Soligenix Investor Relations

Soligenix Receives European Patents for Oral BDP in the Treatment of Acute Radiation Injury of the Gastrointestinal Tract

Patents cover SGX201 in acute radiation enteritis and OrbeShield® for acute total body irradiation

PRINCETON, N.J., July 29, 2019 /PRNewswire/ -- 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 European Patent Office has issued two patents, both titled "Topically Active Steroids for use in Radiation and Chemotherapeutics Injury" with the latest issuing October 24, 2018, following the expiration of the objection period as of July 24, 2019. The new patents (#2,373,160 and #2,902,031) claim use of oral beclomethasone 17,21-dipropionate (BDP) for treatment of damage to the gastrointestinal (GI) tract as a result of acute radiation injury, including total body irradiation in an accidental or biodefense context.

SGX201 and OrbeShield® are proprietary oral formulations of BDP that function as mucosally delivered steroidal treatments for the GI tract while minimizing systemic steroid side effects, including risk of severe infection. SGX201 utilizes an enteric coated tablet to deliver steroid to the distal GI tract, while OrbeShield® employs both immediate and delayed release, enteric-coated formulations to cover both the proximal and distal GI tract. Due to the low systemic bioavailability of BDP, these formulations maximize anti-inflammatory steroid action at the site of injury, while minimizing common side effects of steroids, including immune suppression, enabling their use in expanded populations.

SGX201 has been evaluated in the treatment of acute radiation enteritis in patients with rectal carcinoma. Future studies may include the evaluation of oral BDP in patients with gynecological cancers at risk of acute and chronic radiation enteritis due to radiation therapy. OrbeShield® is being developed in the biodefense context, as a potential treatment in the event of radiation exposure in a mass casualty incident. The combination of immediate and delayed release oral BDP is also being developed as a treatment for Pediatric Crohn's Disease in Soligenix's SGX203 program, for which a pivotal Phase 3 clinical trial protocol has been agreed with U.S. Food and Drug Administration (FDA). The conduct of the Phase 3 trial in Pediatric Crohn's Disease is pending partnership and/or additional funding.

"Soligenix continues to evaluate opportunities for its proprietary formulations of oral BDP," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "These therapeutic use patents are generally valid until 2029 and allow us to expand our intellectual property portfolio across the two business segments of our rare disease pipeline."

About SGX201 and OrbeShield®

SGX201 is formulated for oral administration in cancer patients as a single product consisting of a delayed release (enteric coated) tablet which releases BDP in the distal portions of the GI tract. SGX201 has been awarded fast-track designation from the FDA for the prevention of radiation enteritis. Previous studies with SGX201 have been supported by a National Cancer Institute Small Business Innovation Research (SBIR) grant #R43CA141968.

OrbeShield® is formulated for oral administration in gastrointestinal acute radiation syndrome (GI ARS) patients as a single product consisting of two tablets. One tablet releases BDP in the proximal portions of the GI tract, and the other tablet releases BDP in the distal portions of the GI tract. OrbeShield® has also been granted Orphan Drug and Fast Track designations by the FDA for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster. OrbeShield® development as a medical countermeasure for GI ARS has been supported by the Biomedical Advanced Research and Development Authority (BARDA) (contract #HHSO100201300023C) and the National Institute of Allergy and Infectious Diseases (NIAID) (contract #HHSN27220130030C) contracts.

Oral BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in inhalation products for the treatment of allergic rhinitis and asthma. To date, immediate and delayed release oral BDP has been safely administered to more than 380 human subjects in multiple clinical studies. Oral BDP also is being developed for use in other GI disorders characterized by severe inflammation such as in pediatric Crohn's disease, which uses a combination of immediate and delayed release oral BDP, referred to as SGX203. SGX203 has received both orphan drug and fast track designations in the U.S. for the treatment of Crohn's Disease in the pediatric population.

About Acute Radiation Enteritis

Radiation Enteritis is an inflammatory bowel condition resulting from radiation damage to the abdominal and pelvic areas. Acute Radiation Enteritis occurs during or immediately after a radiation treatment course while the chronic disease represents an inadequate healing process in the intestines after radiation damage.

Radiation enteritis occurs to some degree in almost all patients treated with radiation directed at the abdomen or pelvic area. This includes most patients with cancer of the bladder, uterus, cervix, rectum, prostate, and vagina. The bowel is very sensitive to radiation damage. There are over 100,000 patients annually in the U.S. receiving abdominal or pelvic radiation treatment for cancer who are at risk of developing acute and chronic radiation enteritis

Acute radiation enteritis generally occurs around the second week of radiation treatment and includes symptoms of diarrhea, nausea, vomiting, stomach cramps, fecal urgency and loss of appetite.

Chronic radiation enteritis occurs after radiation is complete. Symptoms vary and may include pain after eating, acute or intermittent small bowel obstruction, nausea, loss of appetite, weight loss, bloating, diarrhea, inability to extract nutrients from food eaten and the excretion of fat in feces. Chronic radiation enteritis is often associated with a thickening or scarring of the intestinal lining (called fibrosis) which is believed to have been caused by the initial radiation damage and subsequent inflammatory response.

About GI ARS

ARS occurs after toxic radiation exposure and involves several organ systems, notably the bone marrow, the GI tract and later the lungs. In the event of a nuclear disaster or terrorist detonation of a nuclear bomb, people exposed to radiation levels greater than 2 Gy are at high risk of developing ARS. According to the U.S. Centers for Disease Control and Prevention (CDC), exposure to high doses of radiation exceeding 10 to 12 Gy causes acute GI injury, which can result in death in 5 to 15 days. The GI tract is highly sensitive to radiation-induced damage due to the requirement for incessant proliferation of crypt stem cells and production of mucosal epithelium. The extent of injury to the bone marrow and the GI tract are the principal determinants of survival after exposure to total body irradiation. Although hematopoietic ARS can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. Therefore, there is an urgent need to develop specific medical countermeasures against the lethal consequences of radiation-induced GI injury.

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 Specialized 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 Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine 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.

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 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 or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the Priority Review Voucher (PRV) program or the amount for which a PRV for RiVax® can be sold. 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.

SOURCE Soligenix, Inc.

For further information: Karen Krumeich, Chief Financial Officer, (609) 538-8200, www.soligenix.com, Soligenix, Inc., 29 Emmons Drive, Suite B-10 Princeton, NJ 08540
