Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Third Quarter 2019 Financial Results

PRINCETON, N.J., Nov. 12, 2019 /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 quarter ended September 30, 2019.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We are now approaching data read-out in two Phase 3 clinical programs. We anticipate completing patient enrollment before the end of the year with final top-line results in the first quarter of 2020 for our pivotal double-blind, placebo-controlled Phase 3 study for the treatment of cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin). Following the recent positive recommendation received from the independent Data Monitoring Committee (DMC), we continue to enroll patients in 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 (HNC) receiving chemoradiation therapy. The study remains on target to complete enrollment and provide topline results in the second quarter of 2020."

Dr. Schaber continued, "Additionally, we continue to advance our heat stable ricin vaccine, RiVax®, with the support of a National Institute of Allergy and Infectious Disease contract award of up to $24.7 million."

Soligenix Recent Accomplishments:

- On October 24, 2019, the Company announced that the United States Patent Office had allowed the divisional patent application titled "Systems and Methods for Producing Synthetic Hypericin". The allowed claims are directed to unique, proprietary methods to produce a novel, highly purified form of synthetic hypericin. Synthetic hypericin is the active pharmaceutical ingredient in SGX301, the Company's photodynamic therapy for the treatment of CTCL. To view this press release, please click here.
- On September 16, 2019, the Company announced that it had appointed Daniel P. Ring as Vice President of Business Development and Strategic Planning. Mr. Ring has over 22 years of business development and commercial experience in the biopharmaceutical industry. In this new role, Mr. Ring will oversee the Company's global business development function, which will include balanced and disciplined management of any current or new strategic business opportunities, initiatives, mergers, acquisitions, partnerships, alliances, and/or licensing agreements. To view this press release, please click here.
- On September 11, 2019, the Company announced that it had appointed Jonathan Guarino, CPA, CGMA, as its Senior Vice President and Chief Financial Officer. Mr. Guarino has over 20 years of diverse experience in the financial and strategic management of emerging growth and commercial companies, including in the life sciences industry. He has a proven track record and expertise in corporate financial operations, partnerships, as well as growth financings. To view this press release, please click here.
- On August 28, 2019, the Company announced it had received a positive recommendation from the independent DMC to continue enrolling into the company's pivotal Phase 3 "DOM–INNATE" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) for SGX942 (dusquetide) in the treatment of oral mucositis in patients with HNC. To view this press release, please click here.
- On August 15, 2019, the Company announced that the National Institute of Dental and Craniofacial Research (NIDCR), part of the National Institutes of Health (NIH), had awarded Soligenix a Phase I Small Business Innovation Research (SBIR) of approximately $150,000 to support the evaluation of SGX942 (dusquetide) in pediatric indications. This award will facilitate the assessment of SGX942 safety in juvenile animals, supporting future studies in pediatric populations, including oral mucositis indications in pediatric patients undergoing stem cell transplants and treatments for HNC. To view this press release, please click here.

Financial Results – Third Quarter Ended September 30, 2019

Soligenix's revenues for the quarter ended September 30, 2019 were $1.3 million as compared to $1.4 million for the quarter ended September 30, 2018. 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.

Soligenix's basic net loss was $2.7 million, or ($0.14) per share, for the quarter ended September 30, 2019, as compared to $1.9 million, or ($0.11) per share, for the quarter ended September 30, 2018.

Research and development expenses were $2.3 million as compared to $1.4 million for the quarters ended September 30, 2019 and 2018, respectively. The increase in research and development spending for the three months ended September 30, 2019 was primarily attributable to higher clinical trial expenditures relating to the two pivotal Phase 3 studies for SGX301 and

SGX942, compared to the same period in 2018.

General and administrative expenses were $0.8 million as compared to $0.7 million for the quarters ended September 30, 2019 and 2018, respectively.

As of September 30, 2019, the Company's cash position was approximately $6.6 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 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 Public Health Solutions 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), the Defense Threat Reduction Agents (DTRA) 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. 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 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, or any of our other clinical/preclinical trials. 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. 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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