Soligenix Investor Relations

Soligenix to Advance Synthetic Hypericin Development in Psoriasis

- Validated clinical pharmacology and positive psoriasis proof-of-concept clinical study with synthetic hypericin sets stage for pipeline expansion
- Plan to initiate follow-on Phase 2a clinical study in mild-to-moderate psoriasis
- Psoriasis affects 60-125 million people worldwide

PRINCETON, N.J., Sept. 16, 2021 /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 following the validation of synthetic hypericin's biologic activity in the positive pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study in cutaneous T-cell lymphoma (CTCL), as well as positive proof-of-concept (PoC) demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients, the Company will be expanding this novel therapy under the research name SGX302 into psoriasis, a large and underserved market with a significant unmet medical need.

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 toxicities. 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 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 of this orphan disease caused by malignant T-cells. Further, 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.

"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. Having treated both CTCL and psoriasis patients for over 20 years and having 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," stated Neal Bhatia, MD, Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego and an investigator in the Phase 3 FLASH study. "The success of synthetic hypericin 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. This success is further supported by both the previous synthetic hypericin PoC study in psoriasis and by the success, albeit confounded by potentially severe toxicity, of other photodynamic therapies in psoriasis."

"During the last year, we have made announcements of several important development milestones that we have achieved with HyBryte™ (synthetic hypericin) in the treatment of early stage CTCL. We have clearly validated synthetic hypericin's biologic activity with the Phase 3 FLASH study in this orphan disease, where we expect to file a New Drug Application (NDA) in the first half of next year. We believe it is now appropriate to expand synthetic hypericin's or SGX302'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. "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. Given our promising results with hypericin to date, including a small Phase 1/2 PoC clinical trial in mild-to-moderate psoriasis, we are hopeful synthetic hypericin will have a role to play in helping patients suffering from this difficult to treat and chronic disease."

Dr. Schaber continued, "As we get closer to initiating a follow-on Phase 2a clinical trial in mild-to-moderate psoriasis, we will provide further details regarding trial design and timeline; however, our high level plan in the interim is to evaluate different topical formulations of synthetic hypericin to ensure optimal absorption for broadly treating this disease. In parallel, we will be working with our psoriasis clinical experts to finalize a protocol with a plan to initiate study enrollment in the latter part of 2022. Given our current cash position and the expected cost of the Phase 2a trial, we do not anticipate needing to raise additional capital to support this Phase 2a trial as we continue to advance towards NDA filing and U.S. commercialization of HyBryte™ in the treatment of CTCL."

About Synthetic Hypericin

Synthetic hypericin, the active ingredient in HyBryte™ (hypericin ointment 0.25%), is a potent photosensitizer that is topically applied to skin lesions and then activated by fluorescent light the following day. This novel treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with the frequently employed DNA-damaging chemotherapeutic drugs and other PDTs that depend on UV 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 1/2 PoC clinical study using synthetic hypericin, efficacy was demonstrated in patients with CTCL (58.3% response, p=0.04) and psoriasis (80% response, p<0.02). Subsequently, a Phase 3 study in CTCL has further confirmed the biological efficacy of synthetic hypericin (termed HyBryte™ in the context of CTCL).

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 synthetic hypericin treatments 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.

The Phase 3 CTCL clinical study was partially funded by the National Cancer Institute via a Phase II SBIR grant (#1R44CA210848-01A1) awarded to Soligenix.

HyBryte™ in CTCL has received orphan drug and fast track designations from the U.S. 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. Hypericin has also received orphan designation from the FDA for T-cell lymphoma.

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 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) and acute radiation enteritis (SGX201).

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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