Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Third Quarter 2021 Financial Results

PRINCETON, N.J., Nov. 12, 2021 /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 its recent accomplishments and financial results for the quarter ended September 30, 2021.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "There continues to be a great deal of activity across our Specialized BioTherapeutics and Public Health Solutions business segments. We continue to work diligently to prepare the new drug application (NDA) for HyBryte™ (SGX301 or synthetic hypericin) following the positive pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study in cutaneous T-cell lymphoma (CTCL). The Office of Orphan Products Development of the United States (U.S.) Food and Drug Administration (FDA) granted orphan drug designation to the active ingredient hypericin for the treatment of T-cell lymphoma, expanding the treatment population beyond CTCL. Additionally, we announced expansion of synthetic hypericin development into psoriasis, under the research name SGX302, where we plan to initiate a Phase 2a clinical study in the second half of 2022. This decision follows validation of synthetic hypericin's biologic activity in the FLASH study, as well as positive proof-of-concept (PoC) demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients, a large and underserved market with a significant unmet medical need. Under our Public Health Solutions business segment, we remain focused on developing heat-stable vaccines for global use. Most notably, we announced publication of compelling pre-clinical immunogenicity studies for CiVax™ (heat stable COVID-19 vaccine program) demonstrating durable broad-spectrum neutralizing antibody responses in non-human primates (NHPs), including against the Beta, Gamma and Delta variants."

Dr. Schaber continued, "With approximately $29 million in cash, not including our non-dilutive government funding, we anticipate having the necessary capital to achieve our upcoming milestones, including NDA filing and expansion into psoriasis with the conduct of the Phase 2a clinical trial. We are also continuing to actively assess various strategic options, including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On November 8, 2021, the Company announced it had been granted a Pediatric Investigation Plan (PIP) product-specific waiver in the United Kingdom from the Medicines and Healthcare products Regulatory Agency for HyBryte™ in the treatment of CTCL. To view this press release, please click here.
- On November 4, 2021, the Company announced the publication of pre-clinical immunogenicity studies for RiVax® (heat stable ricin toxin vaccine) demonstrating enduring protection for at least 12 months post-vaccination. The article titled "Durable Immunity to Ricin Toxin Elicited by a Thermostable, Lyophilized Subunit Vaccine" has been accepted for publication in the journal mSphere. To read the publication, please click here. To view this press release, please click here.
- On September 28, 2021, the Company announced the publication of pre-clinical immunogenicity studies for CiVax™ demonstrating durable broad-spectrum neutralizing antibody responses, including against the Beta, Gamma and Delta variants of concern. The article, titled "Protein Vaccine Induces a Durable, More Broadly Neutralizing Antibody Response in Macaques than Natural Infection with SARS-CoV-2 P.1", has been posted as an accelerated preprint on bioRxiv. To view the publication, please click here. To view this press release, please click here.
- On September 16, 2021, the Company announced that following the validation of synthetic hypericin's biologic activity in the positive pivotal Phase 3 FLASH study in CTCL, as well as PoC demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients, the Company will be expanding this novel therapy under the research name SGX302 into psoriasis, a large and underserved market affecting between 60-125 million people worldwide. To view this press release, please click here.
- On September 9, 2021, the Company announced that the Office of Orphan Products Development of the U.S. FDA had granted orphan drug designation to the active ingredient hypericin for the treatment of T-cell lymphoma, extending the target population beyond CTCL as previously granted. To view this press release, please click here.
- On August 23, 2021, the Company announced a publication describing the formulation of single-vial platform presentations of monovalent (single antigen), bivalent (two antigens) and trivalent (three antigens) combinations of filovirus vaccine candidates. In collaboration with University of Hawai'i at Mānoa (UHM) and University of Colorado co-authors, the manuscript titled "*Single-Vial Filovirus Glycoprotein Vaccines: Biophysical Characteristics and Immunogenicity after Co-lyophilization with Adjuvant*", has been published in *Vaccine*. To read the publication, please click here. To view this press release, please click

here.

- On August 18, 2021, the Company announced positive data demonstrating the efficacy of multiple filovirus vaccine candidates in NHPs, including thermostabilized multivalent vaccines in a single vial platform presentation. Collaborators at UHM describe the potent efficacy of vaccine candidates protecting against three life-threatening filoviruses, *Zaire ebolavirus, Sudan ebolavirus and Marburg Marburgvirus* in an article titled "Recombinant Protein Filovirus Vaccines Protect Cynomolgus Macaques from Ebola, Sudan, and Marburg Viruses", published in *Frontiers in Immunology*. To read the article, please click here. To view this press release, please click here.

Financial Results – Quarter Ended September 30, 2021

Soligenix's revenues for the quarter ended September 30, 2021 were $0.2 million as compared to $0.6 million for the quarter ended September 30, 2020. Revenues primarily included payments on grants received to support the development of: SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases; ThermoVax®, our thermostabilization platform technology; and CiVax™, our vaccine candidate for the prevention of COVID-19.

Soligenix's basic net loss was $3.6 million, or ($0.09) per share, for the quarter ended September 30, 2021, as compared to $1.8 million, or ($0.06) per share, for the quarter ended September 30, 2020. This increased net loss was primarily due to a reduction in revenue from the expiration of government contracts, an increase in research and development expenses associated with the continued development of HyBryte™ and additional interest expense on convertible debt.

Research and development expenses were $2.5 million as compared to $1.3 million for the quarters ended September 30, 2021 and 2020, respectively. The increase in research and development spending for the quarter ended September 30, 2021 was primarily attributable to the increased expenses associated with the continued development of HyBryte™.

General and administrative expenses were $0.9 million and $0.8 million for the three months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, the Company's cash position was approximately $29 million.

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 commercializing SGX301 (synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma. With a successful Phase 3 study completed, regulatory approval and commercialization for this product is 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, 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, 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 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. 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.

For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200 | www.soligenix.com

---