

Soligenix Announces Expansion of SGX302 (Synthetic Hypericin) Phase 2a Study in Mild-to-Moderate Psoriasis

Clear biological signal demonstrated; additional patients to be enrolled

PRINCETON, N.J., July 11, 2023 /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 the expansion of its Phase 2a trial of [SGX302](#) (synthetic hypericin) for the treatment of mild-to-moderate psoriasis after demonstration of biological effect in the initial five subjects. The study is expected to enroll at least an additional five subjects, exploring the use of SGX302 in the standard of care psoriasis setting, prior to undertaking the larger phase of the study.

Evaluation of the initial five subjects enrolled demonstrated a clear biological signal, with the majority of patients recording an improvement in the PASI (psoriasis area and severity index) score. Enrolling additional patients will enable Soligenix to evaluate the use of SGX302 in the context of accelerated light treatment and additional adjunct treatment.

"Patients with mild-to-moderate disease do not qualify for the use of biologics and have fewer treatment options. The patients enrolled in this study all demonstrated clinical improvement and, with the experience gained in this first portion of the study, we anticipate being able to further improve responses as we move forward," stated Neal Bhatia, MD, Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego and Chair of the Company's Psoriasis MAB. "Having previously participated in the positive Phase 3 clinical trial of [HyBryte™ \(synthetic hypericin\) in the treatment of cutaneous T-cell lymphoma \(CTCL\)](#), I have had a clinical interest in this novel therapy and am pleased that the Soligenix team is advancing synthetic hypericin in psoriasis where there remains an unmet medical need. Similar to CTCL, psoriasis is a chronic disease where the management of side effects and toxicities is as important as the management of the disease itself. Psoriasis affects more than 7.5 million patients in the U.S. alone, and 60-125 million people worldwide. Having treated psoriasis patients for over 20 years and seen first-hand how they struggle to find good treatment options, access to an additional effective and safe therapy would add significantly to patient care and quality of life for many people that are living with this disease. I look forward to working with my esteemed colleagues to support Soligenix in advancing this important development program forward."

"We are pleased with the initial results from our Phase 2a trial," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "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 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 being in a position to report additional SGX302 study data before year-end, as well as the outcome of our ongoing discussions with the FDA regarding a feasible and executable trial design for a confirmatory Phase 3 study with HyBryte™ in the treatment of early stage CTCL."

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, $p < 0.02$).

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 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 sodium) 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, 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 at <https://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, and include the expected amount and use of proceeds from the offering and the expected closing date of the offering. 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 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. 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, the Company's preliminary prospectus (Registration No. 333-271049) filed with the SEC on May 4, 2023, and 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

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