

## **Soligenix Announces Recent Accomplishments and Year-End 2015 Financial Results Highlighted by Revenues of \$8.8 Million**

**Princeton, NJ - March 24, 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 recent accomplishments and financial results for the year ended December 31, 2015.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We were extremely pleased with the positive results from the Phase 2 study of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer. The observed positive results will enable us to accelerate discussions with the US Food and Drug Administration (FDA) and other world health authorities regarding the design of a pivotal Phase 2b/3 clinical program, as well as allow us to better define the business development path forward with our Greater China commercial partner SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN). In addition, we ended the year with the initiation of our pivotal Phase 3 study of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma (CTCL). Results of this registration study are expected during the second half of 2016."

Dr. Schaber continued, "Our Vaccine/BioDefense business segment achieved revenues of \$8.8 million through our contracts with the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID). Collectively under these contracts we have approximately \$43 million remaining through current and future option awards to support the ongoing development of our heat stable ricin vaccine, RiVax™ and our therapeutic for gastrointestinal acute radiation syndrome, OrbeShield®. We also continued to see advancement with our ThermoVax® platform technology, collaborating with the University of Hawaii at Mānoa and Hawaii Biotech, Inc. in developing a heat stable Ebola vaccine."

### **Soligenix Recent Accomplishments:**

- On March 17, 2016, the Company announced that NIAID had exercised a contract option of \$660,000 to accelerate regulatory interactions with the FDA for its heat stable ricin toxin vaccine, RiVax™. This funding will further advance the development of its thermostabilization technology, ThermoVax®, combined with RiVax™ as a medical countermeasure to prevent the effects of ricin exposure.
- On December 16, 2015, the Company announced positive preliminary results from its Phase 2 randomized, double-blind, dose-ranging, placebo-controlled clinical trial of SGX942 (dusquetide). This exploratory study, enrolled 111 patients into four dose groups (placebo, 1.5, 3.0 and 6.0 mg/kg of SGX942) achieving all objectives, including identifying a best dose of 1.5mg/kg. This dose of SGX942 decreased the duration of severe oral mucositis by 50% overall compared to the placebo group, from 18 days to 9 days ( $p=0.099$ ). In patients exposed to the most aggressive concomitant chemotherapy, the reduction in the duration of severe oral mucositis was even more significant at 67% when treated with SGX942 1.5 mg/kg, from 30 days to 10 days ( $p=0.04$ ). The p-values surpass the prospectively defined statistical threshold of  $p<0.1$  in the study protocol. Additional observations included increased incidence of "complete response" of tumor at the one month follow up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg), as well as decreases in mortality and infection rate. SGX942 has fast track designation from the FDA for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients.
- On December 14, 2015, the Company announced the initiation of patient enrollment for its pivotal Phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating SGX301 (synthetic hypericin) as a treatment for CTCL. SGX301 has orphan drug designations from the FDA and the European Medicines Agency Committee for Orphan Medicinal Products, as well as fast track designation from the FDA for the first-line treatment of CTCL. CTCL is a rare class of non-Hodgkin's lymphoma, a cancer of the white blood cells that are an integral part of the immune system.

### **Financial Results - Year Ended December 31, 2015**

Soligenix's revenues for the year ended December 31, 2015 were \$8.8 million as compared to \$7.0 million for the prior year. Revenues included contracts with BARDA and NIAID in support of OrbeShield® (oral beclomethasone 17,21-dipropionate or BDP) development in the treatment of gastrointestinal acute radiation syndrome (GI ARS) and advanced 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.

Soligenix's basic net loss was \$7.8 million, or \$0.30 per share, as compared to \$6.7 million, or \$0.32 per share, for the years ended December 31, 2015 and 2014 respectively. Included in the net loss for years ended December 31, 2015 and 2014 is a non-cash expense of (\$1.2) million and a non-cash income of \$3.4 million,

respectively. This non-cash item reflects the change in fair value of the liability related to warrants issued in the Company's June 25, 2013 registered public offering and is included in other income/(expense).

Research and development expenses, including acquired in-process research and development, were \$5.4 million as compared to \$9.1 million for the years ended December 31, 2015 and 2014, respectively. The significant decrease was related to the 2014 expenditure of \$4.0 million attributable to the asset acquisition of SGX301, synthetic hypericin, from Hy BioPharma paid in the form of \$0.25 million in cash and \$3.75 million in restricted common stock. Expenses in 2015 included the completion of patient enrollment in the Phase 2 trial of SGX942 for oral mucositis in head and neck cancer patients and costs associated with the initiation of the pivotal Phase 3 trial of SGX301 for the treatment of patients with CTCL.

General and administrative expenses were \$3.6 million as compared to \$3.4 million for the years ended December 31, 2015 and 2014, respectively. This increase is primarily related to an increase in outside professional fees.

As of December 31, 2015, the Company's cash position was \$4.9 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 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](http://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.*

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