Soligenix Investor Relations

# Soligenix Announces Investor Webcast Event and Presentation Today: Advantages of the CiVax™ Program for Development of a Broadly Distributed Heat Stable COVID-19 Vaccine

**Preclinical data supports potential for:**
**- Broadly applicable vaccine (young, elderly, immunocompromised)**
**- Rapid onset of immunogenicity within 7 days of the first dose**
**- Thermostabilized vaccine (ambient storage/shipping with no need for cold chain)**
**- Multivalent vaccine formulation, if needed**
**- Readily adaptable vaccine for seasonal vaccination use, if needed**

PRINCETON, N.J., Sept. 10, 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, released the presentation for its Investor Webcast event today from 4:00 – 5:00 pm Eastern Time on the use of its thermostabilized glycoprotein vaccine platform for the development of a COVID-19 vaccine, called CiVax™.

The development of CiVax™ is based on the thermostabilized glycoprotein vaccine platform which Soligenix has been developing in collaboration with the University of Hawai'i at Mānoa, focused on multivalent thermostabilized vaccines for filovirus infections such as Ebola.

The vaccine platform includes three essential components:

1) one or more protein antigens, 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;

2) an adjuvant (CoVaccine HT™ - licensed from BTG Specialty Pharmaceuticals ("BTG"), a division of Boston Scientific Corporation) which has been shown to enhance both cell mediated and humoral immunity; and

3) 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. These same components can now be applied to a COVID-19 vaccine, using well-defined surface glycoprotein(s) from one or more coronaviruses. The protection of elderly and immunocompromised populations are particularly important in the context of COVID-19.

Data with a prototype vaccine has confirmed the potential to elicit both strong cell mediated immunity as well as a balanced humoral (antibody) responses. Very strong neutralizing antibody responses, similar to those found in convalescent plasma, have also been shown in mice. These results have been released in a pre-print article available here. More recent studies have demonstrated that when utilizing a more complete Spike protein antigen (as intended in the final CiVax™ formulation) strong antibody responses are evident as soon as 7 days after the first vaccination, with rapid boosting as soon as 7 days after the second vaccination. At the same time, antibody responses and cell mediated immune responses have both demonstrated the desired Th1 bias.

**Conference Call Thursday, September 10 at 4:00 PM Eastern Time**

The Company will share information on its thermostabilized glycoprotein vaccine platform for the development of a COVID-19 vaccine on Thursday, September 10, 2020 during a webcast event. A question and answer (Q&A) session with the featured experts and 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.

Live Event: https://www.webcaster4.com/Webcast/Page/2498/37323
U.S. toll free: 1-866-652-5200
International: 1-412-317-6060
Please request to be entered into the Soligenix call.

An audio recording and transcript of the presentation will be archived for 30 days following the event.

The Investor Event will include presentations from the following:

**Dr. Axel Lehrer**, Associate Professor, Department. of Tropical Medicine, Medical Microbiology and Pharmacology, University of Hawai'i at Mānoa, John A. Burns School of Medicine

**Dr. Oreola Donini**, Chief Scientific Officer of Soligenix

**Mr. Dan Ring,** Vice President, Business Development of Soligenix

**Dr. Christopher J Schaber,** President and Chief Executive Officer of Soligenix

**Featured Expert Biographical Background**

*Axel Lehrer, PhD*
Axel Lehrer, Dr. rer. nat., Associate Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawai'i at Mānoa. Dr. Lehrer has been researching vaccines since 2002 in both commercial and academic settings. He has primarily worked on developing vaccines for filoviruses such as Ebola virus, but also contributed to the development of flavivirus vaccines (Zika virus, Tick-borne encephalitis (TBE) virus, West Nile virus and Dengue virus). His research mostly employs recombinant viral subunits expressed and purified from an insect cell expression system. Dr. Lehrer's is trained in biochemistry, molecular biology, virology, as well as immunology and his research has received funding from NIH and other federal sources.

**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:

1) 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;
2) an adjuvant which has been shown to enhance both cell mediated and humoral immunity; and
3) 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. Pre-clinical work in mice with a prototype vaccine recently have been made available, 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 immune response with a significant Th1 component, believed to be critical to inducing immunity without the risk of aggravating disease pathology;
- induce a neutralizing antibody response; and
- induce a cell mediated immune response.

Recently, pre-clinical studies with a more complete Spike protein (as intended in the final formulation) have demonstrated all the same attributes, including a rapid onset of immunogenicity within 7 days of the first vaccination.

**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 is currently no approved vaccine.

**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 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. In addition, there can be no assurance as to the timing or success of the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy, or any of our other clinical/preclinical trials. 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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http://ir.soligenix.com/2020-09-10-Soligenix-Announces-Investor-Webcast-Event-and-Presentation-Today-Advantages-of-the-CiVax-TM-Program-for-Development-of-a-Broadly-Distributed-Heat-Stable-COVID-19-Vaccine