

Soligenix Announces US Patent Issuance for Use of Dusquetide in Oral Mucositis **Specific therapeutic use claim in oral mucositis adds to existing composition of matter claims**

Princeton, NJ – January 2, 2018 –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 United States (US) Patent Office has granted the patent entitled “Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis.” The newly issued patent claims therapeutic use of dusquetide (active ingredient in SGX942) and related innate defense regulator (IDR) analogs, and adds to composition of matter claims for dusquetide and related analogs that have been granted in the US and worldwide. Dusquetide previously demonstrated positive results in a Phase 2 oral mucositis clinical trial and a pivotal Phase 3 study was recently initiated in 2017.

Soligenix has reported positive Phase 2 results with SGX942 in the treatment of oral mucositis in head and neck cancer (HNC) patients. SGX942 at a dose of 1.5 mg/kg successfully reduced the median duration of severe oral mucositis by 50% in all patients and by 67% in patients receiving the most aggressive chemoradiation therapy for treatment of their HNC. In addition to the oral mucositis findings, an increased incidence of “complete response” of tumor at both the one month and twelve month follow-up visits were observed with SGX942 treatment, as well as decreases in mortality and infection rate. Results from the Phase 2 clinical trial have been published.

The new US patent, number 9,850,270, issued on December 26, 2017, is a significant addition to the patent portfolio for dusquetide and would be expected to expire in 2034.

“Soligenix continues to pursue broad patent coverage for its dusquetide technology, first with composition of matter claims followed by therapeutic use claims in oral mucositis,” stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. “Having successfully pursued composition of matter claims in jurisdictions worldwide, we continue to pursue therapeutic use claims like those issued in the US with this most recent patent. The therapeutic use claims are expected to be generally valid until 2034, which provides significant patent protection and life to dusquetide and our other IDR analogs.”

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 HNC 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 HNC remains an area of unmet medical need where there are currently no approved drug therapies.

About Dusquetide

Dusquetide (the active ingredient in both SGX942 and SGX943) is an 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>.

Dusquetide has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers and positive results in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation therapy (CRT) for HNC. 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 from the Phase 2 study further indicated the safety and tolerability of dusquetide treatment. The long-term follow-up results 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>.

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 HNC 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 HNC 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.

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