Soligenix Investor Relations

Soligenix Announces Publication Demonstrating Complete Protection Against Filovirus Disease in Nonhuman Primate Models of Ebola and Marburg Viruses

Single-vial thermostabilized bivalent vaccine demonstrates simultaneous protection against two lethal viruses

PRINCETON, N.J., Jan. 2, 2024 /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 a publication describing the preclinical efficacy of a novel, single-vial, bivalent vaccine providing 100% protection against both *Sudan ebolavirus* (SUDV) and *Marburg marburgvirus* (MARV) infections. In collaboration with University of Hawai'i at Mānoa (UHM), the manuscript entitled "*Thermostable bivalent filovirus vaccine protects against severe and lethal Sudan ebolavirus and marburgvirus infection*", has been published in *Vaccine*.

This vaccine candidate has been previously demonstrated to be stable to high temperature storage for at least 2 years at 40 degrees Celsius (104 degrees Fahrenheit). There are currently no approved vaccines or therapeutics for either SUDV or MARV infections. Vaccines are available for *Zaire ebolavirus* (EBOV) infections but they provide no protection against SUDV or MARV infection. The published paper describes the potency of the bivalent formulation against both viruses, demonstrating 100% protection in the most rigorous non-human primate challenge models.

"Filoviruses such as *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg marburgvirus* are some of the most lethal viruses known, and they are endemic in areas of the world where the power supply and distribution network can be uncertain. A thermostabilized vaccine in a single vial format would significantly enhance any public health response to a new outbreak, at its source," stated Axel Lehrer, PhD, Associate Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, UHM. "Our work to date has demonstrated the feasibility of rapid and efficient manufacturing, as well as the ability to thermostabilize multiple antigens that can then be stored for extended times at temperatures exceeding 100 degrees Fahrenheit. The use of a bivalent vaccine has the potential to both prevent future infections with these pathogens and potentially mitigate future outbreak events, potentially using an accelerated dosing regimen."

"Our combined vaccine platform includes 3 major components: a robust protein manufacturing process that has been demonstrated on multiple protein antigens, a novel nano-emulsion adjuvant which induces broad immunity and a formulation procedure which enables thermostabilization of the combination of adjuvant and antigens in a single vial," stated Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix. "Elements of this vaccine platform have been utilized in our ricin toxin, filovirus and COVID-19 vaccine candidates, indicating its broad applicability. The ability to package the vaccine candidates in a single vial further adds to their developability, whether as a multivalent or individual monovalent vaccine, particularly against *Marburg marburgvirus* and *Sudan ebolavirus* where there are currently no available vaccines."

Under the Company's Public Health Solutions business segment, ongoing collaborations with Dr. Lehrer have demonstrated the feasibility of developing thermally-stable subunit protein vaccine formulations for filoviruses. The thermostabilized filovirus vaccine program is continuing to advance with the support of a National Institute of Health (NIH) grant R01-AI132323 (awarded to UHM) and a Small Business Innovation Research grant (#1R44AI157593-01; awarded to Soligenix, Inc.). Work to date has demonstrated the compatibility of lyophilizing both antigen and adjuvant in the same vial, with reconstitution with sterile water for injection immediately prior to use. This simple delivery format, as well as the compatibility with ambient storage, enables vaccines that significantly reduce the logistical hurdles that have been required for addressing the current pandemic or deployment of other Ebola virus vaccines in recent outbreaks in Central and West Africa.

About Filovirus Infection

Ebola Virus Disease is caused by one of six species of Ebolavirus, four of which are known to cause disease in humans, including its best-known member, *Zaire ebolavirus* (Ebola virus), with *Sudan ebolavirus* being the second-most common cause of human infection in this genus. All species of ebolavirus belong to the Filoviridae family, a family that further contains the equally human pathogenic Marburg virus. Filoviruses are believed to be harbored in various animal species in Africa, particularly bats, although the specific reservoir host for many of these viruses is still unknown. There have been several known Ebola and Marburg Virus Disease outbreaks since 1967, with the largest outbreak starting in 2014 in Western Africa that involved over 26,000 confirmed/probable/suspected cases with an estimated death toll of more than 11,000 people according to the Centers for Disease Control and Prevention (CDC). These numbers also include some cases of virus introduction and limited spread in Europe and the United States. In 2022 and 2023 several SUDV and MARV outbreaks were observed in continental Africa.

Transmission of filoviruses requires direct contact with bodily fluids from an infected person or contact with infected animals. The mortality rates following filovirus infections are extremely high, and, in the absence of wide availability of effective therapeutics, are affected by the quality of supportive care available with a focus on early initiation of treatment. Resolution of the disease largely depends on the patient's own immune system. There are limited treatment options for Ebola Virus Disease and no available treatments for Sudan Virus or Marburg Virus Disease, although steady progress has also been made in development of immunotherapeutics for filoviruses beyond *Zaire ebolavirus*. There are approved vaccines for Ebola virus (*Zaire ebolavirus*), requiring stringent ultra-low cold-chain storage, but no efficacious vaccines yet available for Marburg virus (*Marburg marburgvirus*) or Sudan virus (*Sudan ebolavirus*).

About John A. Burns School of Medicine, University of Hawai'i at Manoa

The John A. Burns School Medicine (JABSOM) at the University of Hawai‘i at Mānoa is one of the leading medical institutions and one of the most ethnically diverse institutions in the United States. For more than a decade, JABSOM has ranked in the top 10% of allopathic medical schools for graduate retention with one of our UH-sponsored residency programs. Hawai‘i's cultural diversity and geographical setting affords JABSOM a unique research environment to excel in research directed at eliminating diseases that disproportionately affect people in Hawaii and the Pacific region. JABSOM faculty bring in extramural funds of $46 million into the state, annually. In addition, JABSOM was the first U.S. medical school to create a clinical department dedicated to the health and well-being of an indigenous population, Native Hawaiians.

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 sodium) 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 expansion of synthetic hypericin (SGX302) into psoriasis, 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 (SGX945) in Behçet's Disease. The Company also is developing proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation such as pediatric Crohn's disease (SGX203).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, as well as our vaccine programs targeting filoviruses (such as Marburg, Sudan 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 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, and include the expected amount and use of proceeds from the offering and the expected closing date of the offering. 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 2a 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. Despite the positive efficacy results demonstrated in the Phase 2 and 3 clinical studies of SGX942 for the treatment of oral mucositis due to chemoradiation therapy for head and neck cancer, there can be no assurance as to the timing or success of the clinical trials of SGX945 for the treatment of Behçet's Disease. 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 (the "SEC"), 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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