Soligenix Investor Relations

Soligenix Presents at the National Foundation for Infectious Diseases Annual Conference on Vaccinology Research

COVID-19 Vaccine Program Demonstrates Immunogenicity In Non-Human Primates

PRINCETON, N.J., April 28, 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 that its Senior Vice President and Chief Scientific Officer, Oreola Donini, PhD, delivered a presentation demonstrating the potency of the CiVax™ (COVID-19 vaccine) development program in mice and non-human primates (NHPs), at the Annual Conference on Vaccinology Research (ACVR) on April 26-27, 2021. Utilizing its heat-stabilization technology, in conjunction with a novel, clinically-tested, adjuvant (CoVaccine HT™), Soligenix and its collaborators at the University of Hawaiʻi at Mānoa are developing a heat-stable subunit vaccine, targeted to enable ambient shipping and storage.

Oral Presentation:

Progress towards a Thermostabilized, Single-Vial, COVID-19 Subunit Vaccine with a Nano-emulsion Adjuvant The presentation is available until June 30, 2021 for conference registrants and registration is available here.

Key Data Highlights:

The proprietary subunit protein antigen, locked into its receptor-binding configuration, was shown to be immunogenic in both mice and NHPs. Critical immune responses including high total antibody levels, robust neutralizing antibody levels and specific cell mediated responses were demonstrated in mice, and strong total and neutralizing antibody responses were also demonstrated in NHPs, with additional analysis pending. Use of the CoVaccine HT™ adjuvant enabled dose-sparing in the antigen dose, which has potential advantages of reducing the amount of material needed to vaccinate each person, thereby increasing the speed of production of more vaccine doses. The CoVaccine HT™ adjuvant was shown to be robust working equally well in both its native and lyophilized formats, and supports advancing development of a heat stable CiVax™ vaccine candidate.

Oreola Donini, PhD, Chief Scientific Officer of Soligenix noted, "The CiVax™ program builds on the prior successes in the filovirus vaccine program which we have been pursuing with the University of Hawaiʻi at Mānoa, where we have demonstrated an ability to combine antigen and adjuvant into a single vial, which is reconstituted with water for injection immediately prior to use. This prior experience enhances our confidence that the CiVax™ program could yield a robust vaccine, able to be shipped worldwide at ambient temperatures to address ongoing vaccination requirements, including potential annual vaccinations for COVID-19. The demonstration of potency in NHPs is an important step in advancing CiVax™ to human clinical trials. This work is continuing under a grant award from the National Institutes of Health."

About the Annual Conference on Vaccinology Research

The ACVR conference is sponsored by the National Foundation for Infectious Diseases (NFID), as described here.

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. Nonclinical 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 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.

These results have been further confirmed with a "full length" Spike protein antigen, produced by the insect cell expression system, and locked into its pre-fusion configuration, as described here. Most recently, Soligenix has also demonstrated the potency of this vaccine in non-human primates, including in combination with thermostabilized vaccine adjuvant.

CiVax™ development is being funded through an SBIR grant from National Institute of Allergy and Infectious Diseases (NIAID) (grant number 1 R44 AI157593-01).

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 innate defense regulator (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 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 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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