Soligenix Investor Relations

## Soligenix Announces Recent Accomplishments And Year-End 2022 Financial Results

PRINCETON, N.J., March 31, 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 year ended December 31, 2022.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "2023 will be another important year for Soligenix. We are preparing for a Type A Meeting with the United States (U.S.) Food and Drug Administration (FDA) to discuss the contents of a refusal to file (RTF) letter issued by the FDA in response to the Company's new drug application (NDA) for HyBryte™ (synthetic hypericin) submitted in December 2022. The Type A meeting with the FDA will provide clarity regarding the issues raised in the RTF letter with respect to the NDA for HyBryte™ in the treatment of early stage cutaneous T-cell lymphoma (CTCL), a rare cancer, which has successfully demonstrated statistically significant results in a Phase 3 clinical trial. In addition to HyBryte™, we have expanded synthetic hypericin's (SGX302) development into mild-to-moderate psoriasis where we have begun patient enrollment in a Phase 2a study. We anticipate the clinical study results in the second half of 2023.

With approximately $13.4 million in cash at year end, not including our non-dilutive government funding, we continue to manage cash burn very carefully to achieve our near-term milestones, as we continue to assess all strategic options, including but not limited to, partnership and merger and acquisition opportunities."

**Soligenix Recent Accomplishments**

- On March 9, 2023, the Company announced it had submitted a Type A meeting request to the U.S. FDA to discuss the contents of a RTF letter previously issued by the FDA regarding the Company's NDA for HyBryte™ (synthetic hypericin) in the treatment of early stage CTCL. To view this press release, please click here.
- On February 14, 2023, the Company announced that the U.S. FDA had provided the Company with a RTF letter for its HyBryte™ NDA in the treatment of early stage CTCL. To view this press release, please click here.
- On February 9, 2023, the Company announced that it intended to effect a reverse stock split of its common stock at a ratio of 1 post-split share for every 15 pre-split shares. To view this press release, please click here.
- On December 23, 2022, the Company announced its Board of Directors declared a dividend of one one-thousandth of a share of newly designated Series D Preferred Stock, par value $0.001 per share, for each outstanding share of the Company's common stock held of record as of 5:00 p.m. Eastern Standard Time on January 3, 2023. To view this press release, please click here.
- On December 20, 2022, the Company announced publication of preclinical immunogenicity challenge studies for RiVax® demonstrating statistically significant correlates of protection predicting survival after lethal aerosolized ricin challenge in non-human primates (NHPs). The article titled "Serum antibody profiling identifies vaccine-induced correlates of protection against aerosolized ricin toxin in rhesus macaques" has been accepted for publication in the journal npj Vaccines (available here). To view this press release, please click here.
- On December 19, 2022, the Company announced patient enrollment had been opened for its Phase 2a study (protocol number HPN-PSR-01) evaluating SGX302 (synthetic hypericin) in the treatment of mild-to-moderate psoriasis. To view this press release, please click here.
- On December 15, 2022, the Company announced it submitted a NDA to the U.S. FDA for HyBryte™ (synthetic hypericin) in the treatment of early stage CTCL, a rare cancer and area of unmet medical need affecting over 25,000 patients in the U.S. To view this press release, please click here.
- On November 15, 2022, the Company announced it had received preliminary approval for a tax credit from the New Jersey Economic Development Authority's (NJEDA) New Jersey Technology Business Tax Certificate Transfer program. As a result, the Company received approximately $1.2 million in net proceeds. To view this press release, please click here.

**Financial Results – Year Ended December 31, 2022**

Soligenix's revenues for the year ended December 31, 2022 were $0.9 million as compared to $0.8 million for the year ended December 31, 2021. 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; and CiVax™, its vaccine candidate for the prevention of COVID-19.

Soligenix's net loss was $13.8 million, or ($4.81) per share, for the year ended December 31, 2022, as compared to $12.6

million, or ($4.69) per share, for the year ended December 31, 2021. The increase in net loss is primarily attributed to an increase in legal and consulting expenses associated with the arbitration against Emergent as well as no gain on forgiveness of the loan under the Paycheck Protection Program (PPP) in 2022.

Research and development expenses were $7.9 million as compared to $8.2 million for the year ended December 31, 2022 and 2021, respectively. The decrease in research and development spending for the year ended December 31, 2022 was related to the conclusion of the CTCL and oral mucositis Phase 3 studies in 2021.

General and administrative expenses were $6.7 million and $5.0 million for the year ended December 31, 2022 and 2021, respectively. This increase in general and administrative expenses is primarily related to an increase in legal and consulting expenses associated with the arbitration against Emergent.

As of December 31, 2022, the Company's cash position was approximately $13.4 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). 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. HyBryte™ potential market information is a forward-looking statement, and investors are urged not to place undue

reliance on this information. While the Company has determined this potential market size based on assumptions that it believes are reasonable, there are a number of factors that could cause expectations to change or not be realized. 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.

SOURCE Soligenix, Inc.

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