate to government contracts and grants awarded in support of SGX943, our therapeutic candidate for treatment of emerging and/or antibiotic-resistant infectious diseases; and CiVax™, our vaccine candidate for the prevention of COVID-19.

Soligenix's net loss was $1.7 million, or ($0.16) per share, for the quarter ended September 30, 2023, as compared to $3.3 million, or ($1.15) per share, for the quarter ended September 30, 2022. The decrease in net loss was primarily due to decreases in operating expenses and interest expense and an increase in other income.

Research and development expenses were $0.8 million as compared to $1.8 million for the quarters ended September 30, 2023 and 2022, respectively. The decrease was primarily due to the decrease in manufacturing and regulatory costs associated with the HyBryte™ new drug application filing.

General and administrative expenses were $1.0 million and $1.3 million for the quarters ended September 30, 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 BioSolutions, Inc. and certain of its subsidiaries.

As of September 30, 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, as well as 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, and include the expected amount and use of proceeds from the offering and the expected closing date of the offering. 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. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 2a 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. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission (the "SEC"), including, but not limited to, the Company's preliminary prospectus (Registration No. 333-271049) filed with the SEC on May 4, 2023, and 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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For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200
