Soligenix Investor Relations

Soligenix Receives USAN Approval for "Hypericin Sodium" as Nonproprietary Name for Novel Active Ingredient in HyBryte™ and SGX302

PRINCETON, N.J., April 5, 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 that the United States Adopted Names (USAN) Council has approved the use of the nonproprietary name of "hypericin sodium" for the novel active ingredient in both HyBryte™ (research name SGX301) for the treatment of cutaneous T-cell lymphoma (CTCL) and SGX302 for the treatment of mild-to-moderate psoriasis.

"We are pleased that USAN has approved the proposed name," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We look forward to continuing to work with the World Health Organization (WHO) to advance the International Nonproprietary Name (INN) hypericin from a proposed INN to a recommended INN, which is expected to occur later this year."

Information on hypericin sodium will be posted on the USAN website (www.ama-assn.org/go/usan) before the end of 2023 and will be submitted to the U.S. Pharmacopeial Convention for publication in the U.S. Pharmacopeia Dictionary of USAN and International Drug Names.

About USAN

The USAN Council serves health professionals in the U.S. by selecting simple, informative, and unique nonproprietary names for drugs by establishing logical nomenclature classifications based on pharmacological and/or chemical relationships to ensure that drug information is communicated accurately and unambiguously. The USAN Council aims for global standardization and unification of drug nomenclature by working closely with the International Nonproprietary Name Program of WHO and various national nomenclature groups.

About Synthetic Hypericin Sodium

Visible light-activated synthetic hypericin sodium 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 sodium 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 both CTCL and 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 previous clinical trials.

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 sodium coupled with safe, visible light also avoids the risk of serious infections and cancer associated with the systemic immunosuppressive treatments used in CTCL and psoriasis.

In a published Phase 1/2 proof of concept clinical study using synthetic hypericin sodium, efficacy was demonstrated in patients with CTCL (58.3% response, $p=0.04$) as well as psoriasis (80% response, $p<0.02$).

The recently published Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study 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™ (the tradename used in CTCL) 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.

A HyBryte™ new drug application (NDA) has been submitted for the treatment of CTCL with the U.S. Food and Drug Administration (FDA). It is currently the subject of an FDA Refusal to File (RTF) letter, as upon preliminary assessment, the FDA determined that it was not sufficiently complete to permit substantive review. A Type A meeting with the FDA has been scheduled to gain further clarity and to respond to the issues identified in the RTF letter, as well as to seek additional guidance concerning information that the agency would require for a resubmitted NDA to be deemed acceptable.

SGX302 (synthetic hypericin sodium) is currently being evaluated in a Phase 2a clinical trial targeting enrollment of up to 42 patients ages 18 years or older with mild to moderate, stable psoriasis covering 2 to 30% of their body. 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. The study is divided into two parts. 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.

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 sodium (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 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, 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. HyBryte™ potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this information. While the Company has determined this potential market size based on assumptions that its believes are reasonable, there are a number of factors that could cause expectations to change or not be realized. 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.

SOURCE Soligenix, Inc.

For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200, www.soligenix.com; Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540
