Soligenix Investor Relations

Soligenix Announces Recent Accomplishments and Year End 2023 Financial Results

PRINCETON, N.J., March 15, 2024 /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, 2023.

"Our primary focus in 2024 continues to be advancing our multiple clinical programs in our rare disease pipeline," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Our collaborative discussions continue with the U.S. Food and Drug Administration (FDA) regarding the design of a second, confirmatory Phase 3 pivotal study evaluating HyBryte™ (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL), where we successfully demonstrated statistically significant results in the first Phase 3 clinical trial. We also continue to engage in discussions with the European Medicines Agency to explore potential marketing approval and partnership in Europe. Recently, we shared successful preliminary top-line results of our ongoing Phase 2a clinical trial of SGX302 (synthetic hypericin) for the treatment of mild-to-moderate psoriasis. Following the clearance of the Investigational New Drug (IND) application for a Phase 2a clinical trial with SGX945 (dusquetide) in Behçet's Disease and the recent receipt of "Fast Track" designation from the FDA, we anticipate initiating this study in the second half of 2024. Under our Public Health Solutions business segment, we recently announced publication of the preclinical efficacy of a novel, single-vial, bivalent vaccine providing 100% protection against both *Sudan ebolavirus* (SUDV) and *Marburg marburgvirus* (MARV) infections. The published paper describes the potency of the bivalent formulation against both lethal viruses, demonstrating 100% protection in the most rigorous non-human primate (NHP) challenge models."

Dr. Schaber continued, "With approximately $8.4 million in cash at December 31, 2023, not including our non-dilutive government funding, we are managing cash burn very carefully in order to achieve our near-term milestones. We recently received $0.6 million, net of transaction costs, from the state ofNew Jersey's (NJ) Technology Business Tax Certificate Transfer Program. This is our fourteenth year participating in the program, over that time we have received approximately $9.4 million in non-dilutive capital. We continue to evaluate a number of strategic options, including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On February 8, 2024, the Company announced the formation of a Medical Advisory Board to provide medical/clinical strategic guidance to the Company as it advances the clinical development of SGX945 (dusquetide) for the treatment of Behçet's Disease. To view this press release, please click here.
- On January 8, 2024, the Company announced its SGX945 development program for the treatment of oral lesions of Behçet's Disease has received "Fast Track" designation from the FDA. To view this press release, please click here.
- On January 4, 2024, the Company announced positive preliminary top-line results of its ongoing Phase 2a trial of SGX302 for the treatment of mild-to-moderate psoriasis. To view this press release, please click here.
- On January 2, 2024, the Company announced publication describing the preclinical efficacy of a novel, single-vial, bivalent vaccine providing 100% protection against both SUDV and MARV infections in NHP models. This vaccine candidate had been previously demonstrated to be stable to high temperature storage for at least 2 years at 40 degrees Celsius (104 degrees Fahrenheit). To view this press release, please click here.
- On December 1, 2023, the Company announced publication of an article describing the potential use of HyBryte™ in the treatment of CTCL in *Frontiers in Drug Discovery*. To view this press release, please clickhere.
- On November 30, 2023, the Company announced the FDA had cleared the IND application for a Phase 2a clinical trial entitled, "*Pilot Study of SGX945 (Dusquetide) in the Treatment of Aphthous Ulcers in Behçet's Disease*" To view this press release, please click here.

Financial Results – Year Ended December 31, 2023

Soligenix's revenues for the year ended December 31, 2023 was $0.8 million as compared to $0.9 million for the year ended December 31, 2022. Revenues primarily relate to government contracts and grants awarded in support of HyBryte™, our therapeutic candidate for early-stage CTCL; 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 $6.1 million, or ($0.79) per share, for the year endedDecember 31, 2023, as compared to $13.8 million, or ($4.81) per share, for the year endedDecember 31, 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 $3.3 million as compared to $7.9 million for the years ended December 31, 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 $4.5 million and $6.7 million for the years ended December 31, 2023 and 2022,

respectively. This decrease in general and administrative expenses is primarily attributable to a reduction in legal and consulting expenses.

As of December 31, 2023, the Company's cash position was approximately$8.4 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 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). Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, and our first-in-class innate defense regulator (IDR) technology, dusquetide for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer (SGX942) and in Behçet's Disease (SGX945).

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, Sudan 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 athttps://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. Despite the positive efficacy results demonstrated in the Phase 2 and 3 clinical studies of SGX942 for the treatment of oral mucositis due to chemoradiation therapy for head and neck cancer, there can be no assurance as to the timing or success of the clinical trials of SGX945 for the treatment of Behçet's Disease. 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, 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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