Soligenix Investor Relations

Soligenix and SciClone Establish Regional Licensing Agreement for SGX942, a Novel Product Candidate for Oral Mucositis

Princeton, NJ and Foster City, CA – September 12, 2016 –Soligenix, Inc. (OTCQB: SNGX), a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need, and SciClone Pharmaceuticals, Inc. (NASDAQ:SCLN), a US-based China-focused specialty pharmaceutical company, announced today that the companies have entered into an exclusive license agreement granting rights to SciClone to develop, promote, market, distribute and sell SGX942 (dusquetide), a novel, first-in-class therapy being developed for the treatment of oral mucositis in patients with head and neck cancer. The licensing agreement includes the People's Republic of China, including Hong Kong and Macau, as well as Taiwan, South Korea and Vietnam (the "Territory"). This exclusive agreement builds on an existing collaboration between the two companies, in which SciClone provided its complete oral mucositis clinical and regulatory data library to Soligenix in exchange for certain, previously undisclosed, commercialization rights to SGX942 in the Greater China market.

Under the terms of the agreement, SciClone will make a $3 million upfront equity investment in Soligenix for 3,529,412 shares of Soligenix common stock. In addition, SciClone will be responsible for all aspects of development, product registration and commercialization in the Territory, having access to data generated by Soligenix. In exchange for exclusive rights, SciClone will pay to Soligenix royalties on net sales, and Soligenix will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

Friedhelm Blobel, PhD, President and Chief Executive Officer of SciClone, commented, "We believe that SGX942 can be an excellent fit within our growing oncology portfolio, and expands our strategy to in-license programs that can potentially utilize accelerated development and regulatory pathways in China. SciClone has a well established commercial presence in China, and key to driving our long-term growth is the expansion of our pipeline with innovative product candidates. We believe that oral mucositis represents an unmet medical need and is a frequent complication of anticancer treatment, including chemotherapy and radiation therapy. We appreciate the strong performance of the Soligenix clinical team in advancing this potentially important therapeutic, and are looking forward to developing SGX942 for potentially multiple Asia markets."

"We are very pleased to expand on our partnership with SciClone," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "SciClone has a significant commercial presence and expertise in China, and their clinical and regulatory contribution to the dusquetide oral mucositis program has the potential to bring high quality development and potential commercialization of SGX942 in the Territory. In the US, our multi-center, double-blind, placebo-controlled, Phase 2 clinical study in oral mucositis in head and neck cancer patients is currently ongoing with completion of long-term follow-up expected by the end of 2016."

This exclusive license agreement builds on an existing collaboration, wherein SciClone provided its significant oral mucositis clinical and regulatory data library, thus increasing the probability of success for the Soligenix SGX942 Phase 2 exploratory clinical study. By analyzing data available from the placebo subjects in the SciClone trials, Soligenix acquired essential insight into disease progression, along with quantitative understanding of its incidence and severity in the head and neck cancer patient population. This information assisted with the design of the SGX942 Phase 2 clinical trial, in which positive preliminary results were announced in December 2015.

About SGX942 (dusquetide)

SGX942 is an innate defense regulator (IDR), which contains a new class of short, synthetic peptide, having the chemical name dusquetide. It has a novel mechanism of action in that it modulates the body's reaction to both injury and infection towards an anti-inflammatory and an anti-infective response. IDRs have no direct antibiotic activity but, by modulating the host's innate immune system responses, increase survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens. It also accelerates resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- and/or radiation therapy. Preclinical efficacy and safety has been demonstrated in numerous animal disease models including mucositis, colitis, melioidosis and other bacterial infections. Some of these preclinical findings have been published in an article entitled "A novel approach for emerging and antibiotic resistant infections: Innate defense regulators as an agnostic therapy" and are available at the following link: http://dx.doi.org/10.1016/j.jbiotec.2016.03.032.

SGX942 has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers. Recently, SGX942 has demonstrated preliminary efficacy and safety in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation (CRT) therapy for head and neck cancer. Consistent with preclinical findings, SGX942 at a dose of 1.5 mg/kg demonstrated positive improvements in decreasing 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 receiving 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 meet the prospectively defined statistical threshold of $p<0.1$ in the study protocol. Additional observations included an improved tumor response to CRT therapy at the one month follow up visit (47% in placebo versus 63% in SGX942 at 1.5 mg/kg), as well as decreases in infection rate.

Dusquetide and related analogs have a strong intellectual property position, including composition of matter. Dusquetide was developed pursuant to discoveries made by Professors B. Brett Finlay, PhD and Robert Hancock, PhD of the University of British Columbia, Canada.

SGX942 has received fast track designation from the US Food and Drug Administration (FDA) for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients. Fast track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, Soligenix will be eligible to submit a new drug application (NDA) for SGX942 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for fast track development programs ordinarily will be eligible for priority review, which imparts an abbreviated review time of approximately six months.

About Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the US per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The gastrointestinal damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is now regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of oral mucositis, that oral mucositis in head and neck cancer is a subpopulation of approximately 90,000 patients in the US, with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with chemoradiation therapy and is severe, causing inability to eat and/or drink, in >80% of patients. It is common (40-100% incidence) in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

Oral mucositis in head and neck cancer remains an area of unmet medical need where there are currently no approved drug therapies.

About SciClone Pharmaceuticals, Inc.

SciClone Pharmaceuticals is a revenue-generating, specialty pharmaceutical company with a substantial commercial business in China and a product portfolio spanning major therapeutic markets including oncology, infectious diseases and cardiovascular disorders. SciClone's proprietary lead product, ZADAXIN® (thymalfasin), is approved in over 30 countries and may be used for the treatment of hepatitis B (HBV), hepatitis C (HCV), and certain cancers, and as an immune system enhancer, according to the local regulatory approvals. The Company has successfully in-licensed and commercialized products with the potential to become future market leaders and to drive the Company's long-term growth, including DC Bead®, a novel treatment for liver cancer, now approved in China, and several other products in late-stage development in China. Through its promotion business with pharmaceutical partners, SciClone also markets multiple branded products in China which are therapeutically differentiated. SciClone is a publicly-held corporation based in Foster City, California, and trades on the NASDAQ Global Select Market under the symbol SCLN. For additional information, please visit www.sciclone.com.

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 dusquetide (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 $58 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 atwww.soligenix.com.

Soligenix Forward-Looking Statements

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 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. 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.

SciClone Forward-Looking Statements

This press release contains forward-looking statements regarding the development of SGX942, the prospects for SGX942 in the Territory and other matters. Readers are urged to consider statements that include the words "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "designed," "goal," "approximately" or the negative of those words or other comparable words to be uncertain and forward-looking. These statements are subject to risks and uncertainties that are difficult to predict and actual outcomes may differ materially. These include risks and uncertainties relating to risks relating to the product development and clinical trial process, including uncertainties regarding the time and costs related thereto, and risks relating to performance by us and by Soligenix of obligations under the agreement with Soligenix, as well as well as risks and uncertainties relating to the course, cost and outcome of regulatory matters, including regulatory approvals and future pricing decisions by authorities in China. Please also refer to other risks and uncertainties described in SciClone's filings with the SEC. All forward-looking statements are based on information currently available to SciClone and SciClone assumes no obligation to update any such forward-looking statements.
