Soligenix Investor Relations

# Key Binding Characteristics of Dusquetide to Important Intracellular Protein Identified

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PRINCETON, N.J., June 1, 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 a publication describing the binding of its Innate Defense Regulator (IDR), dusquetide, to the p62 protein. Dusquetide has demonstrated anti-infective, anti-tumor and anti-inflammatory actions in multiple animal models by modulating the body's own innate immune system. Dusquetide previously demonstrated significant benefits in reducing the duration of severe oral mucositis (SOM) in a Phase 2 clinical trial and reduction in SOM rates in the per protocol population in a Phase 3 study. In addition to the reduction of SOM, an acceleration in the clearance of tumor response and an increase in overall survival were also observed in the Phase 2 clinical study as an ancillary benefit to treating oral mucositis in patients receiving chemo-radiation for their head and neck cancer (HNC). This was corroborated by more recent findings confirming dusquetide's anti-tumor activity in xenograft models of breast cancer.

Based on the biological proof of principle shown both nonclinically and clinically with dusquetide, a novel synthetic peptide that modulates the body's innate immune system, Soligenix continues to explore product opportunities, both in the reduction of oral mucositis in HNC and as a potential anti-cancer treatment. Dusquetide binds to p62 or SQSTM-1, a scaffold protein implicated in a number of intracellular signaling networks implicated in tumor cell survival, including autophagy. This recent publication elaborates on the direct interaction of dusquetide with p62, as well as some of the direct downstream consequences of that interaction, consistent with its observed anti-infective, anti-tumor and anti-inflammatory activities. This information advances the understanding of dusquetide's novel mechanism of action and supports the development of analogs related to dusquetide.

"Soligenix continues to pursue potential product opportunities with our new chemical entity dusquetide," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With the supportive data from the Phase 2 and 3 oral mucositis trials, and the nonclinical anti-tumor efficacy demonstrated, we will continue to pursue potential partnership opportunities for this novel molecule and its potential analogs."

## About Dusquetide

Dusquetide (the active ingredient in SGX942) 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 has been demonstrated in numerous animal disease models including mucositis, colitis, macrophage activation syndrome (MAS) as well as bacterial infections, including melioidosis. Potential anti-tumor activity has been demonstrated in *in vitro* and *in vivo* xenograft studies.

SGX942 has demonstrated safety and tolerability in a Phase 1 clinical study in 84 healthy human volunteers. Positive efficacy results were demonstrated in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to CRT for HNC, including potential long-term ancillary benefits. The Phase 3 multinational, placebo-controlled, randomized study evaluated the impact of dusquetide on the duration of SOM in 268 subjects with squamous cell carcinoma of the oral cavity and oropharynx, receiving CRT. While the Phase 3 clinical study did not achieve the required level of statistical significance ($p \leq 0.05$) in its primary endpoint of median duration of SOM, a clinically meaningful reduction was observed, including a statistically significant reduction in the duration of SOM in the per-protocol population ($p=0.049$), consistent with the findings in the Phase 2 trial.

SGX942 has received Fast Track Designation from the FDA for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in HNC patients, as well as Promising Innovative Medicine designation in the United Kingdom by the Medicines and Healthcare products Regulatory Agency for the treatment of severe oral mucositis in HNC patients receiving CRT. In addition, products containing the same active ingredient, dusquetide, have been granted Fast Track Designation as an adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis and Orphan Drug Designations in the treatment of MAS and the treatment of acute radiation syndrome.

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. Soligenix has received partial funding from NIH for its oral mucositis clinical studies. The Phase 2 study was supported with a Phase I SBIR grant (#R43DE024032) award, with the Phase 3 study being supported by a Phase II SBIR grant (#R44DE024032) award.

In addition, a high level review of the IDR technology platform is available here.

## 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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