Soligenix Investor Relations

Soligenix Announces Top-line Results of the Phase 2a Study of SGX302 (Synthetic Hypericin) in Patients with Mild-to-Moderate Psoriasis

Optimized Gel Formulation Demonstrates Clinical Success in Third Cohort of Patients

PRINCETON, N.J., Dec. 17, 2025 /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 extended results of its ongoing Phase 2a trial of SGX302 (synthetic hypericin) for the treatment of mild-to-moderate psoriasis. In this extension (Cohort 3) of the exploratory phase of the study, an additional four patients were enrolled and treated with an improved topical gel formulation of synthetic hypericin.

The Cohort 3 patients were treated for the same 18-week period as Cohorts 1 and 2, but utilized an optimized gel formulation of synthetic hypericin. The gel formulation was specifically designed to improve ease of application to larger areas of the skin. SGX302 gel therapy was well tolerated by all patients with no drug related adverse events identified. On average over the three evaluable patients (one patient discontinued for personal reasons), there were improvements in the Investigator Global Assessment (IGA), the Psoriasis Activity and Severity Index (PASI), the simplified psoriasis index, the dermatology life quality index and the Skindex-29 questionnaire. One patient achieved a disease status of "Almost Clear" using the IGA, which is considered a standard clinical measure for treatment success in psoriasis, with a substantial improvement in their PASI score, exceeding 50%. These outcomes were very similar to or improved relative to those obtained with the previous ointment formulation, as expected given the comparable release characteristics of the two formulations and the enhanced ease of application of the gel. In totality, the initial exploratory phase of the study has confirmed that SGX302 improves psoriasis lesions, consistent with the general success of photodynamic therapies in psoriasis, and is well tolerated, potentially providing a non-carcinogenic, non-mutagenic treatment for the thicker lesions found in psoriasis.

"We are pleased with the preliminary findings from our ongoing Phase 2a trial," statedChristopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The optimized gel formulation was designed to improve the patient experience, with both easier dispensation and skin application. The expansion of this psoriasis study continues our evaluation of synthetic hypericin into other disease indications, including non-orphan indications, where there remains an unmet medical need. Current estimates show as many as 60-125 million people worldwide living with the condition, with a global treatment market valued at approximately $15 billion in 2020 and projected to reach as much as$40 billion by 2027. The success of HyBryte™ in targeting malignant T-cells during cutaneous T-cell lymphoma (CTCL) clinical trials is a promising indicator of the ability of SGX302 to provide a much-needed approach for the treatment of mild-to-moderate psoriasis, also caused by dysregulated T-cells. We anticipate continuing to pursue SGX302 in psoriasis as we advance the confirmatory Phase 3 trial for HyBryte™ in the treatment of early-stage CTCL where topline results are expected in the second half of 2026."

About Synthetic Hypericin

Visible light-activated synthetic hypericin is a novel, first-in-class, photodynamic therapy (PDT) that is expected to avoid many of the long-term risks associated with other PDT treatments. Synthetic hypericin is a potent photosensitizer that is topically applied to skin lesions and absorbed 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™ (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, $p<0.02$).

In an ongoing Phase 2a study in mild-to-moderate psoriasis, patients enrolled in the initial portion of the trial (Part A) have completed treatment. In Cohort 1, the initial five patients enrolled received twice weekly treatment for 18 weeks with 0.25% hypericin ointment, followed by light activation approximately 24 hours later. Light doses were increased by up to 1 J/cm^2 on subsequent visits until mild erythema was observed in the treated lesions. Light doses for all patients were still being intermittently increased when the scheduled treatments ended, and light doses were generally safe and well tolerated. Evaluation of the initial cohort of five patients demonstrated a clear biological signal, with the majority of patients recording an improvement in the PASI (psoriasis area and severity index) score, providing evidence of biological improvement, but no patient met the definition of treatment success (IGA score of 0 or 1) at the 18-week treatment timepoint. The second cohort of five patients were enrolled once the Cohort 1 patients had completed all treatment visits. Given how well-tolerated light treatments were in the first Cohort, it was determined that the second cohort of patients could safely receive an accelerated light treatment with increases in the light dose by up to 2 J/cm^2 at each visit and allowing the maximum light dose (25 J/cm^2) to be reached earlier by approximately week 14, allowing more treatments at the maximum light dose to be completed in the 18-week

treatment schedule. Two of the four evaluable patients achieved a clinical success score at some point during the 18-week treatment period and all evaluable patients improved, yielding an average reduction of approximately 50% in the PASI score. One patient in Cohort 2 dropped out of the study for personal reasons unrelated to the study. The third cohort of the study enrolled four patients, and one of the three evaluable patients achieved a clinical success score, and all evaluable patients improved in multiple indices, including PASI, simplified psoriasis index, and dermatology Life Quality Index. One patient in Cohort 3 discontinued the study for personal reasons and was considered not evaluable. The third cohort specifically assessed the use of an improved formulation of SGX302, designed as a gel as opposed to the previous ointment format. The gel formulation was designed for ease of application and for use in squeezable tubes, instead of jars.

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.

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 light, carry a risk of increased skin cancer.

Psoriasis is the most common immune-mediated inflammatory skin disease. According to theWorld 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 sodium) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With successful completion of the second Phase 3 study, regulatory approvals will be sought to support potential commercialization worldwide. 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 (SGX945) in Behçet's Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate, as well as 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'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 the timing or success of any of its clinical/preclinical trials. Despite the statistically significant result achieved in the first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma or any other studies (including the open-label, investigator-initiated study), there can be no assurance that the second HyBryte™ (SGX301) Phase 3 clinical trial will be successful or that a marketing authorization from the FDA or EMA will be granted. Additionally, although the EMA has agreed to the key design components of the second HyBryte™ (SGX301) Phase 3 clinical trial, no assurance can be given that the Company will be able to modify the development path to adequately address the FDA's concerns or that the FDA will not require a longer duration comparative study. Notwithstanding the result in the first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 2a 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. Additionally, despite the biologic activity observed in aphthous ulcers induced by chemotherapy and radiation, there can be no assurance as to the timing or success of the clinical trials of SGX945 for the treatment of Behçet's Disease. 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 (the "SEC"), 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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