

## **Soligenix Announces Recent Accomplishments And Year-End 2016 Financial Results Highlighted by Revenues of \$10.4 Million**

**PRINCETON, NJ - March 27, 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 year ended December 31, 2016.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "We are 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. We are encouraged by the response received from the EMA that the proposed Phase 3 clinical study, if positive, is sufficient to establish the efficacy and safety of SGX942 in support of potential marketing authorization in Europe. We believe that this positive Scientific Advice outcome represents a significant step forward in our oral mucositis development program and has the potential to accelerate the registration timetable in Europe. Given the current timeline, we anticipate initiating this pivotal Phase 3 clinical trial in the first half of 2017."

Dr. Schaber continued, "We also continue to actively enroll patients in our pivotal Phase 3 study in cutaneous T-cell lymphoma with SGX301 (synthetic hypericin), in which we expect data by the end of 2017. Our Vaccines/BioDefense business segment achieved revenues of \$10.4 million through our government contracts as we continued to advance the development of our heat stable ricin vaccine, RiVax™ and our therapeutic for gastrointestinal acute radiation syndrome, OrbeShield®."

### **Soligenix Recent Accomplishments:**

- On February 22, 2017, the Company announced that its proprietary formulation of synthetic hypericin had been granted a European patent for the treatment of psoriasis. The issued patent, EP 2571507, Formulations and methods of treatment of skin conditions, complements the method of treatment claims covered by the previously issued US patent 6001882, Photoactivated hypericin and the use thereof.
- On February 2, 2017, the Company announced that SGX301 had been granted Promising Innovative Medicine (PIM) designation in the United Kingdom (UK) by the Medicines and Healthcare Products Regulatory Agency (MHRA) for the treatment of cutaneous T-cell lymphoma (CTCL). The PIM designation is the first step towards inclusion in the Early Access to Medicines Scheme which offers severely ill patients with life-threatening and seriously debilitating conditions the lifeline of trying ground-breaking new medicines much earlier than they would normally be accessible.
- On January 5, 2017, the Company announced it had received positive Scientific Advice from the European Medicines Agency (EMA) for the development of SGX942 as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy (CRT). The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, multinational, Phase 3 pivotal study (IDR-OM-02), if successful, in conjunction with the Phase 2 dose-ranging study IDR-OM-01, is generally considered sufficient to support a marketing authorization application (MAA) to the EMA for potential licensure in Europe.
- On December 16, 2016, the Company announced the completion of an underwritten public offering of its common stock and warrants and the simultaneous uplisting to the Nasdaq Capital Market. Gross proceeds from this offering were approximately \$5.3 million before deducting underwriting discounts and commissions and other estimated offering expenses.
- On December 12, 2016, the Company announced that SGX942 had been granted PIM designation in the UK by the MHRA for the treatment of severe oral mucositis in head and neck cancer patients receiving chemoradiation therapy.
- On December 8, 2016, the Company announced the long-term follow-up data from its Phase 2 clinical trial with SGX942, a first-in-class Innate Defense Regulator (IDR), in the treatment of oral mucositis in head and neck cancer patients undergoing CRT. The additional 12-month safety data remains consistent with the preliminary positive safety and efficacy findings from the Phase 2 study. The study met all of its objectives including defining a clinically effective dose of SGX942 - specifically the 1.5 mg/kg as seen in both the acute and long-term follow-up phases of the trial. It also identified the most appropriate clinical endpoint and patient population to use in the future Phase 3 pivotal study. The impact of the drug on the reported infection rates as well as the trends in improved survival rates and complete tumor responses at both one and 12 months following CRT confirmed the long-term safety and tolerability of SGX942 in a sick patient population.

### **Financial Results - Year Ended December 31, 2016**

Soligenix's revenues for the year ended December 31, 2016 were \$10.4 million as compared to \$8.8 million for

the prior year. Revenues included contracts with BARDA and NIAID in support of OrbeShield® (oral beclomethasone 17,21-dipropionate) 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 \$3.2 million, or \$0.93 per share, as compared to \$7.8 million for the prior year, or \$3.00 per share, on a split adjusted basis. Included in the net loss for years ended December 31, 2016 and 2015 is non-cash income of \$1.5 million and a non-cash expense of (\$1.2) 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 were \$4.3 million as compared to \$5.4 million for the years ended December 31, 2016 and 2015, respectively. The decrease is primarily a result of the completion of patient enrollment during 2015 in the Phase 2 trial of SGX942 for the treatment of oral mucositis in head and neck cancer patients.

General and administrative expenses were \$3.4 million as compared to \$3.6 million for the years ended December 31, 2016 and 2015, respectively. This decrease is primarily a result of a decrease in professional fees.

As of December 31, 2016, the Company's cash position was \$8.8 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 melioidosis therapeutic candidate. 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](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," "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 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.*

---

<https://ir.soligenix.com/2017-03-27-soligenix-announces-recent-accomplishments-and-year-end-2016-financial-results>