Soligenix Investor Relations

Soligenix Receives FDA IND Clearance for Phase 2 Clinical Trial of Dusquetide in the Treatment of Aphthous Ulcers in Behçet's Disease

Pipeline Expansion of Novel Innate Defense Regulator Technology

PRINCETON, N.J., Nov. 30, 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 U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for a Phase 2a clinical trial entitled, "*Pilot Study of SGX945 (Dusquetide) in the Treatment of Aphthous Ulcers in Behçet's Disease*." The study is designed to evaluate the safety and efficacy of SGX945 (dusquetide) and is expected to begin patient enrollment in the second half of 2024.

"We are pleased to have received FDA clearance on our SGX945 Phase 2 pilot trial in aphthous ulcers of Behçet's disease," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Our previous studies with dusquetide in oral mucositis have clearly validated the biologic activity in aphthous ulcers induced by chemotherapy and radiation. Given the role of the innate immune system in ulcers associated with Behçet's Disease, and the unmet medical need particularly for more severe ulcers such as genital and leg ulcers, we believe that dusquetide may offer significant relief to patients. We are excited to expand dusquetide's development into different innate immune-related inflammatory conditions such as Behçet's disease, as a component of our long-term strategy to enhance the value of this unique compound. Behçet's disease is an unmet medical need, with up to 18,000 people in the U.S., 80,000 in Europe, 350,000 people in Turkey and as many as 1 million people worldwide affected by this incurable disease. Given our promising results with aphthous ulcers in oral mucositis, we are hopeful dusquetide will have a role to play in helping underserved patients suffering from this difficult to treat and chronic disease."

Under this IND, the pilot clinical trial of SGX945 will be an open-label study that will enroll approximately 25 patients age 18 years or older with mild to moderate Behçet's disease active oral and/or genital ulcers. Patients will receive SGX945 as a twice weekly 4-minute intravenous (IV) infusion for 4 weeks. Efficacy endpoints will include the extent of lesion clearance, timeline to lesion clearance, and patient reported quality of life indices.

About Dusquetide

Dusquetide (the active ingredient in SGX945 and SGX942 in development for oral mucositis) is an innate defense regulator (IDR), a new class of short, synthetic peptides. It has a novel mechanism of action whereby it modulates the body's reaction to both injury and infection towards an anti-inflammatory, anti-infective, and tissue healing response. IDRs have no direct antibiotic activity but, by modulating the host's innate immune system responses, increase survival after infections caused by a broad range of bacterial Gram-negative and Gram-positive pathogens. It also accelerates resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma, and chemo- and/or radiation therapy. Preclinical efficacy and safety have been demonstrated in numerous animal disease models including mucositis, colitis, macrophage activation syndrome (MAS) as well as bacterial infections, including melioidosis. In addition, potential anti-tumor activity has been demonstrated in multiple *in vitro* and *in vivo* xenograft studies.

Dusquetide has demonstrated safety and tolerability in a Phase 1 clinical study in 84 healthy human volunteers. In Phase 2 and 3 clinical studies with SGX942 in over 350 subjects with oral mucositis due to chemoradiation therapy for head and neck cancer, positive efficacy results were demonstrated, including potential long-term ancillary benefits.

Soligenix has a strong intellectual property position in the IDR technology platform, including composition of matter for dusquetide and related analogs. Dusquetide was developed pursuant to discoveries made by Professors B. Brett Finlay, PhD and Robert Hancock, PhD of the University of British Columbia, Canada.

About Behçet's Disease

Behçet's Disease (BD) is commonly known as an inflammatory disorder of the blood vessels (vasculitis). Often first diagnosed in young adults, it's effects and severity will wax and wane over time. Major signs and symptoms usually include mouth sores (approximately 95% of patients), skin rashes and lesions (approximately 50% of patients), genital sores (approximately 50% of patients), leg ulcers (approximately 40% of patients) and eye inflammation (approximately 15% of patients). It is a painful disease, directly impacting the patient's quality of life and ability to productively engage in life activities, including work.

BD is thought to be an auto-immune disease with both genetic and environmental factors. It is most common along the "Silk Road" in the Middle East and East Asia, including Turkey, Iran, Japan and China. There are approximately 18,000 known cases of BD in the U.S. and 80,000 in Europe. There are as many as 1,000,000 people worldwide living with BD.

There is no cure for BD, rather treatments are prescribed to manage symptoms. Treatments may include both maintenance therapies and those specifically addressing flares (e.g., mouth ulcers, genital ulcers and leg ulcers). Corticosteroids are

generally applied topically to sores and as eyedrops and may also be given systemically to reduce inflammation. Although used frequently, they have limited efficacy over the long-term and have significant side effects that become more concerning with more chronic use. Genital ulcers are often associated with significant genital scarring while leg ulcers can result in a post-thrombotic syndrome. Other treatments for BD flares involve suppressing the immune system with drugs (e.g., cyclosporine or cyclophosphamide). These drugs come with a higher risk of infection, liver and kidney problems, low blood counts and high blood pressure. Finally, anti-inflammatory drugs are also used, including anti-TNF medications. The only approved drug in BD is apremilast, which is used as a maintenance therapy to prevent formation of oral ulcers. Unfortunately, apremilast is associated with both high cost and side effects including diarrhea, nausea, upper respiratory tract infection and headache.

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 (SGX945) in Behçet's Disease. The Company also is developing proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation such as 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. Despite the positive efficacy results demonstrated in the Phase 2 and 3 clinical studies of SGX942 for the treatment of oral mucositis due to chemoradiation therapy for head and neck cancer, 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 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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