Soligenix Investor Relations

Soligenix Enters into Exclusive Option Agreement with Silk Road Therapeutics for Rights to Topical Pentoxifylline Designed to Treat Behçet's Disease

Phase 2/3-Ready Orphan Disease Program Complements Company's Existing Late-Stage Rare Disease Pipeline

PRINCETON, N.J., May 1, 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, today announced that it has entered into an exclusive option agreement with Silk Road Therapeutics, a privately-held company. The option agreement grants the Company the right to acquire a novel topical formulation of Pentoxifylline (PTX), a non-biological anti-TNF-alpha inhibitor, for the treatment of mucocutaneous ulcers in patient's suffering from Behçet's Disease (BD). BD is a rare multisystem inflammatory vasculitis with no cure, characterized by debilitating recurrent ulcers in the oral mucosa (95%), skin/genitalia (50%), and eye compartment (15%). An orphan disease and area of unmet medical need affecting approximately 18,000 people in the United States (U.S.) and 80,000 in Europe, there are as many as 1,000,000 people worldwide living with this painful and life altering disease. Terms of the deal were not disclosed.

"The novel muco-adherent topical formulation of PTX has the potential to fill a significant void in the current treatment armamentarium for BD, where a clear unmet medical need exists," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "General agreement amongst treating physicians is that current front-line treatment/management options, such as oral and topical steroids, are largely ineffective and have a number of potentially significant safety issues when used long-term. When transitioning to the more effective therapies, like biologics (e.g., adalimumab) and apremilast, the only approved treatment in BD, these longer-term safety concerns persist and are associated with a much higher financial burden to patients and/or payors in treating this lifelong condition. PTX has the potential to be an efficacious, safe, and more cost-effective treatment in BD. With the positive Phase 2 proof-of-concept (POC) study demonstrating accelerated oral ulcer healing and decreased pain compared to standard of care in patients with BD, we will be working to complete our remaining diligence activities under the exclusive option agreement, including discussion with the U.S. Food and Drug Administration (FDA) on the appropriate Phase 2/3 trial design to advance PTX in this orphan indication."

PTX was found to be superior to colchicine in a Phase 2 POC trial. This trial enrolled patients with BD randomized to standard of care colchicine therapy (n=21) or colchicine plus topical PTX (n=18). Patients applied the designed PTX mucoadhesive gel four times daily for up to 14 days to treat existing mouth ulcers, in addition to their standard colchicine regimen. Eighty-three percent (83%) of patients receiving PTX had index ulcer area shrinkage by Day 2, compared to 19% of patients receiving colchicine only ($p<0.0001$). By Day 4, 72% of patients receiving PTX had an undetectable index mouth ulcer, as compared to 29% of patients receiving colchicine only ($p<0.0001$). In parallel, pain scores were also found to decrease in patients taking PTX. No serious adverse events were reported, consistent with the systemic use of PTX in the published literature.

About Pentoxifylline

Pentoxifylline (PTX) is a known drug, administered orally, for the treatment of intermittent claudication (intermittent blockage of blood flow to muscles causing cramps). It has been FDA approved as an oral drug since 1999 and has an extensive safety database. PTX is known to have a number of biological actions. It inhibits erythrocyte phosphodiesterase, modulates neutrophil motility and functions as both an immunomodulator and an anti-inflammatory drug, including reducing TNF-alpha.

PTX has received both Orphan Drug and Fast Track designation from the FDA. It is being developed under a 505(b)(2) accelerated regulatory pathway in the U.S.

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, its 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) 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). 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. Other treatments for BD 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) 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 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 it 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.

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