Soligenix Investor Relations

Soligenix Announces Expansion of European Medical Advisory Board for Cutaneous T-Cell Lymphoma

In preparation for health authority interactions in pursuit of marketing approvals in Europe

PRINCETON, N.J., Sept. 30, 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 the expansion of its European Medical Advisory Board (MAB) to provide additional medical/clinical strategic guidance to the Company as it advances its confirmatory Phase 3 multicenter, double-blind, placebo-controlled study evaluating the safety and efficacy of HyBryte™ (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL) patients with early-stage disease. This confirmatory, 18-week study is expected to enroll approximately 80 patients and is targeted to report top-line results in the second half of 2026.

"We are excited to expand our European MAB to include Drs. Scarisbrick and Vermeer who are each esteemed dermatologists that will bring valuable guidance to our program," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We consider expert European involvement a necessary component for the development and approval of HyBryte™ in both the European Union (EU) and the United Kingdom (UK). As such, it is a privilege to expand the MAB to five members that are highly-respected leaders in their field and committed to working with us as we advance HyBryte™ towards commercialization. We look forward to working with the MAB and reporting top-line results for the confirmatory Phase 3 study in 2026."

Comprised of internationally renowned physicians with extensive experience in treating and running clinical research trials in CTCL, this esteemed expanded MAB will play an important advisory role in the conduct and interpretation of the upcoming Phase 3 clinical study and the associated regulatory interactions with health authorities. The MAB will provide expert feedback, input, and guidance on clinical strategies and their implementation, as well as on other critical items, such as health economics and reimbursement, to assist Soligenix in meeting the needs of patients suffering from CTCL.

European MAB Members

Martine Bagot, MD, PhD – France

Martine Bagot is Professor and Head of the Department of Dermatology at the HôpitalSaint Louis in Paris, France and co-directs the INSERM Unit 976 Human Immunology, Pathophysiology and Immunotherapy. Dr. Bagot also chairs the French Group for the Study of Cutaneous Lymphomas. Dr. Bagot has co-authored more than 750 peer-reviewed publications, most of which are in the complementary fields of dermatology, immunology, and oncology. Main publications include numerous clinical trials in dermato-oncology. Dr. Bagot is involved with major European international societies such as the International Society for Cutaneous Lymphoma (ISCL), The European Society for Dermatological Research (ESDR), and the European Organisation for Research and Treatment of Cancer (EORTC) Cutaneous Lymphoma Task Force, where she previously served as its President and is currently a steering committee member.

Pietro Quaglino, MD – Italy

Pietro Quaglino is Associate Professor of Dermatology at the Department of Medical Sciences, University of Turin Medical School, Italy. His clinical and research activities focus on melanoma, cutaneous lymphoma, and immune dermatology. He is the principal investigator of several clinical trials in melanoma and cutaneous lymphoma. He is board member of the GIPMe (Gruppo Italiano Polidisciplinare sul Melanoma), board member and treasurer of the IMI (Italian Melanoma Intergroup), past chairman and current steering committee member of the EORTC Cutaneous Lymphoma Task Force, and member of the Board Directors of the ISCL. He has published more than 160 peer-reviewed scientific papers. Dr. Quaglino is Assistant Editor of the Giornale Italiano di Dermatologia e Venereologia, reviewer of international journals on dermatology and referee for ANVUR (National Agency for the Evaluation of Universities and Research Institutes).

Pablo Luis Ortiz-Romero, MD, PhD – Spain

Pablo Luis Ortiz-Romero is Professor of Dermatology and Head of the Dermatology Department at Hospital Universitario 12 de Octubre, Spain. He is a distinguished dermatologist and researcher specializing in cutaneous lymphomas, particularly mycosis fungoides and Sézary syndrome forms of CTCL. His experience is extensive, having contributed to over 200 publications and numerous clinical studies in the field. Dr. Ortiz-Romero is affiliated with the ISCL and has served on its Board of Directors. His research includes innovative treatments for CTCL, and he is one of the leading physicians focused on novel treatments for CTCL in Spain. He served as the Secretary General of the EORTC Cutaneous Lymphoma Tumor Group and is currently a member of its steering committee.

Julia Scarisbrick, MBhons, ChB, FRCP, MD – United Kingdom

Julia Scarisbrick leads the Specialist Cutaneous Lymphoma Service at University HospitalBirmingham, UK. She holds an honorary Chair as Professor for the Institute of Immunology and Immunotherapy and Dermatology Co-Lead for Dermatology Research Group, Clinical Sciences, University of Birmingham. Prof. Scarisbrick is an internationally renowned dermatologist in the UK specializing in clinical and molecular research involving cutaneous lymphomas with over 150 publications as well as a number of book chapters to her name. She is the President of the ISCL, Past Chairperson of the EORTC Cutaneous Lymphoma Group, the European Director for Cutaneous Lymphoma International Consortium, the Chairperson and Trustee for the UK Photopheresis Society and Treasurer and Trustee for the UK Cutaneous Lymphoma Group (Past Chair).

Maarten H. Vermeer, MD, PhD – The Netherlands

Maarten H. Vermeer is the Head of the Department of Dermatology of the Leiden University Medical Center (LUMC). Dr. Vermeer has been researching the pathogenesis and treatment of cutaneous lymphomas for more than 25 years. He has more than 175 scientific publications to his name. Recently, his research activities have concentrated on clinicopathologic studies, genomic analysis of genetic and epigenetic alterations in cutaneous lymphoma tumor cells as well as international collaborative studies to develop diagnostic markers and standardize flowcytometry in cutaneous lymphomas. Dr. Vermeer served on the board of the European Society Dermatological Research, and the EORTC Cutaneous Lymphoma Working Group and chaired the board of the ISCL.

About HyBryte™

HyBryte™ (research name SGX301) is a novel, first-in-class, photodynamic therapy utilizing safe, visible light for activation. The active ingredient in HyBryte™ is synthetic hypericin, a potent photosensitizer that is topically applied to skin lesions that is taken up by the malignant T-cells, and then activated by safe, visible light approximately 24 hours later. The use of visible light in the red-yellow spectrum has the advantage of penetrating more deeply into the skin (much more so than ultraviolet light) and therefore potentially treating deeper skin disease and thicker plaques and lesions. This treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with the frequently employed DNA-damaging drugs and other phototherapy that are dependent on ultraviolet 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 2 clinical study in CTCL, patients experienced a statistically significant ($p=0.04$) improvement with topical hypericin treatment whereas the placebo was ineffective. HyBryte™ has received orphan drug and fast track designations from the FDA, as well as orphan designation from the European Medicines Agency (EMA).

The published 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 for the first 6 weeks and treatment response was determined at the end of the 8th week of each cycle. In the first double-blind treatment cycle (Cycle 1), 116 patients received HyBryte™ treatment (0.25% synthetic hypericin) 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 (graded using a standard measurement of dermatologic lesions, the CAILS score) compared to only 4% of patients in the placebo group at 8 weeks ($p=0.04$) during the first treatment cycle (primary endpoint). HyBryte™ treatment in this cycle was safe and well tolerated.

In the second open-label treatment cycle (Cycle 2), all patients received HyBryte™ treatment of their index lesions. Evaluation of 155 patients in this cycle (110 receiving 12 weeks of HyBryte™ treatment and 45 receiving 6 weeks of placebo treatment followed by 6 weeks of HyBryte™ treatment), demonstrated that the response rate among the 12-week treatment group was 40% ($p<0.0001$ vs the placebo treatment rate in Cycle 1). Comparison of the 12-week and 6-week treatment responses also revealed a statistically significant improvement ($p<0.0001$) between the two timepoints, indicating that continued treatment results in better outcomes. HyBryte™ continued to be safe and well tolerated. Additional analyses also indicated that HyBryte™ is equally effective in treating both plaque (response 42%, $p<0.0001$ relative to placebo treatment in Cycle 1) and patch (response 37%, $p=0.0009$ relative to placebo treatment in Cycle 1) lesions of CTCL, a particularly relevant finding given the historical difficulty in treating plaque lesions in particular.

The third (optional) treatment cycle (Cycle 3) was focused on safety and all patients could elect to receive HyBryte™ treatment of all their lesions. Of note, 66% of patients elected to continue with this optional compassionate use / safety cycle of the study. Of the subset of patients that received HyBryte™ throughout all 3 cycles of treatment, 49% of them demonstrated a positive treatment response ($p<0.0001$ vs patients receiving placebo in Cycle 1). Moreover, in a subset of patients evaluated in this 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.

Overall safety of HyBryte™ is a critical attribute of this treatment and was monitored throughout the three treatment cycles (Cycles 1, 2 and 3) and the 6-month follow-up period. HyBryte's™ mechanism of action is not associated with DNA damage, making it a safer alternative than currently available therapies, all of which are associated with significant, and sometimes fatal, side effects. Predominantly these include the risk of melanoma and other malignancies, as well as the risk of significant skin damage and premature skin aging. Currently available treatments are only approved in the context of previous treatment failure with other modalities and there is no approved front-line therapy available. Within this landscape, treatment of CTCL is strongly motivated by the safety risk of each product. HyBryte™ potentially represents the safest available efficacious treatment for

CTCL. With very limited systemic absorption, a compound that is not mutagenic and a light source that is not carcinogenic, there is no evidence to date of any potential safety issues.

Following the first Phase 3 study of HyBryte™ for the treatment of CTCL, the FDA and the EMA indicated that they would require a second successful Phase 3 trial to support marketing approval. With agreement from the EMA on the key design components, the second, confirmatory study, called FLASH**2**, is ongoing. This study is a randomized, double-blind, placebo-controlled, multicenter study that will enroll approximately 80 subjects with early-stage CTCL. The FLASH**2** study replicates the double-blind, placebo-controlled design used in the first successful Phase 3 FLASH study that consisted of three 6-week treatment cycles (18 weeks total), with the primary efficacy assessment occurring at the end of the initial 6-week double-blind, placebo-controlled treatment cycle (Cycle 1). However, this second study extends the double-blind, placebo-controlled assessment to 18 weeks of *continuous* treatment (no "between-Cycle" treatment breaks) with the primary endpoint assessment occurring at the end of the 18-week timepoint. In the first Phase 3 study, a treatment response of 49% ($p<0.0001$ vs patients receiving placebo in Cycle 1) was observed in patients completing 18 weeks (3 cycles) of therapy. In this second study, all important clinical study design components remain the same as in the first FLASH study, including the primary endpoint and key inclusion-exclusion criteria. The extended treatment for a continuous 18 weeks in a single cycle is expected to statistically demonstrate HyBryte's™ increased effect over a more prolonged, "real world" treatment course. Given the extensive engagement with the CTCL community, the esteemed Medical Advisory Board and the previous trial experience with this disease, accelerated enrollment in support of this study is anticipated, including the potential to enroll previously identified and treated HyBryte™ patients from the FLASH study. Discussions with the FDA on an appropriate study design remain ongoing. While collaborative, the agency has expressed a preference for a longer duration comparative study over a placebo-controlled trial. Given the shorter time to potential commercial revenue and the similar trial design to the first FLASH study afforded by the EMA accepted protocol, this study is being initiated. At the same time, discussions with the FDA will continue on potential modifications to the development path to adequately address their feedback.

Additional supportive studies have demonstrated the utility of longer treatment times with a75% response rate after 18 weeks treatment (Study RW-HPN-MF-01), the lack of significant systemic exposure to hypericin after topical application (Study HPN-CTCL-02) and its relative efficacy and tolerability compared to Valchlor® (Study HPN-CTCL-04).

In addition, the FDA awarded an Orphan Products Development grant to support the investigator-initiated study evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL, including in the home use setting. The grant, totaling $2.6 million over 4 years, was awarded to theUniversity of Pennsylvania that was a leading enroller in the Phase 3 FLASH study.

About Cutaneous T-Cell Lymphoma (CTCL)

CTCL is a class of non-Hodgkin's lymphoma (NHL), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These malignant cells migrate to the skin where they form various lesions, typically beginning as patches and may progress to raised plaques and tumors. Mortality is related to the stage of CTCL, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no cure for CTCL. Typically, CTCL lesions are treated and regress but usually return either in the same part of the body or in new areas.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the more than 1.7 million individuals living with the disease in the U.S. and Europe (European Union and United Kingdom). It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL that it affects approximately 31,000 individuals in the U.S. (based on SEER data, with approximately 3,200 new cases seen annually) and approximately 38,000 individuals in Europe (based on ECIS prevalence estimates, with approximately 3,800 new cases annually).

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 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 the Company'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 SEC, including, but not limited to, the Company'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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