Soligenix Investor Relations

Dusquetide Demonstrates Positive Anti-tumor Efficacy in Multiple Nonclinical Animal Studies

Complementary treatment with chemotherapy, radiation and targeted therapy supports development as potential anti-cancer agent

PRINCETON, N.J., Jan. 4, 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 that dusquetide is effective at reducing tumor size in nonclinical xenograft models. Recent studies, recapitulating results from previously published studies, have confirmed the efficacy of dusquetide as a stand-alone and combination anti-tumor therapy, with radiation, chemotherapy and targeted therapy, in the context of the MCF-7 breast cancer cell line. Dusquetide previously demonstrated 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 severe oral mucositis, 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).

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. The role of p62 is best characterized in multiple myeloma and breast cancer. All variants of breast cancer, including metastatic breast cancer, estrogen receptor positive (ER+), human epidermal growth factor receptor 2 high expressing (HER2+) and triple negative expressing cell lines, have demonstrated a significant role for p62 in tumorigenesis.

The MCF-7 cell line tested in the xenograft studies with dusquetide is both ER+ and responsive to anti-HER2 treatment. Treatment with dusquetide was effective not only as a stand-alone treatment ($p<0.01$ for tumor size), but also in conjunction with radiation ($p<0.05$ vs radiation only for survival), chemotherapy (paclitaxel) and targeted treatment (trastuzumab; $p<0.001$ vs. placebo only for tumor size), reducing tumor size and enhancing overall survival. Other tumor types also have been shown to be dependent on p62 expression, including multiple myeloma, liver cancer (hepatocellular carcinoma), lung cancer (non-small cell lung cancer, EGFR-TKI-resistant lung cancer), intestinal cancer (small intestinal adenocarcinoma and gastric cancer), and colorectal cancer and ovarian cancer (multi-drug resistant).

"Soligenix continues to pursue potential product opportunities with our new chemical entity dusquetide, including in oncology," 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 continue to pursue potential partnership for this novel molecule."

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 (Study IDR-OM-01) 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, scheduled to receive a minimum total cumulative radiation dose of 55 Gy with concomitant cisplatin chemotherapy. A clinically meaningful reduction in the duration of SOM was observed in the ITT population and a clinically and statistically significant reduction was observed in the per protocol population.

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 our first-in-class 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) and acute radiation enteritis (SGX201).

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. 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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For further information: Company Contact: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200 | www.soligenix.com, Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540
