Soligenix Announces Recent Accomplishments And First Quarter 2018 Financial Results

PRINCETON, NJ - May 11, 2018 - 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 first quarter ended March 31, 2018.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We are actively enrolling patients in our pivotal double-blind, placebo-controlled, multinational Phase 3 clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy, and expect final results in the second half of 2019. We also continue to actively enroll patients in our pivotal double-blind, placebo-controlled Phase 3 study for the treatment of cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin), where we expect an interim analysis in the second half of 2018 and expect final results in the first half of 2019."

Dr. Schaber continued, "We have been fortunate to secure non-dilutive funding from various government sources, allowing us to advance multiple development programs across our biodefense and biotherapeutics pipelines. For the first quarter of 2018, our combined revenues from both our business segments were \$1.1 million and we expect this non-dilutive government funding to continue throughout 2018 and beyond."

Soligenix Recent Accomplishments:

- On March 22, 2018, the Company announced the European Commission, acting on the positive recommendation from the European Medicines Agency (EMA) Committee for Orphan Medicinal Products, had granted orphan drug designation to the Company's recombinant modified ricin toxin A-chain subunit (the active pharmaceutical ingredient in RiVax®) for the prevention of ricin poisoning. RiVax® has previously been granted orphan drug designation from the US Food and Drug Administration (FDA).
- On January 25, 2018, the Company issued an update letter from Dr. Schaber. This letter summarized our progress and accomplishments during 2017 as well as provided further guidance on the development programs for 2018.
- On January 2, 2018, the Company announced that the United States (US) Patent and Trademark Office had granted the patent titled "Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis." The newly issued patent claims therapeutic use of dusquetide (active ingredient in SGX942) and related innate defense regulator analogs, and adds to composition of matter claims for dusquetide and related analogs that have been granted in the US and worldwide. Dusquetide previously demonstrated positive results in a Phase 2 oral mucositis clinical trial and a pivotal Phase 3 study was initiated in 2017.

Financial Results - First Quarter Ended March 31, 2018

Soligenix's revenues for the quarter ended March 31, 2018 were \$1.1 million as compared to \$1.3 million for the quarter ended March 31, 2017. Revenues included contracts in support of RiVax®, in addition to the grants received to support the development of SGX301 for the treatment of CTCL and SGX942 for the treatment of oral mucositis in head and neck cancer, as well as the subaward from the Ebola collaboration with the University of Hawaii.

Soligenix's basic net loss was \$2.4 million, or (\$0.27) per share, for the quarter ended March 31, 2018 as compared to \$1.7 million, or (\$0.32) per share, for the quarter ended March 31, 2017.

Research and development expenses were \$1.8 million as compared to \$1.2 million for the quarters ended March 31, 2018 and 2017, respectively. The increase is primarily related to expenditures incurred in the Phase 3 clinical trial of SGX942 and the ongoing Phase 3 clinical trial of SGX301.

General and administrative expenses were \$0.7 million as compared to \$0.8 million for the quarters ended March 31, 2018 and 2017, respectively.

As of March 31, 2018, the Company's cash position was \$6.4 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 BioTherapeutics business segment is developing SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment

of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Vaccines/BioDefense business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome therapeutic candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. 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) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website at <u>www.soligenix.com</u>.

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. 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 US 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 US 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 the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. 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 nondilutive 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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