Soligenix Investor Relations

Soligenix Receives European Patent for Formulation of Synthetic Hypericin to Treat Psoriasis

PRINCETON, NJ – February 22, 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 that its proprietary formulation of synthetic hypericin has been granted a European patent for the treatment of psoriasis. The issued patent, EP 2571507, Formulations and methods of treatment of skin conditions, complements the method of treatment claims covered by the previously issued US patent 6001882, Photoactivated hypericin and the use thereof.

Synthetic hypericin, the active ingredient in SGX301, completed a Phase 2 clinical study demonstrating significant improvement in both Cutaneous T-cell lymphoma (CTCL) and psoriasis. Positive results were published in the *Journal of the American Academy of Dermatology*(https://dx.doi.org/10.1016/j.jaad.2010.02.039). Soligenix is currently enrolling patients into a pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL.

“We are pleased to be granted additional protection for our intellectual property in Europe while we aggressively pursue SGX301 in CTCL. In the meantime, we are positioning synthetic hypericin for potential product expansion into other cutaneous T-cell diseases, such as psoriasis, as a component of our long-term strategy to enhance the value of our compound,” stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. “With the promising Phase 2 results in both CTCL and psoriasis, we eagerly await the results of our ongoing Phase 3 CTCL clinical study, which are expected by the end of this year.”

About Synthetic Hypericin

Synthetic hypericin, the active ingredient in SGX301, is a potent photosensitizer that is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. This novel 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, patients with CTCL experienced a statistically significant ($p \leq 0.04$) improvement with topical hypericin treatment whereas the placebo was ineffective: 58.3% vs. 8.3%, respectively. In patients with psoriasis, a statistically significant ($p < 0.02$) improvement with topical hypericin treatment was also experienced, whereas the placebo was ineffective: 54.6% vs. 0.0%, respectively.

SGX301 in CTCL 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) and promising innovative medicine designation from the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom.

About Psoriasis

Psoriasis is a chronic, noncommunicable, painful skin condition for which there is no cure with great negative impact on patients’ quality of life. It is caused by rapidly proliferating skin cells, driven by autoimmune T-cell mediated inflammation. Of the various types of psoriasis, plaque psoriasis is the most common and is characterized by red plaques that are covered by white scales. Moderate psoriasis is characterized by the involvement of 3-10% of the body surface area, while severe psoriasis will involve >10% of the body surface area. There is a genetic component to psoriasis, as children with one parent with psoriasis have a 10% risk of inheriting the disease. About 30% of people with psoriasis will also develop psoriatic arthritis.

Psoriasis is usually associated with T-cell lymphocytic and neutrophilic infiltrates superficially in lesional skin. Treatments vary from topical options including photodynamic therapy to reduce pain and itching and potentially reduce the inflammation driving plaque formation, to systemic treatments. Most common systemic treatments and even current topical photodynamic therapy carry a risk of increased skin cancer.

According to the World Health Organization Global Report on Psoriasis 2016 (http://apps.who.int/iris/bitstream/10665/204417/1/9789241565189_eng.pdf), the prevalence of psoriasis is between 1.5% and 5% in developed countries, with some suggestions of incidence increasing with time. It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of psoriasis, that it affects approximately 2% of the total population in the US.

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 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®. 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. 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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