

## **Soligenix Receives Additional BARDA and NIAID Funding to Advance Development of OrbeShield® in GI ARS**

**Princeton, NJ - July 25, 2016** – Soligenix, Inc. (OTCQB: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company developing products that address unmet medical needs in the areas of inflammation, oncology and biodefense, announced today that the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, have each provided Soligenix additional funding to advance preclinical development of OrbeShield® (oral beclomethasone 17,21-dipropionate or oral BDP) as a medical countermeasure (MCM) for civilian and military use in treatment of gastrointestinal acute radiation syndrome (GI ARS). The additional funding totals \$634,000 (\$284,000 from NIAID and \$350,000 from BARDA).

Soligenix's GI ARS program is supported by contract awards from both BARDA and NIAID, totaling up to approximately \$33 million with the supplemental funding if all options are exercised. To date, exercised funds have included \$7M from NIAID and \$11M from BARDA, including all additional funds. In addition to developing oral BDP as a MCM, the Company is also pursuing oral BDP as a treatment for GI inflammation in pediatric Crohn's disease and acute radiation enteritis.

"The supplemental funding provided by both BARDA and NIAID reflects the government's ongoing commitment to developing MCMs for GI ARS and the compelling nature of Soligenix's OrbeShield® product and development team," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "This continued funding has the potential to provide the necessary resources to accelerate the development of OrbeShield® while building upon the scientific evidence supporting its use as a potential MCM in GI ARS. We thank both agencies for their past and present support and look forward to continuing our close collaboration as we advance this technology."

### **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 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, oral BDP has been safely administered to more than 350 human subjects in multiple clinical studies. Oral BDP is also 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 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 \$57 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 [www.soligenix.com](http://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 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/2016-07-25-soligenix-receives-additional-barda-and-niaid-funding-to-advance-development-of-orbeshield-R-in-gi-ars>