Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Second Quarter 2022 Financial Results

PRINCETON, N.J., Aug. 12, 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 June 30, 2022.

"We have accomplished a number of important milestones thus far in 2022, with more significant milestones anticipated before year-end," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Under our Specialized Biotherapeutics business segment, the results of our successful Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study evaluating HyBryte™ (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma (CTCL) were published in the prestigious JAMA Dermatology. We received agreement from the U.S. Food & Drug Administration (FDA) on an initial pediatric study plan for HyBryte™ which stipulates our intention to request a full waiver of pediatric studies upon submission of the HyBryte™ new drug application (NDA) in the fourth quarter of this year. Additionally, we are expanding into new disease indications with synthetic hypericin (SGX302) having received FDA investigational new drug (IND) clearance for a Phase 2a clinical trial in mild-to-moderate psoriasis, also expected to begin in the fourth quarter of this year.

Our Public Health Solutions business segment, supported by funding from the National Institute of Allergy and Infectious Diseases, continues to achieve key objectives that have the potential to play an important role in the Biden-Harris Administration's initiatives for pandemic preparedness. Recently, we demonstrated 100% protection of non-human primates against both lethal *Sudan ebolavirus* and *Marburg marburgvirus* challenge using a bivalent, thermostabilized vaccine formulated in a single vial. This same heat stable subunit vaccine platform technology has been applied to the development of our COVID-19 vaccine, CiVax™, which has demonstrated rapid and broadly functional vaccine and booster responses, including against delta and omicron variants. We also entered into a strategic partnership with SERB Pharmaceuticals to supply our novel ricin antigen in support of their early stage ricin therapeutic development program."

Dr. Schaber continued, "With approximately $20.2 million in cash, not including our non-dilutive government funding, we anticipate having the capital required to achieve our near-term milestones, including NDA filing and initiation of the Phase 2a psoriasis study, while we continue to evaluate various strategic options, including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On July 27, 2022, the Company announced it had received agreement from the FDA on an initial pediatric study plan for HyBryte™ for the treatment of CTCL. To view this press release, please click here.
- On July 25, 2022, the Company announced it had signed a worldwide exclusive license to supply its ricin antigen to SERB Pharmaceuticals, for development of a novel therapeutic treatment against ricin toxin poisoning. To view this press release, please click here.
- On July 20, 2022, the Company announced that the results of its successful Phase 3 FLASH study evaluating HyBryte™ for the treatment of CTCL has been published in the Journal of the American Medical Association (JAMA) Dermatology. To view this press release, please click here.
- On June 28, 2022, the Company announced that the FDA had cleared the IND application for its Phase 2a clinical trial titled, "Phase 2 Study Evaluating SGX302 in the Treatment of Mild-to-Moderate Psoriasis." To view this press release, please click here.
- On June 23, 2022, the Company announced it had achieved 100% protection of non-human primates against lethal *Marburg marburgvirus* challenge using a bivalent, thermostabilized vaccine formulated in a single vial, reconstituted only with sterile water immediately prior to use. To view this press release, please click here.
- On June 1, 2022, the Company announced a publication describing key binding characteristics of its Innate Defense Regulator, dusquetide, to the p62 protein. To view this press release, please click here.
- On May 23, 2022, the Company announced the United States Patent and Trademark Office had issued a Notice of Allowance for the patent application titled "Compositions and Methods of Manufacturing Trivalent

Filovirus Vaccines." To view this press release, please click here.

Financial Results – Year Ended June 30, 2022

Soligenix's revenues for the quarter ended June 30, 2022 were $0.4 million as compared to $0.2 million for the quarter ended June 30, 2021. Revenues primarily included licensing revenue from the Company's strategic partnership with SERB Pharmaceuticals and payments on government contracts and grants. The Company has received government funding to support the development 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 basic net loss was $2.4 million, or ($0.06) per share, for the quarter ended June 30, 2022, as compared to $1.9 million, or ($0.05) per share, for the three months ended June 30, 2021. The increase in net loss was primarily attributed to an increase in legal and consulting services associated with the arbitration against Emergent BioSolutions, Inc. and certain of its subsidiaries as well as an increase in research and development expenses associated with preparation of the upcoming HyBryte™ NDA filing.

Research and development expenses were $2.0 million as compared to $1.9 million for the quarter ended June 30, 2022 and 2021, respectively. The increase in research and development spending for the quarter ended June 30, 2022 was primarily attributable to the increased expenses associated with preparation of the upcoming HyBryte™ NDA filing.

General and administrative expenses were $1.4 million and $1.1 million for the quarter ended June 30, 2022 and 2021, respectively. This increase in general and administrative expenses is primarily attributable to an increase in legal and consulting services associated with the arbitration against Emergent BioSolutions, Inc. and certain of its subsidiaries.

As of June 30, 2022, the Company's cash position was approximately $20.2 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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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
