# Soligenix Announces Poster Presentations from its Gastrointestinal Acute Radiation Syndrome Program at the 2016 Radiation Research Society Meeting

**Princeton, NJ - October 13, 2016 -** Soligenix, Inc. (OTCQB: SNGXD) (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 it has been invited to present preliminary results from its gastrointestinal acute radiation syndrome (GI ARS) program at the Radiation Research Society Meeting on October 15-19, 2016 in Waikoloa Village, HI. The program is evaluating OrbeShield® as a potential medical countermeasure (MCM) for civilian and military use.

OrbeShield® is the Company's proprietary formulation of beclomethasone 17,21-dipropionate (BDP) that includes immediate and delayed release tablets for treatment of the GI tract. The presented results will address both model development and OrbeShield® efficacy data facilitating the potential approval of OrbeShield® as an MCM. Soligenix's GI ARS program is supported by contract awards from both the Biomedical Advanced Research Development Authority (BARDA) and National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, with potential options, totaling up to approximately \$34 million. In addition to developing oral BDP as an MCM, the Company is pursuing oral BDP as a treatment for GI inflammation in pediatric Crohn's disease and acute radiation enteritis.

## Poster Presentation Details:

- Gastrointestinal structure and function in a preclinical partial body irradiation (PBI) Göttingen mini-pig model of acute radiation syndrome presented by Dr. Oreola Donini, Chief Scientific Officer, Soligenix, Inc., on Wednesday, October 19, 2016, 5:15-7:00 PM.
- Functional evaluations in GI acute radiation syndrome: Evaluation of nutrient absorption in Gottingen mini-pigs and Rhesus monkeys presented by Dr. Simon Authier, Senior Director of Scientific Operations and Veterinary Services, CiToxLAB North America on Sunday, October 16, 2016, 1:45-3:15 PM.
- OrbeShield® efficacy in a preclinical partial body irradiation Göttingen mini-pig model of acute radiation syndrome presented by Dr. Oreola Donini, Chief Scientific Officer, Soligenix, Inc., on Wednesday, October 19, 2016, 5:15-7:00 PM.
- Gastrointestinal Acute Radiation Syndrome in Rhesus Monkeys: Comparison of Total Body Irradiation and Partial Body Irradiation presented by Dr. Simon Authier, Senior Director of Scientific Operations and Veterinary Services, CiToxLAB North America on Wednesday, October 19, 2016, 5:15-7:00 PM.

## About the Radiation Research Society Meeting

The Radiation Research Society holds an annual meeting, bringing together experts from many disciplines and interests worldwide. The Society has three major objectives, including encouraging the advancement of radiation research, facilitating cooperative research in the disciplines of physics, chemistry, biology and medicine and promoting dissemination of knowledge. Details regarding the annual meeting can be found at: <a href="http://www.radres.org/mpage/2016Home">http://www.radres.org/mpage/2016Home</a>.

## About OrbeShield®

OrbeShield® is formulated for oral administration in 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. BDP has been marketed in the US and worldwide since the early 1970s as the active pharmaceutical ingredient in inhalation products for the treatment of allergic rhinitis and asthma. To date, OrbeShield® has been safely administered to more than 380 human subjects in multiple clinical studies. OrbeShield® also is being developed for use in other GI disorders characterized by severe inflammation such as pediatric Crohn's disease and radiation enteritis.

The US Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for OrbeShield® for the mitigation of morbidity and mortality associated with GI ARS. 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 an MCM for GI ARS is currently being supported by BARDA (contract #HHSO100201300023C) and NIAID (contract #HHSN27220130030C) contracts valued up to \$26.9 million and \$7.0 million, respectively, if all options are exercised and all supplemental funds are included.

## 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 US 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 MCMs 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 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<sup>™</sup>, our ricin toxin vaccine candidate, OrbeShield<sup>®</sup>, 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<sup>®</sup>. 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 at <u>www.soligenix.com</u>.

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.

https://ir.soligenix.com/2016-10-13-soligenix-announces-poster-presentations-from-its-gastrointestinal-acuteradiation-syndrome-program-at-the-2016-radiation-research-society-meeting