

## **Soligenix Announces \$1.5 Million NIDCR SBIR Grant Award Supporting the Pivotal Phase 3 Clinical Trial of SGX942 for the Treatment of Oral Mucositis in Head and Neck Cancer**

**2017 Non-Dilutive Funding Reaches \$7.5 Million**

**PRINCETON, NJ - September 20, 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 that the National Institute of Dental and Craniofacial Research (NIDCR), part of the National Institutes of Health (NIH), has awarded Soligenix a Small Business Innovation Research (SBIR) grant of approximately \$1.5 million over two years to support the conduct of its Phase 3, multinational, randomized, double-blind, placebo-controlled study evaluating SGX942 (dusquetide) as a treatment for severe oral mucositis in patients with head and neck cancer receiving chemoradiation therapy (CRT).

"We are appreciative of the support provided by NIDCR for the previous Phase 2 clinical study and now for the recently initiated pivotal Phase 3 clinical study of SGX942 in the treatment of oral mucositis," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We believe this SBIR grant award further validates dusquetide's novel mechanism of action, as well as the positive clinical data generated to date. Oral mucositis remains an extremely debilitating side effect of cancer treatment and is particularly severe and prevalent in head and neck cancer patients. We look forward to completing the study to potentially demonstrate the clinical efficacy of SGX942."

Dr. Schaber continued, "With approximately \$7.5 million in non-dilutive NIH funding awarded to Soligenix thus far in 2017 across our biotherapeutics and biodefense pipelines, we would like to thank NIH for its continued support and for its recognition of the merits of the important work we are doing in areas of unmet medical need."

Dusquetide (the active ingredient in SGX942) is an innate defense regulator (IDR), a new class of short, synthetic peptides. It has a novel mechanism of action whereby 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 caused by 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.

Based on the positive and previously published Phase 2 results (Study IDR-OM-01), the pivotal Phase 3 clinical trial (Study IDR-OM-02) is a highly powered, double-blind, randomized, placebo-controlled, multinational trial seeking to enroll approximately 190 subjects with squamous cell carcinoma of the oral cavity and oropharynx who are scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m<sup>2</sup> every third week. Subjects will be randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for two weeks following completion of CRT. The primary endpoint for the study is the median duration of severe oral mucositis, which will be assessed by oral examination at each treatment visit and then through six weeks following completion of CRT. Oral mucositis is evaluated using the WHO Grading system. Severe oral mucositis is defined as a WHO Grade of  $\geq 3$ . Subjects will be followed for an additional 12 months after the completion of treatment.

Soligenix is working with leading oncology centers to advance this Phase 3 clinical trial referred to as the "DOM-INNATE" study (Dusquetide treatment in Oral Mucositis - by modulating INNATE immunity). The study design incorporates feedback from the US Food and Drug Administration (FDA) as well as from the European Medicines Agency (EMA) via the Scientific Advice process. The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, multinational, Phase 3 pivotal study, if successful, in conjunction with results from the Phase 2 dose-ranging study, generally will be considered sufficient to support a marketing authorization application for potential licensure in Europe.

### **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 SGX942**

Dusquetide (the active ingredient in SGX942) is an innate defense regulator (IDR), a new class of short, synthetic peptides. It has a novel mechanism of action whereby 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 caused by 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, macrophage activation syndrome (MAS) 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," 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 had positive results in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to CRT 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 at the highest risk of developing severe oral mucositis (i.e., those receiving concomitant cisplatin chemotherapy of 80-100 mg/m<sup>2</sup> every third week), 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 met the prospectively defined statistical threshold of  $p<0.1$  in the study protocol. Additional observations included an improved tumor response to CRT at the one month follow-up visit, as well as decreases in mortality and infection rate. The study results are reviewed in "Dusquetide: A Novel Innate Defense Regulator Demonstrating a Significant and Consistent Reduction in the Duration of Oral Mucositis in Preclinical Data and a Randomized, Placebo-Controlled Phase 2 Clinical Study," published online in the *Journal of Biotechnology* and available at the following link: <http://dx.doi.org/10.1016/j.jbiotec.2016.10.010>.

Long-term (12 month) follow-up data further indicated the safety and tolerability of SGX942 treatment, with a sustained trend towards reduced mortality and increased tumor resolution in the 1.5 mg/kg SGX942 treatment group compared to the placebo group. Opioid pain medication use was also seen to decrease over the course of CRT in the 1.5 mg/kg SGX942 treatment group at the point of highest oral mucositis risk, while it increased in the placebo group. Detailed clinical results from the Phase 2 study, as well as a review of the pathogenesis of oral mucositis and the mechanism of action of SGX942, are discussed [here](#). The long-term follow-up results from the Phase 2 study are reviewed in, "Dusquetide: Reduction in Oral Mucositis associated with Enduring Ancillary Benefits in Tumor Resolution and Decreased Mortality in Head and Neck Cancer Patients", published online in *Biotechnology Reports* and available at the following link: <https://doi.org/10.1016/j.btre.2017.05.002>.

Soligenix has received partial funding from NIDCR for its oral mucositis clinical studies. The Phase 2 study was supported with a Phase I SBIR grant (#R43DE024032) award, with the Phase 3 study being supported by a Phase II SBIR grant (#R44DE024032) award.

Drug products containing dusquetide have also received Fast Track Designations from the FDA for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients, and as an adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis. Orphan

Drug Designations for use of dusquetide in the treatment of MAS as well as for the treatment of acute radiation syndrome have also been granted. In addition, dusquetide has been granted Promising Innovative Medicine designation in the United Kingdom by the Medicines and Healthcare Products Regulatory Agency for the treatment of severe oral mucositis in head and neck cancer patients receiving CRT.

Soligenix has a strong intellectual property position in the IDR technology platform, including composition of matter for dusquetide and related analogs. Dusquetide was developed pursuant to discoveries made by Professors B. Brett Finlay, PhD and Robert Hancock, PhD of the University of British Columbia, Canada.

### **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 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) 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).

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<https://ir.soligenix.com/2017-09-20-soligenix-announces-1-5-million-nidcr-sbir-grant-award-supporting-the-pivotal-phase-3-clinical-trial-of-sgx942-for-the-treatment-of-oral-mucositis-in-head-and-neck-cancer>