Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And First Quarter 2019 Financial Results

PRINCETON, NJ – May 14, 2019 – 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 March 31, 2019.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We have completed the approximate 90 subject enrollment necessary to support the interim efficacy analysis of our pivotal double-blind, placebo-controlled Phase 3 clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. This interim analysis, to be conducted by the independent Data Monitoring Committee (DMC) for the trial, is anticipated to occur in September 2019. We expect completion of full enrollment in the study in the second half of 2019, with final top-line results expected in the first half of 2020, pending the DMC recommendation."

Dr. Schaber continued, "Following the positive recommendation received from the independent DMC for our double-blind, placebo-controlled Phase 3 study for the treatment of cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin), we continue to enroll patients and anticipate completing study enrollment in the second half of 2019, with final top-line results in the first quarter of 2020."

Soligenix Recent Accomplishments:

- On April 23, 2019, the Company issued an update letter from Dr. Schaber. This letter provided an update as well as further guidance on the development programs for 2019. To view this press release, please click here.

- On April 18, 2019, the Company announced it had reached a significant milestone in the Phase 3 clinical study (the "DOM-INNATE" study) for SGX942 (dusquetide) in the treatment of oral mucositis in patients with head and neck cancer. Patient enrollment is sufficient to support the planned interim efficacy analysis by the independent DMC. In accordance with the clinical protocol, approximately 90 subjects have been enrolled into the study as required for the planned interim efficacy analysis. To view this press release, please click here.

- On April 15, 2019, the Company announced it had received approximately $611,000, net of transaction costs, in non-dilutive financing via the state of New Jersey's Technology Business Tax Certificate Transfer Program. To view this press release, please click here.

- On April 9, 2019, the Company announced that the Pediatric Committee of the European Medicines Agency agreed to the Company's Pediatric Investigation Plan (PIP) for SGX942 (dusquetide). It was also agreed that the Company may defer conducting the PIP until successful completion of its ongoing pivotal Phase 3 clinical study evaluating SGX942 as a treatment for oral mucositis in patients with

head and neck cancer. To view this press release, please click here.

- On April 4, 2019, the Company announced that the US Patent Office would be issuing the patent titled "Novel Peptides for Treating and Preventing Immune-Related Disorders, Including Treating and Preventing Infection by Modulating Innate Immunity". The new patent (#10,253,068) claims composition of matter for novel innate defense regulator analogs, expanding patent protection to more diverse analog structures. Therapeutic use claims in oral mucositis, colitis, and infectious disease, both alone and in conjunction with antibiotics, will also issue. To view this press release, please click here.

Financial Results – First Quarter Ended March 31, 2019

Soligenix's revenues for the quarters ended March 31, 2019 and 2018 were each $1.1 million. 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 head and neck cancer, as well as the subaward from the Ebola collaboration with the University of Hawai'i at Mānoa.

Soligenix's basic net loss was $1.6 million, or ($0.09) per share for the quarter ended March 31, 2019, as compared to $2.4 million for the quarter ended March 31, 2018, or ($0.27) per share.

Research and development expenses were $1.6 million as compared to $1.8 million for the quarters ended March 31, 2019 and 2018, respectively. The decrease in research and development spending for the three months ended March 31, 2019 was primarily attributable to higher clinical trial site fees incurred during the period ended March 31, 2018 compared to the same period in 2019.

General and administrative expenses were $0.9 million as compared to $0.7 million for the quarters ended March 31, 2019 and 2018, respectively. This increase was primarily attributable to higher professional fees incurred during the period ended March 31, 2019.

As of March 31, 2019, the Company's cash position was approximately $7.2 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 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 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 https://www.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 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 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. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the PRV program or the amount for which a PRV for RiVax® can be sold. 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.
