Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Third Quarter 2018 Financial Results

PRINCETON, NJ – November 9, 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 third quarter ended September 30, 2018.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "Our primary focus remains the quality execution of our two pivotal Phase 3 clinical programs. Following the positive recommendation recently received from the independent Data Monitoring Committee (DMC), we continue to enroll patients in our double-blind, placebo-controlled Phase 3 study for the treatment of cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin). With this new level of clarity from the DMC's analysis of the interim Phase 3 study data, we expect to complete the study before the end of 2019 with topline results coming no later than the first quarter of 2020. Additionally, we are actively enrolling patients in our 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 (HNC) receiving chemoradiation therapy. We currently anticipate final results for this pivotal study in the second 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 third quarter of 2018, our combined revenues from both our business segments were $1.4 million, and we expect this non-dilutive government funding to continue throughout the remainder of 2018 and beyond."

Soligenix Recent Accomplishments:

- On October 15, 2018, the Company announced it had received a positive recommendation from the independent DMC to continue enrolling into the Company's Phase 3 "Fluorescent Light Activated Synthetic Hypericin" (FLASH) study for SGX301 (synthetic hypericin) in the treatment of CTCL. No safety concerns were reported by the DMC based on the interim analysis. To view this press release, please click here.
- On September 13, 2018, the Company announced that the National Institutes of Health (NIH) selected Soligenix's SGX942 (dusquetide) development program for the treatment of oral mucositis in HNC patients as a Small Business Innovation Research/Small Business Technology Transfer Commercialization Accelerator Program Phase II awardee for 2018-2019. To view this press release, please click here.
- On September 4, 2018, the Company announced publication of extended stability studies for RiVax® showing up to 100% protection in mice even after 12 months storage at 40 degrees Celsius (104 degrees Fahrenheit), as well as the identification of a potential *in vitro* stability indicating assay, critical to adequately confirming long-term shelf-life of the vaccine. The article, entitled "Thermal Stability and Epitope Integrity of a Lyophilized Ricin Toxin Subunit Vaccine", is published in the journal Vaccine online and is available here. To view this press release, please click here.
- On August 22, 2018, the Company announced that the United States Patent Office had granted the patent titled "Systems and Methods for Producing Synthetic Hypericin". The newly issued patent's claims are directed to a novel, highly purified form of synthetic hypericin manufactured through a unique proprietary process. Synthetic hypericin is the active pharmaceutical ingredient in SGX301, the Company's photodynamic therapy currently in a Phase 3 clinical trial for the treatment of CTCL. To view this press release, please click here.

Financial Results – Third Quarter Ended September 30, 2018

Soligenix's revenues for the quarter ended September 30, 2018 were $1.4 million as compared to $1.8 million for the quarter ended September 30, 2017. Revenues included payments on a contract 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 HNC, as well as the subaward from the Ebola collaboration with the University of Hawaii.

Soligenix's basic net loss was $1.9 million, or ($0.11) per share, for the quarter ended September 30, 2018 as compared to $1.0 million, or ($0.17) per share, for the quarter ended September 30, 2017.

Research and development expenses were $1.4 million as compared to $0.6 million for the quarters ended September 30, 2018 and 2017, respectively. The increase is primarily due to the expenditures incurred in the Phase 3 clinical trial of SGX942, including the expansion of the trial to select countries in Europe, as well as the ongoing Phase 3 clinical trial of SGX301.

General and administrative expenses were $0.7 million for the quarters ended September 30, 2018 and 2017.

As of September 30, 2018, the Company's cash position was $11.7 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 17,21-dipropionate (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 program 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 atwww.soligenix.com.

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 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®. 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.
