

## **Soligenix Announces SGX301 Receives Promising Innovative Medicine Designation from the UK Medicines and Healthcare Products Regulatory Agency**

**Princeton, NJ – February 2, 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 SGX301 (synthetic hypericin) has been granted Promising Innovative Medicine (PIM) designation in the United Kingdom (UK) by the Medicines and Healthcare Products Regulatory Agency (MHRA) for the treatment of cutaneous T-cell lymphoma (CTCL).

The PIM designation is the first step towards inclusion in the Early Access to Medicines Scheme (EAMS). Launched in April 2014, EAMS offers severely ill patients with life-threatening and seriously debilitating conditions the lifeline of trying ground-breaking new medicines much earlier than they would normally be accessible.

PIM status, the first phase of EAMS, which is awarded following an assessment of early nonclinical and clinical data by the MHRA, has been created as an early signal to companies that the development plan is appropriate and indicates that a product could be a candidate for the second phase of the EAMS scheme, once further development work has been conducted. In this second phase, the product is made available to UK patients before a marketing authorization is approved. This early boost to a drug's potential is expected to be beneficial to companies, especially small and medium-sized enterprises.

The criteria products must meet to obtain the PIM designation are:

- Criterion 1 – The condition should be life-threatening or seriously debilitating with a high unmet medical need (i.e., there is no method of treatment, diagnosis or prevention available or existing methods have serious limitations).
- Criterion 2 – The medicinal product is likely to offer major advantage over methods currently used in the UK.
- Criterion 3 – The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance. A positive benefit risk balance should be based on preliminary scientific evidence, as justified by the applicant, that the safety profile of the medicinal product is likely to be manageable and acceptable in relation to the estimated benefits.

“We are excited that the MHRA agrees that SGX301 meets the specified criteria for PIM designation,” stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. “This is now the second of our programs to receive this important designation, with the first being SGX942 for the treatment of severe oral mucositis in head and neck cancer patients receiving chemoradiation therapy. We look forward to working with the MHRA to advance both programs and leverage the potential benefits of the EAMS scheme to make these important products available to patients and physicians facing the challenges of CTCL and severe oral mucositis.”

### **About Cutaneous T-Cell Lymphoma**

Cutaneous T-cell lymphoma (CTCL) is a class of non-Hodgkin's lymphoma (NHL), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These malignant cells migrate to the skin, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. Mortality is related to the stage of CTCL, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no cure for CTCL.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the approximate 500,000 individuals living with the disease. It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL that it affects over 20,000 individuals in the US, with approximately 2,800 new cases seen annually.

### **About SGX301**

SGX301 is a novel first-in-class photodynamic therapy utilizing safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a potent photosensitizer that is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. This treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with the frequently employed DNA-damaging chemotherapeutic drugs and other photodynamic therapies that are dependent on ultraviolet exposure. Combined with photoactivation, hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In a published

Phase 2 clinical study in CTCL, patients experienced a statistically significant ( $p \leq 0.04$ ) improvement with topical hypericin treatment whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively. SGX301 has received orphan drug and fast track designations from the US Food and Drug Administration (FDA), as well as orphan designation from the European Medicines Agency (EMA).

## **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 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 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 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. 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.

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