Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Second Quarter 2017 Financial Results

PRINCETON, NJ – August 11, 2017 – 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 second quarter ended June 30, 2017.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We are pleased to initiate the pivotal Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer that incorporates feedback from both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), and that has the potential to support marketing approval in both the US and the European Union. In an effort to better maintain study quality and more effectively manage clinical expense, we intend to begin with a controlled roll-out of US study sites, followed by the addition of European centers in early 2018. This will allow us to first ensure protocol adherence in the US before expansion of the study to centers outside the US. We look forward to advancing this pivotal trial in an effort to address the significant unmet medical need that currently exists in this patient population."

Dr. Schaber continued, "We also continue to actively enroll patients in our pivotal Phase 3 study in cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin), in which we expect data in the first half of 2018. In our Vaccines/BioDefense business segment, we are encouraged by the continued support of the National Institute of Allergy and Infectious Diseases (NIAID) as we advance the development of RiVax®, our ricin toxin vaccine program."

Soligenix Recent Accomplishments:

- On July 27, 2017, the Company announced that patient enrollment has been opened for its Phase 3, multinational, randomized, double-blind, placebo-controlled study evaluating SGX942 (dusquetide) as a treatment for severe oral mucositis in patients with head and neck cancer receiving chemoradiation therapy (CRT). The trial, referred to as the "DOM–INNATE" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity), incorporates feedback from the FDA as well as from the EMA via the Scientific Advice process. The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, Phase 3 study, if successful, in conjunction with results from the Phase 2 dose-ranging study, generally will be considered sufficient to support a marketing authorization application for potential licensure in Europe.
- On June 21, 2017, the Company announced that NIAID, part of the National Institutes of Health, has exercised a $2M option to fund additional RiVax®animal efficacy studies. The overall objectives of the contract are to advance the development of Soligenix's thermostabilization technology, ThermoVax®, in combination with the Company's ricin toxin vaccine, RiVax®, as a medical countermeasure to prevent the effects of ricin exposure.
- On May 18, 2017, the Company announced that long-term follow-up data from its recent positive Phase 2 clinical trial, in which SGX942 (dusquetide) demonstrated a significant reduction in the median duration of severe oral mucositis in patients with head and neck cancer, have been published in the peer-reviewed journal *Biotechnology Reports*. These 12-month data further support the safety and tolerability of SGX942, with the 1.5 mg/kg treatment group demonstrating accelerated tumor resolution and a decreased (p=0.08) mortality rate relative to the placebo group. The results were published online and are available here.
- On May 9, 2017, the Company announced that it has been granted a Japanese patent (number 6110845) further extending protection around ThermoVax®including coverage of the Company's ricin toxin vaccine candidate, RiVax®. ThermoVax® is a proprietary vaccine heat stabilization platform technology and the patent, entitled "Thermostable vaccine compositions and methods of preparing same," is also being pursued in other major markets worldwide, such as China, Europe, and the US.
- On May 3, 2017 the Company announced that it has received FDA clearance to advance a pivotal Phase 3 clinical trial evaluating SGX942 for the treatment of oral mucositis in head and neck cancer patients being treated with CRT. Based on positive Phase 2 results (Study IDR-OM-01), the upcoming pivotal Phase 3 clinical trial (Study IDR-OM-02) will be a highly powered, double-blind, randomized, placebo-controlled, multinational trial that will seek to enroll approximately 190 subjects with squamous cell carcinoma of the oral cavity and oropharynx who are scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m2 every third week. Subjects will be randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for 2 weeks following completion of CRT.

Financial Results – Second Quarter Ended June 30, 2017

Soligenix's revenues for the quarter ended June 30, 2017 were $1.0 million as compared to $3.2 million for the prior year. Revenues included a contract with NIAID in support of the development of the Company's thermostabilization technology, ThermoVax®, combined with its ricin toxin vaccine, RiVax®, as a medical countermeasure to prevent the effects of ricin exposure.

Research and development expenses were $1.78 million as compared to $0.83 million for the quarters ended June 30, 2017 and 2016, respectively. The increase was related to expenditures incurred in the preparation and initiation of the Phase 3 oral mucositis clinical trial of SGX942, as well as the ongoing CTCL clinical trial of SGX301.

General and administrative expenses were $0.8 million as compared to $1.0 million for the quarters ended June 30, 2017 and 2016, respectively. This decrease is the result of a decrease in professional fees, as well as a decrease in our employee stock based compensation expenses.

Soligenix's basic net loss was $2.3 million, or $(0.41) per share, for the quarter ended June 30, 2017 as compared to $0.09 million, or $(0.03) per share, for the same quarter of the prior year. Included in the net loss for the three months ended June 30, 2016 is non-cash income of $525,328, representing the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public financing, which were reclassified to equity in November 2016.

As of June 30, 2017, the Company's cash position was $5.8 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 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 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. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 and the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the

treatment of cutaneous T-cell lymphoma. 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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