Soligenix Investor Relations

Soligenix Initiates Phase 2 Clinical Trial of SGX302 (synthetic hypericin) for the Treatment of Mild-to-Moderate Psoriasis

Study HPN-PSR-01 opens patient enrollment

PRINCETON, N.J., Dec. 19, 2022 /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 patient enrollment has been opened for its Phase 2a study (protocol number HPN-PSR-01) evaluating SGX302 (synthetic hypericin) in the treatment of mild-to-moderate psoriasis. Psoriasis is an ongoing unmet medical need, with as many as 7.5 million people in the U.S. and 60-125 million people worldwide affected by this incurable disease.

"We are excited to expand synthetic hypericin's development into different cutaneous T-cell diseases such as psoriasis, as a component of our long-term strategy to enhance the value of this unique compound," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Given our promising published results with hypericin to date, including a small Phase 1/2 proof of concept clinical trial in mild-to-moderate psoriasis, and the Phase 3 FLASH study in cutaneous T-cell lymphoma, where we filed a New Drug Application (NDA) this month, we are hopeful synthetic hypericin will have a role to play in helping patients suffering from this difficult to treat and chronic disease."

The Phase 2a clinical trial (protocol number HPN-PSR-01) will target enrollment of up to 42 patients ages 18 years or older with mild to moderate, stable psoriasis covering 2 to 30% of their body. In both Parts A and B, all patients will apply the study drug twice per week and will activate the drug with visible light 24 ± 6 hours later using the supplied visible light devices and according to the manufacturer's instructions. Patients will undergo treatments for a total of 18 weeks and, on completion, will be followed for a 4-week follow-up period in which patients will not receive other psoriasis treatments. In Part A, 5-10 patients will be assigned open-label SGX302 (0.25% hypericin) at the time of enrollment. Once the tolerability and response to SGX302 has been established, Part B of the protocol will commence. In Part B, patients will be randomized to double-blind treatment groups at a ratio 1:1 of active drug to placebo ointment.

Active dermatologic assessment of treated lesions for adverse events will be performed immediately before and during light treatments. Patients will be assessed for overall disease status through 4 weeks of follow-up. Efficacy endpoints will include the extent of lesion clearance and patient reported quality of life indices. Routine safety laboratories also will be collected.

About Synthetic Hypericin

Visible light-activated synthetic hypericin is a novel, first-in-class, photodynamic therapy (PDT) that is expected to avoid much of the long-term risks associated with other PDT treatments. Synthetic hypericin is a potent photosensitizer that is topically applied to skin lesions and taken up by cutaneous T-cells. With subsequent activation by safe, visible light, T-cell apoptosis is induced, addressing the root cause of psoriasis lesions. Other PDTs have shown efficacy in psoriasis with a similar apoptotic mechanism, albeit using ultraviolet (UV) light associated with more severe potential long-term safety concerns. The use of visible light in the red-yellow spectrum has the advantage of deeper penetration into the skin (much more than UV light) potentially treating deeper skin disease and thicker plaques and lesions, similar to what was observed in the positive Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study in CTCL. Synthetic hypericin or HyBryte™ (the tradename used in CTCL) was demonstrated in this study to be equally effective in treating both plaque (42% treatment response rate after 12 weeks treatment, $p<0.0001$ relative to placebo treatment) and patch (37%, $p=0.0009$) lesions in this orphan disease caused by malignant T-cells. In a published Phase 1/2 proof of concept clinical study using synthetic hypericin, efficacy was demonstrated in patients with CTCL (58.3% response, $p=0.04$) as well as psoriasis (80% response, $p<0.02$).

This treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with both the frequently used DNA-damaging drugs and other phototherapies that are dependent on UV A or B exposure. The use of synthetic hypericin coupled with safe, visible light also avoids the risk of serious infections and cancer associated with the systemic immunosuppressive treatments used in psoriasis.

The Phase 3 FLASH trial enrolled a total of 169 patients (166 evaluable) with Stage IA, IB or IIA CTCL. The trial consisted of three treatment cycles. Treatments were administered twice weekly in 6-week cycles. In the first double-blind treatment cycle, 116 patients received HyBryte™ treatment and 50 received placebo treatment of their index lesions. A total of 16% of the patients receiving HyBryte™ achieved at least a 50% reduction in their lesions (using the standard Composite Assessment of Index Lesions Severity [CAILS] score) compared to only 4% of patients in the placebo group after just 6 weeks of treatment ($p=0.04$). Further treatment with HyBryte™ increased the number of treatment successes to 40% and 49% after 12 and 18 weeks, respectively ($p<0.0001$ for both). Additional analyses also indicated that HyBryte™ is equally effective in treating both plaque (42% treatment response rate after 12 weeks treatment, $p<0.0001$ relative to placebo treatment in Cycle 1) and patch (37%, $p=0.0009$) lesions of CTCL, a particularly relevant finding given the historical difficulty in treating plaque lesions. This is also relevant to psoriasis where the lesions can be thicker than the patches observed in CTCL.

In a subset of patients evaluated during their third treatment cycle, it was demonstrated that HyBryte™ is not systemically available, consistent with the general safety of this topical product observed to date. At the end of Cycle 3, HyBryte™ continued to be well tolerated despite extended and increased use of the product to treat multiple lesions.

About Psoriasis

Psoriasis is a chronic, non-communicable, itchy and often painful inflammatory skin condition for which there is no cure. Psoriasis has a significantly detrimental impact on patients' quality of life, and is associated with cardiovascular, arthritic, and metabolic diseases, as well as psychological conditions such as anxiety, depression and suicide. Many factors contribute to development of psoriasis including both genetic and environmental factors (e.g., skin trauma, infections, and medications). The lesions develop because of 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 dry, red raised plaques that are covered by silvery-white scales occurring most commonly on the elbows, knees, scalp, and lower back. Approximately 80% of patients have mild-to-moderate disease. Mild psoriasis is generally characterized by the involvement of less than 3% of the body surface area (BSA), while moderate psoriasis will typically involve 3-10% BSA and severe psoriasis greater than 10% BSA. Between 20% and 30% of individuals with psoriasis will go on to develop chronic, inflammatory arthritis (psoriatic arthritis) that can lead to joint deformations and disability. Studies have also associated psoriasis, and particularly severe psoriasis, with an increased relative risk of lymphoma, particularly CTCL. Although psoriasis can occur at any age, most patients present with the condition before age 35.

Treatment of psoriasis is based on its severity at the time of presentation with the goal of controlling symptoms. It varies from topical options including PDT to reduce pain and itching, and potentially reduce the inflammation driving plaque formation, to systemic treatments for more severe disease. Most common systemic treatments and even current topical photo/photodynamic therapy such as UV A and B, carry a risk of increased skin cancer.

Psoriasis is the most common immune-mediated inflammatory skin disease. According to the World Health Organization (WHO) Global Report on Psoriasis 2016, the prevalence of psoriasis is between 1.5% and 5% in most 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 that psoriasis affects 3% of the U.S. population or more than 7.5 million people. Current estimates have as many as 60-125 million people worldwide living with the condition. The global psoriasis treatment market was valued at approximately $15 billion in 2020 and is projected to reach as much as$40 billion by 2027.

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 and moving toward potential commercialization of HyBryte™ (SGX301 or synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With a successful Phase 3 study completed, regulatory approval is being sought and commercialization activities for this product candidate are being advanced initially in the U.S. Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including 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).

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, and our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). 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), the Defense Threat Reduction Agency (DTRA) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website athttps://www.soligenix.com and follow us on LinkedIn and Twitter at @Soligenix_Inc.

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, such as experienced with the COVID-19 outbreak. 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 the timing or success of any of its clinical/preclinical trials. Despite the statistically significant result achieved in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that a marketing authorization from the FDA or EMA will be successful. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 1/2 proof-of-concept clinical trial of SGX302 for the treatment of psoriasis, there can be no assurance as to the timing or success of the clinical trials of SGX302 for the treatment of psoriasis. Further, there can be no assurance that RiVax® will qualify for a biodefense Priority Review Voucher (PRV) or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. Also, no assurance can be provided that the Company will receive or continue to receive non-dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. 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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For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200, www.soligenix.com

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