Soligenix Investor Relations

Soligenix Provides 2016 Business Outlook Reviews 2015 Achievements and 2016 Milestones

Princeton, NJ – January 26, 2016 – Soligenix, Inc. (OTCQB: 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 2016 business outlook. This outlook is intended to provide Soligenix investors with a summary of the 2015 accomplishments as well as the anticipated activities and milestones for the coming year.

Soligenix made significant progress in advancing its development pipeline in 2015, achieving several important regulatory, clinical, business and operational milestones.

2015 KEY ACCOMPLISHMENTS

BioTherapeutics

SGX301 (synthetic hypericin) – Initiation of the Pivotal Phase 3 Clinical Study for the Treatment of Cutaneous T-Cell Lymphoma (CTCL)

This trial has been cleared through the US Food and Drug Administration (FDA) and is anchored with positive Phase 2 clinical data in the CTCL patient population. This study is a highly powered, multicenter, randomized, double-blind, placebo-controlled study enrolling approximately 120 subjects. During the year, we welcomed the collaboration with the National Organization for Rare Disorders (NORD) and the Cutaneous Lymphoma Foundation (CLF) to assist in the education and recruitment of patients for the Phase 3 study. In addition to having Orphan Drug designation in the US, the Company also received Fast Track designation from the FDA in early January. In August, Orphan Drug designation was granted by the European Medicines Agency Committee for Orphan Medicinal Products. The Phase 3 study began enrolling subjects in December with results expected during the second half of 2016.

SGX942 (dusquetide) – Positive Preliminary Results from the Phase 2 Proof-of-Concept Clinical Study for the Treatment of Oral Mucositis in Patients with Head & Neck Cancer

Results from the Phase 2 double-blind, dose-ranging, placebo-controlled study in 111 subjects were announced in December. The data identified the optimal dose regimen and clinically relevant endpoints, as well as characterized the patient population to be used for follow-on pivotal trial(s). The 1.5 mg/kg dose of SGX942 appeared to be the most effective dose and decreased the duration of severe oral mucositis by 50% overall compared to the placebo group. In patients treated with the 1.5 mg/kg dose and also exposed to the most aggressive concomitant chemotherapy, the reduction in severe oral mucositis was even more significant at 67%. In addition to the oral mucositis findings, a trend towards increased incidence of “complete response” of tumor at the 1-month follow-up visit was observed (47% placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and significant decreases in infection rate were also observed. Long-term follow-up data will be collected in a blinded fashion over the next 12 months for further analysis. These positive results will enable the Company to accelerate its discussions with the FDA and other health authorities in designing a pivotal Phase 2b/3 clinical program. In addition, the results provide the necessary clarity to better define the business and development path forward with SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN), the Company’s commercial partner for SGX942 in oral mucositis in the Greater China market.

SGX203 (oral beclomethasone 17,21-dipropionate) – FDA Clearance of Pivotal Phase 3 Clinical Study for the Treatment of Pediatric Crohn’s Disease

In April, the Company received FDA protocol clearance for its pivotal Phase 3 clinical trial of SGX203 in the treatment of pediatric Crohn’s disease. This adaptive study is a multicenter, randomized, double-blind study expected to enroll approximately 150 subjects. Previously, SGX203 had been granted both Orphan Drug and Fast Track designations from the FDA. The oral formulation of immediate and delayed release beclomethasone dipropionate (BDP) tablets treat gastrointestinal (GI) inflammation with less toxicity than the current standard systemic steroid therapy. Study initiation is currently anticipated during the first half of 2016 should funding and/or partnering opportunities arise.

Vaccine / BioDefense

ThermoVax® – Vaccine Thermostability Platform

During 2015, the Company announced two significant events relating to ThermoVax®:

·The publication of positive data from research conducted by Drs. Theodore Randolph and Robert Garcea at the University of Colorado, Boulder, demonstrating a heat stable vaccine formulation of a human papillomavirus (HPV) vaccine. This research demonstrated the successful conversion of a commercial virus-like particle-based vaccine requiring cold-chain storage to a subunit, alum-adjuvanted vaccine which is stable at ambient temperatures. This is the first demonstration of the utility of the ThermoVax® technology, licensed from the University of Colorado, for the development of a subunit-based commercially available vaccine.

·A feasibility collaboration was initiated with the University of Hawaii at Mānoa and Hawaii Biotech, Inc. to develop a heat stable subunit Ebola vaccine utilizing the ThermoVax® platform technology. The initial work on the potential Ebola vaccine will focus on a single protein subunit antigen. Preliminary feasibility results are anticipated in the first half of 2016.

RiVax™ – Heat Stable Ricin Vaccine for Pre Exposure Ricin Toxin

In August 2015, the National Institute of Allergy and Infectious Diseases (NIAID) exercised its option in awarding the Company $2.7 million in funding of a potential total award of up to $24.7 million. This funding will further advance the development of the thermostabilization technology, ThermoVax®, combined with the ricin toxin vaccine, RiVax™, as a medical countermeasure to prevent the effects of ricin exposure. To date, the Company has been awarded total funding of $8.5 million under this contract.

OrbeShield® (Oral BDP) – Therapeutic for the Treatment of GI Acute Radiation Syndrome (GI ARS)

Both NIAID and the Biomedical Advanced Research and Development Authority (BARDA) have funded the GI ARS program up to $6.4 million (3 years) and $26.3 million (5 years), respectively. To date, the Company has been awarded total funding of $17.1 million. This funding is instrumental in advancing OrbeShield® as a medical countermeasure for the treatment of GI ARS.

2016 KEY MILESTONES

The Company expects to leverage the momentum gained in 2015 to further advance, and where possible accelerate, its development programs to increase shareholder value. Key strategic activities and milestones anticipated in 2016 include:

· completing enrollment in the pivotal Phase 3 clinical study of SGX301 in the treatment of CTCL and reporting of preliminary results;

· initiating the pivotal Phase 3 clinical study of SGX203 in the treatment of pediatric Crohn’s disease;

· securing potential strategic/business partnership(s) to fund development efforts, with specific focus on SGX942 and ThermoVax®;

· publishing the findings from the SGX942 Phase 2 proof-of-concept study in the treatment of oral mucositis in head and neck cancer patients in a peer reviewed journal;

·obtaining FDA agreement on a pivotal Phase 2b/3 protocol of SGX942 in the treatment of oral mucositis in head and neck cancer patients;

·providing further information regarding the SciClone Pharmaceuticals collaboration for the Greater China market with SGX942 in oral mucositis;

·completing feasibility work for a heat stable subunit Ebola vaccine utilizing ThermoVax® and reporting preliminary results;

·establishing the efficacy of OrbeShield® in a non-human primate model of GI ARS;

· initiating development of the commercial-scale manufacturing processes for RiVax™ vaccine;

·leveraging existing government contract awards of up to $57 million by continuing to secure contractual option awards to advance the RiVax™ and OrbeShield® development programs;

·evaluating the SGX94, novel Innate Defense Regulator technology platform, in other rare disease indications, such as melioidosis; and

·pursuing new government grant and/or contract funding opportunities to support ongoing development activities.

“On behalf of the dedicated employees and Board of Directors of Soligenix, thank you for your patience and

continued support of the Company," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We look forward to a very exciting 2016 and to providing additional updates as we advance our development programs, including our two pivotal Phase 3 clinical studies, further building shareholder value."

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 first-in-class photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, 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), and our novel innate defense regulator technology (SGX942) for the treatment of oral mucositis.

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 melioidosis therapeutic candidate. The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. Currently, this business segment is supported with up to $57 million in 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. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "intends," "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, including SGX942, particularly in light of the significant uncertainty inherent in developing vaccines against bioterror threats conducting preclinical and clinical trials of vaccines, obtaining regulatory approvals and manufacturing 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. Positive results from the Phase 2 study evaluating SGX942 does not ensure that the follow-on Phase 2/3 clinical study will be successful. 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.
