Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Third Quarter 2022 Financial Results

PRINCETON, N.J., Nov. 10, 2022 /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, 2022.

"We have continued to achieve significant milestones across our development pipeline in 2022. The most important is still to come this quarter with the filing of our new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for HyBryte™ (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL)," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We were also pleased with the FDA Orphan Products Development grant award of a $2.6 million over 4 years to support the evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL, including in the home setting. Additionally, we are advancing synthetic hypericin development into other disease indications, such as psoriasis, where we plan to work in conjunction with our recently established Medical Advisory Board (MAB) to initiate a Phase 2a clinical study for the treatment of mild-to-moderate psoriasis in December.

Supported by funding from the National Institute of Allergy and Infectious Diseases, we were able to demonstrate 100% protection of non-human primates against both lethal *Sudan ebolavirus* and *Marburg marburgvirus* challenge with our SuVax™ and MarVax™ vaccines, respectively. With the achievement of these important milestones, we were fortunate to receive an invitation by the Biomedical Advanced Research and Development Authority (BARDA) Division of Chemical, Biological, Radiological and Nuclear (CBRN) Medical Countermeasures to submit a full contract proposal for the further development of these novel vaccine candidates as medical countermeasures for use in the event of a *Sudan ebolavirus* or *Marburg marburgvirus* outbreak. While an invitation to submit a contract proposal is not a guarantee of funding, we believe that we are well-positioned to receive BARDA development support for this indication allowing us to further demonstrate the growing body of compelling scientific evidence supporting our heat stable filovirus vaccine platform, including vaccine candidates directed towards *Sudan ebolavirus* and *Marburg marburgvirus*."

Dr. Schaber continued, "With approximately $16.9 million in cash, not including our non-dilutive government funding, we anticipate having the necessary capital to achieve our near-term milestones, as we continue to assess various strategic options, including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On October 27, 2022, the Company announced it had been invited by BARDA Division of CBRN Medical Countermeasures to submit a full contract proposal for the development of single-vial, adjuvanted, heat stable subunit vaccines to prevent filovirus infection. To view this press release, please click here.
- On October 25, 2022, the Company announced the formation of a MAB to provide medical/clinical strategic guidance to the Company as it advances the Phase 2a clinical development of SGX302 (synthetic hypericin) for the treatment of mild-to-moderate psoriasis. To view this press release, please click here.
- On September 6, 2022, the Company announced the FDA had awarded an Orphan Products Development grant to support the evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL. To view this press release, please click here.

Financial Results – Quarter Ended September 30, 2022

Soligenix's revenues were $0.2 million for the quarter ended September 30, 2022 and 2021, respectively. Revenues primarily relate to third party licensing and the government contracts and grants awarded in support of RiVax®, its ricin toxin vaccine candidate; SGX943, for treatment of emerging and/or antibiotic-resistant infectious diseases; ThermoVax®, its thermostabilization platform technology; and CiVax™, its vaccine candidate for the prevention of COVID-19.

Soligenix's net loss was $3.3 million, or ($0.08) per share, for the quarter ended September 30, 2022, as compared to $3.6 million, or ($0.09) per share, for the three months ended September 30, 2021. The decrease in net loss was primarily attributed to decrease in research and development expenses partially offset by an increase in legal and consulting expenses associated with the arbitration against Emergent BioSolutions, Inc. (EBS) and certain of its subsidiaries.

Research and development expenses were $1.9 million as compared to $2.2 million for the quarter ended September 30, 2022 and 2021, respectively. The decrease in research and development spending for the quarter ended September 30, 2022 was primarily attributable to the completion of the oral mucositis Phase 3 clinical trial.

General and administrative expenses were $1.2 million and $1.1 million for the quarter ended September 30, 2022 and 2021, respectively. This increase in general and administrative expenses is primarily attributable to an increase in expenses associated with the 2022 Annual Shareholder Meeting as well as increased expenses associated with the commercialization of HyBryte™.

As of September 30, 2022, the Company's cash position was approximately $16.9 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 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. 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. 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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