Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And First Quarter 2024 Financial Results

PRINCETON, N.J., May 10, 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 quarter ended March 31, 2024.

"Recently we completed a public offering with gross proceeds of approximately$4.75 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. "While we continue our ongoing discussions with the United States (U.S.) Food and Drug Administration (FDA), we shared that the European Medicines Agency (EMA) has agreed to the study design of a confirmatory Phase 3 placebo-controlled study evaluating the safety and efficacy of HyBryte™ (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL) patients with early-stage disease. This study will enroll approximately 80 patients across the U.S. and Europe, starting before the end of 2024, with top-line results expected in the second half of 2026. We also will be initiating a Phase 2 study with SGX945 (dusquetide) in Behçet's disease later this year with top-line results expected in the first half of 2025, along with top-line results expected during the same timeframe from our ongoing SGX302 (synthetic hypericin) Phase 2 study in mild-to-moderate psoriasis. Additionally, we were recently granted orphan drug designations from the FDA's Office of Orphan Products Development for the active ingredients in both SuVax™, for "the prevention and post-exposure prophylaxis against Sudan ebolavirus (SUDV) infection and MarVax™, for "the prevention and post-exposure prophylaxis against Marburg marburgvirus (MARV) infection."

Dr. Schaber continued, "With approximately $7.1 million in cash atMarch 31, 2024, exclusive of the approximate$4.3 million in net proceeds from our recent financing and our non-dilutive government funding, we continue to manage cash burn very carefully to achieve our near-term milestones. We have a clear vision for the future, and we are actively pursuing new opportunities to create long-term value for our shareholders including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On April 25, 2024, the Company announced it had received notice of intent to grant additional patents based on its patent application titled "Compositions and Methods of Manufacturing Trivalent Filovirus Vaccines" in the United Kingdom and South Africa, with other international jurisdictions pending. To view this press release, please clickhere.
- On April 18, 2024, the Company announced the pricing of its public offering of 11,875,000 shares of common stock (or common stock equivalents in lieu thereof) and warrants to purchase up to 11,875,000 shares of common stock at a combined public offering price of $0.40 per share and accompanying warrants for aggregate gross proceeds of approximately $4.75 million, before deducting placement agent fees and other offering expenses. To view this press release, please click here.
- On April 15, 2024, the Company announced the Office of Orphan Products Development of the U.S. FDA had granted orphan drug designation to the active ingredient in SuVax™, the subunit protein vaccine of recombinantly expressed SUDV glycoprotein, for "the prevention and post-exposure prophylaxis against SUDV infection." To view this press release, please click here.
- On April 11, 2024, the Company announced the Office of Orphan Products Development of the U.S. FDA had granted orphan drug designation to the active ingredient in MarVax™, the subunit protein vaccine of recombinantly expressed MARV glycoprotein, for "the prevention and post-exposure prophylaxis against MARV infection." To view this press release, please click here.
- On April 3, 2024, the Company announced it had received agreement from the EMA on the key design components of a confirmatory Phase 3 placebo-controlled study evaluating the safety and efficacy of HyBryte™ (synthetic hypericin) in the treatment of CTCL patients with early-stage disease. To view this press release, please click here.

Financial Results – Quarter Ended March 31, 2024

Soligenix's revenues for the quarter ended March 31, 2024 were $0.1 million as compared to $0.3 million for the quarter ended March 31, 2023. Revenues primarily relate to government contracts and grants awarded in support of SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases; development of CiVax™, our vaccine candidate for the prevention of COVID-19, and evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL.

Soligenix's net loss was $1.9 million, or ($0.18) per share, for the quarter endedMarch 31, 2024, as compared to $1.0 million, or ($0.36) per share, for the quarter endedMarch 31, 2023. The increase in net loss was primarily due to the recognition of an income tax benefit during the three months ended March 31, 2023 with no corresponding income tax benefit recognized during the three months ended March 31, 2024.

Research and development expenses were $1.1 million as compared to $0.9 million for the quarters ended March 31, 2024 and 2023, respectively. The increase was primarily due to an increase in preliminary costs associated with the anticipated initiation of our Phase 2 study in Behçet's Disease and the second confirmatory Phase 3 CTCL trial.

General and administrative expenses were $1.0 million and $1.2 million for the quarters ended March 31, 2024 and 2023, respectively. This decrease in general and administrative expenses is primarily attributable to a reduction in legal and professional fees associated with the reverse stock split of our issued and outstanding shares of common stock during the three months ended March 31, 2023.

As of March 31, 2024, the Company's cash position, exclusive of the approximate$4.3 million in net proceeds from our recent financing, was approximately $7.1 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 successful completion of the second Phase 3 study, regulatory approvals will be sought to support potential commercialization worldwide. 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 (SGX945) in Behçet's Disease.

Our Public Health Solutions business segment includes 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 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 first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that the second HyBryte™ (SGX301) Phase 3 clinical trial will be successful or that a marketing authorization from the FDA or EMA will be granted. Additionally, although the EMA has agreed to the key design components of the second HyBryte™ (SGX301) Phase 3 clinical trial, no assurance can be given that the Company will be able to modify the development path to adequately address the FDA's concerns or that the FDA will not require a longer duration comparative study. Notwithstanding the result in the first 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, 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.

SOURCE SOLIGENIX, INC.

For further information: Jonathan Guarino, CPA, CGMA | Senior Vice President and Chief Financial Officer | (609) 538-8200 | www.soligenix.com | Soligenix, Inc. | 29 Emmons Drive, Suite B-10 | Princeton, NJ 08540
