Soligenix Investor Relations

Soligenix Announces Formation of Psoriasis Medical Advisory Board

Phase 2a clinical study in mild-to-moderate psoriasis initiating in December 2022

PRINCETON, N.J., Oct. 25, 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 the formation of a Medical Advisory Board (MAB) to provide medical/clinical strategic guidance to the Company as it advances the Phase 2a clinical development of SGX302 (synthetic hypericin) for the treatment of mild-to-moderate psoriasis. The Company previously announced that the U.S. Food and Drug Administration (FDA) had cleared the investigational new drug (IND) application and Phase 2a clinical protocol. The study is anticipated to begin in December 2022.

"The MAB enthusiastically supports Soligenix in their efforts to improve outcomes for patients with psoriasis, which affects more than 7.5 million patients in the U.S. alone," 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 pivotal 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. 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. My colleagues and I look forward to working with Soligenix in advancing this important development program."

"We are pleased to be able to attract such esteemed and enthusiastic professionals to participate as members of our MAB," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The initiation of a psoriasis program marks an important first step in expansion of synthetic hypericin into other disease indications where there remains an unmet medical need. 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. This success is further supported by the previous synthetic hypericin proof of concept study in psoriasis. We look forward to working with the MAB and initiating the Phase 2a clinical trial before yearend."

Comprised of dermatologic thought leaders with extensive experience in psoriasis, the MAB will play an important advisory role in the conduct of the upcoming Phase 2a clinical study, as well as in the design of subsequent clinical studies and associated regulatory interactions with health authorities. The MAB will provide feedback, input and guidance on clinical strategies and their implementation, as well as on other critical issues, such as health economics and reimbursement, to assist Soligenix in meeting the needs of the psoriasis patients.

The MAB Members

Neal Bhatia, MD

Dr. Bhatia is a board-certified dermatologist in private practice and serves as Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego. He has experience in treating a wide range of dermatologic issues, including acne, psoriasis, rosacea, skin cancer and more. He is chief medical editor of *Practical Dermatology*. Dr. Bhatia also is a member of the American Academy of Dermatology (AAD), where he has served on the AAD board of directors and most recently as AAD Vice President. He has held several academic positions and has served as Principal Investigator in multiple clinical trials. To date, he has authored or co-authored over 100 publications in professional journals. He earned his medical degree from the University of Wisconsin.

George Han, MD, PhD

Dr. Han is a board-certified dermatologist and serves as associate professor in the Department of Dermatology at the Donald and Barbara Zucker School of Medicine at Hofstra / Northwell, where he leads efforts in clinical research and teledermatology. He is the current Vice President of the Dermatologic Society of Greater New York, a member of the board of directors of the New York State Society of Dermatology and Dermatologic Surgery, a member of the Medical Board of the National Psoriasis Foundation, and an Associate of the International Eczema Council. He remains active in both basic science research and clinical trials, serving as Principal Investigator in studies encompassing multiple clinical areas, including Psoriasis. Dr. Han currently serves as the Chairman of the Department of Dermatology at Mount Sinai Beth Israel. He is also the Director of Teledermatology for the Department of Dermatology at the Icahn School of Medicine at Mount Sinai. He is an internationally recognized lecturer and researcher, and has been the recipient of multiple awards in the field of dermatology. To date, he has over 70 publications in well-respected journals as well as several book chapters and patents. He is also the recipient of a Women's Dermatologic Society grant for his research. He earned his medical and doctoral degrees from the Albert Einstein College of Medicine.

Jonathan S. Weiss, MD

Dr. Weiss is a board-certified dermatologist and serves as adjunct assistant clinical professor of Dermatology at the Emory University School of Medicine. He also practices at Georgia Dermatology Partners and Gwinnett Clinical Research Center, Inc. Dr. Weiss oversees an active clinical trial unit studying a wide range of dermatologic conditions and pharmaceutical compounds, having been an investigator in over 200 studies. He has authored or co-authored over 90 publications in medical and dermatology journals, including *JAMA*, *Pediatric Dermatology*, *International Journal of Dermatology*, *Journal of Drugs in Dermatology*, and the *Journal of the AAD*. He earned his medical degree from the University of Michigan in Ann Arbor, where he also served as chief resident in the dermatology department.

Paul S Yamauchi, MD, PhD

Dr. Yamauchi is a board-certified dermatologist in private practice and serves as Medical Director at both the Dermatology Institute & Skin Care Center and Clinical Science Institute in Santa Monica, California. He is a clinical assistant professor of medicine in the Division of Dermatology at the David Geffen School of Medicine at UCLA where he also completed his residency in dermatology. Dr. Yamauchi serves on the editorial board of various journals and is on several task force committees for the AAD. He is the author and co-author of over 120 publications, including several books. Additionally, he conducts numerous clinical research trials at the Clinical Science Institute in Santa Monica and is recognized as a key opinion leader in psoriasis and atopic dermatitis. He is currently serving his second term on the Medical Board for the National Psoriasis Foundation and was previously on the Scientific Advisory Council for the National Eczema Association. He earned his doctoral degree in biochemistry from the University of California at Santa Barbara and his medical degree from Case Western Reserve University School of Medicine.

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) 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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