Soligenix Investor Relations

Soligenix Announces $1.5 Million NIH Small Business Innovation Research Award Advancing COVID-19 Vaccine Development

Supports CoVaccine HT™ platform development

PRINCETON, N.J., Dec. 28, 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 that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has awarded Soligenix a Direct to Phase II Small Business Innovation Research (SBIR) grant of approximately $1.5 million to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 (Coronavirus Disease 2019) and EVD (Ebola Virus Disease) vaccine candidates in conjunction with the CoVaccine HT™ (CoVaccine) adjuvant. This award also will support immune characterization of this novel, emulsified adjuvant that has unique potency and compatibility with lyophilization strategies to enable thermostabilization of subunit vaccines.

CiVax™ is the Company's heat stable subunit vaccine candidate for the prevention of COVID-19, the infection caused by SARS-CoV-2. Ongoing collaborations with Axel Lehrer, PhD, Associate Professor (Vaccinology) in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), University of Hawai'i at Mānoa (UHM) have demonstrated the feasibility of developing a highly immunogenic vaccine for COVID-19. With significant research dedicated worldwide to the generation of COVID-19 vaccines, it is noteworthy that the essential attributes of a vaccine successful in controlling the ongoing pandemic are believed to include the ability to rapidly stimulate a Th1/Th2 balanced antibody response, raising significant virus neutralizing antibodies, as well as induce potent cell-mediated immunity. Previous work with the CoVaccine adjuvant, which Soligenix licensed from BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation, has indicated that CoVaccine has these critical characteristics. In addition, unlike other vaccine candidates that have logistical challenges due to cold chain requirements (in some cases requiring maintenance of temperatures less than -70 degrees Celsius), the underlying technology platform has demonstrated the ability to produce single vial vaccines which are stable up to temperatures at least as high as +40 degrees Celsius.

The awarded grant enables detailed immunogenicity evaluation of CoVaccine in the presence of either the SARS-CoV-2 Spike protein antigen or the Zaire ebolavirus glycoprotein antigen in both mice and non-human primates, and will significantly enhance both vaccine programs. It also will enable re-initiation of key CoVaccine manufacturing processes.

Many programs are focused on the development of vaccines for COVID-19 and two vaccines have recently received Emergency Use Approval by the FDA. However, the worldwide extent of the problem suggests that a complete solution to the pandemic will require parallel approaches. Moreover, there is the potential need for annual vaccinations. The total number of vaccine doses required to control the ongoing pandemic also suggests that multiple vaccines, based on different manufacturing platforms, will be necessary to efficiently vaccinate the worldwide population. Subunit vaccines are considered the gold standard for vaccine safety, but are relatively under-represented in fast-tracked COVID-19 vaccine candidates to date. Unlike virally vectored vaccines, there is no limit to the number of times the adjuvant and antigen can be used and the typical safety profile of a subunit vaccine results in a vaccine that is suitable for immune compromised or elderly populations as well. Further, while RNA vaccines are rapid to manufacture, the requirements for cold chain distribution remain a real constraint.

"We are appreciative of the continued support provided by NIAID for our thermostabilization program," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "This SBIR grant award will further advance our studies with the CoVaccine adjuvant, as well as our CiVax™ and filovirus vaccine programs. We remain dedicated to progressing our Public Health Solutions business segment and look forward to accelerating our CiVax™ program in particular with this funding."

NIAID support is being provided through SBIR grant number 1 R44 AI157593-01.

About CiVax™

CiVax™ is the Company's heat stable subunit vaccine candidate for the prevention of COVID-19, the infection caused by SARS-CoV-2. Under the Company's Public Health Solutions business segment, ongoing collaborations with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UHM have demonstrated the feasibility of developing heat stable subunit filovirus vaccines, including hemorrhagic disease caused by *Zaire ebolavirus*, *Sudan ebolavirus* as well as *Marburg marburgvirus*, with both monovalent and bivalent vaccine combinations. Formulation conditions have been identified to enable heat stabilization of each antigen, alone or in combination, for at least 12 weeks at 40 degrees Celsius (104 degrees Fahrenheit). In March 2020, Soligenix and its collaborators expanded the technology platform to assess compatibility with vaccine candidates targeting SARS-CoV-2, the cause of COVID-19.

The vaccine platform includes three essential components:

- a protein antigen, specifically a viral surface glycoprotein, which mediates entry and fusion of the virus with host cells and is manufactured with a proprietary insect cell expression system coupled with protein-specific affinity purification;
- an adjuvant which has been shown to enhance both cell mediated and humoral immunity; and

- a formulation which enables thermostabilization of the resulting mixture, avoiding the need for cold chain storage and shipping.

The resulting vaccine is broadly applicable, including to individuals often excluded from common viral vector vaccine approaches such as children, the elderly and the immunocompromised. The protection of elderly and immunocompromised populations are particularly important in the context of COVID-19. The ability to provide a thermostabilized, single vial vaccine, is particularly important in the context of rapid and broad vaccine distribution.

These same components are now being applied to coronavirus vaccine, using the well-defined surface glycoprotein, known as the Spike protein, as the antigen. Nonclinical work in mice with a prototype vaccine recently have been published, demonstrating the ability of the CoVaccine adjuvant in combination with a prototype antigen, to:

- stimulate immunity within 14 days after the first vaccination;
- induce a balanced Th1 response, believed to be critical to inducing immunity without aggravating disease pathology;
- induce a neutralizing antibody response; and
- induce a cell mediated immune response.

About Coronavirus Infection

Coronavirus infections can cause a wide spectrum of disease in humans, ranging from a common cold to a more severe respiratory infection, such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), which have a case mortality rate of approximately 10% and 30%, respectively. Similar to filoviruses, coronaviruses also are endemic in wildlife populations and can be transmitted to humans with close contact. The COVID-19 outbreak, caused by SARS-CoV-2, is the most recent example of a suspected species crossover seen with this virus family. Although the case fatality rate of COVID-19 is still under investigation, COVID-19 has been declared a global pandemic by the World Health Organization. The global impact of this emerging infection demonstrates the urgent need for robust technology platforms to rapidly develop new vaccines for novel diseases. The only FDA sanctioned treatments for COVID-19 are available under Emergency Use Authorization. There are currently two vaccines available under FDA Emergency Use Authorization.

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 innate defense regulator (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 atwww.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.

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For further information: 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
