Soligenix Investor Relations

Soligenix Announces Topline Results from its Phase 3 Clinical Trial of SGX942 for the Treatment of Oral Mucositis in Head and Neck Cancer Patients

Company to Host Investor Conference Call Today at 8:30AM EST

PRINCETON, N.J., Dec. 22, 2020 /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 preliminary top-line results for its pivotal Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE Immunity) trial evaluating SGX942 (dusquetide) in the treatment of severe oral mucositis (SOM) in patients with head and neck cancer (HNC) receiving chemoradiation. The study enrolled 268 patients randomized 1:1 to receive either SGX942 or placebo. The primary endpoint of median duration of SOM did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group. Despite this clinically meaningful improvement, the variability in the distribution of the data yielded a p-value that was not statistically significant.

Other secondary endpoints supported the biological activity of dusquetide, including a statistically significant 50% reduction in the duration of SOM in the per-protocol population, which decreased from 18 days in the placebo group to 9 days in the SGX942 treatment group ($p=0.049$), consistent with the findings in the Phase 2 trial. Similarly, incidence of SOM also followed this biological trend as seen in the Phase 2 study, decreasing by 16% in the SGX942 treatment group relative to the placebo group in the per-protocol population. The per-protocol population was defined as the population receiving a minimum of 55 Gy radiation and at least 10 doses of study drug (placebo or SGX942) throughout the intended treatment period, with no major protocol deviations (e.g. breaks in study drug administration longer than 8 days between successive doses).

"We are obviously very disappointed with the unanticipated outcome of the study," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Despite the fact that SGX942 demonstrated clinically meaningful reductions in oral mucositis consistent with the Phase 2 study, the Phase 3 trial did not achieve the statistically significant benefit we expected. Over the coming weeks, we will be analyzing the data to better determine why the study did not meet expectations. If there is any clarity gained from further analysis of the dataset, especially with respect to specific subsets of patients that may benefit from SGX942 therapy, we will certainly communicate our findings and explore follow-up discussions with the FDA and the EMA."

Dr. Schaber continued, "With approximately $20 million of cash and our non-dilutive government funding, we will evaluate strategic options as we continue to execute on the multiple development programs across our rare disease pipeline. Most importantly, this will include the preparation of a New Drug Application for SGX301 in the treatment of cutaneous T-cell lymphoma, which demonstrated statistical significance in its pivotal Phase 3 clinical trial earlier this year, as well as continuing activities towards SGX301 U.S. commercialization where we expect peak annual sales to exceed $75 million."

The Company will host a webcast and conference call today at 8:30 AM EST to review the top-line findings.

Conference Call, December 22, 2020 at 8:30 AM Eastern Time

The Company will share information on its Phase 3 top-line results for its SGX942 program in oral mucositis. A question and answer (Q&A) session with management will follow the presentations. If you would like to ask a question during the Q&A, please submit your request via email to ir@soligenix.com at least 15 minutes prior to the scheduled start of the call.

U.S. toll free: 1-866-652-5200
International: 1-412-317-6060
Please request to be entered into the Soligenix call.

A transcript of the presentation will be archived for 30 days following the event.

About Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the U.S. per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The gastrointestinal damage causes severe

diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is now regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of oral mucositis, that oral mucositis in HNC is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with HNC treated with CRT and is severe, causing inability to eat and/or drink, in >80% of patients. It is common (40-100% incidence) in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

In the pediatric population, head and neck cancer is a rarer occurrence and is caused by different underlying pathologies. The major types of HNC in children are lymphoma, sarcomas (including rhabdomyosarcomas), and neuroblastoma rather than squamous cell carcinoma, the major type of adult HNC cancers. Hematopoietic stem cell transplantation (HSCT), especially allogeneic transplantation with higher risk of oral mucositis, is more frequently used in the pediatric population than in adults when treating a number of primary tumor types, as seen in leukemia and lymphoma. Both treatment of HNC and HSCT are associated with high risk of oral mucositis in the pediatric population.

Oral mucositis remains an area of unmet medical need where there are currently no approved drug therapies in the context of any solid tissue tumors.

About the Phase 3 DOM-INNATE Study

This multinational, placebo-controlled, randomized study enrolled 268 subjects with squamous cell carcinoma of the oral cavity and oropharynx, scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m^2 every third week. Subjects were randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for two weeks following completion of CRT. The primary endpoint for the study is the median duration of SOM, assessed by oral examination at each treatment visit and then through six weeks following completion of CRT. Oral mucositis is evaluated using the WHO (World Health Organization) Grading system. SOM is defined as a WHO Grade of ≥3. A positive interim analysis was conducted in August 2019, resulting in the recommended addition of 35 subjects / group to the study to maintain 90% power. Subjects are being followed for an additional 12 months after the completion of treatment. Soligenix has been working with leading oncology centers internationally, a number of which participated in the Phase 2 study.

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.

SGX942 has demonstrated safety 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.

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 SOM 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 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 SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our first-in-class IDR technology, dusquetide (SGX942) for the treatment of 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, SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and our research programs to identify and develop novel vaccine candidates targeting viral infection including Ebola, Marburg and SARS-CoV-2 (the cause of COVID-19). 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 Agents (DTRA) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website at www.soligenix.com.

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 US 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 US Congress may not pass any legislation that would provide additional funding for the Project BioShield program. Despite the statistically significant result achieved in the 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.

SOURCE Soligenix, Inc.

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