

FDA Grants Soligenix Orphan Drug Designation for the Prevention and Post-Exposure Prophylaxis Against Sudan Ebolavirus Infection

Provides SuVax™ Heat Stable Vaccine Seven Years of U.S. Market Exclusivity Upon FDA Approval

PRINCETON, N.J., April 11, 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 that the Office of Orphan Products Development of the United States (U.S.) Food and Drug Administration (FDA) has granted orphan drug designation to the active ingredient in SuVax™, the subunit protein vaccine of recombinantly expressed *Sudan ebolavirus* (SUDV) glycoprotein, for "the prevention and post-exposure prophylaxis against SUDV infection."

The U.S. Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders, defined as one that affects fewer than 200,000 people in the U.S. In addition to providing a seven-year term of market exclusivity upon final FDA approval, orphan drug designation also positions Soligenix to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of expensive FDA user fees for the potential submission of a Biologics License Application (BLA), and certain tax credits.

"SuVax™ is based on our novel vaccine platform which includes three 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 antigen in a single vial," stated Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix. "The SuVax™ vaccine specifically addresses the potentially lethal Sudan Virus Disease, caused by SUDV. SUDV is a type of ebolavirus for which there is no current treatment or vaccine. The SuVax™ vaccine has demonstrated 100% protection of non-human primates infected with a lethal amount of SUDV. Although vaccines exist for *Zaire ebolavirus*, they are ineffective against SUDV. With recent outbreaks in 2022 and 2023, developing vaccines for all Ebola type diseases remains an important worldwide priority. The FDA's decision to grant orphan drug designation signifies an important step for Soligenix as we continue to advance the program and adds significantly to the existing patent estate surrounding this novel technology."

About SuVax™

SuVax™ is a subunit protein vaccine of recombinantly expressed Sudan Ebola virus glycoprotein, developed in partnership with Dr. Axel Lehrer at the University of Hawai'i at Mānoa. The vaccine includes a protein found on the surface of *Sudan ebolavirus* (SUDV), to engender an appropriate immune response without posing a risk of infection, as well as a novel adjuvant which stimulates both humoral and cell mediated immune responses, in combination with Generally Regarded as Safe (GRAS) excipients that enable lyophilization (i.e., freeze-drying) of the vaccine. The resulting product is manufactured as a heat stable powder in a vial which is reconstituted with generically available water for injection immediately prior to use. SuVax™, as a heat stable protein subunit vaccine, has [protected 100% of non-human primates](#) exposed to a lethal injection of SUDV. Stability studies have demonstrated that SuVax™ is heat stable for at [least 2 years at temperatures of at least 40 degrees Celsius](#) (104 degrees Fahrenheit).

Manufacture of the recombinant protein utilized in SuVax™ utilizes a robust protein manufacturing process, developed and tested in other subunit vaccines advanced through clinical testing. Similarly, the selected adjuvant, while novel, has also been independently tested in Phase 1 and Phase 2 clinical studies. SuVax™ can also be expressed as part of a multivalent vaccine, in combination with antigens against *Marburg marburgvirus* (MARV) for example.

About Sudan ebolavirus Infection

Ebola-like disease can be 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* (EBOV; causing Ebola Virus Disease), with *Sudan ebolavirus* (SUDV; causing Sudan Virus Disease) being the second-most common cause of human infection. All species of ebolavirus belong to the Filoviridae family, a family that further contains the equally human pathogenic *Marburg marburgvirus* (MARV). 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 (both Sudan and Zaire) and Marburg Virus Disease outbreaks since 1967 with the most recent SUDV outbreak occurring in August – October, 2022 in Uganda according to the Centers for Disease Control and Prevention (CDC).

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. While there are limited treatment options for disease caused by EBOV, there are no available treatments or vaccines available for Sudan Virus Disease. The approved vaccines for EBOV

utilize a viral vector approach which has contraindications for some individuals and require stringent, ultra-low cold-chain storage, inhibiting their broad use in challenging conditions where power supply can be uncertain and ambient temperature can be very high.

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 successful completion of the second Phase 3 study, regulatory approvals will be sought to support potential commercialization worldwide. 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.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate, as well as 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 <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 first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that the second HyBryte™ (SGX301) Phase 3 clinical trial will be successful or that a marketing authorization from the FDA or EMA will be granted. Additionally, although the EMA has agreed to the key design components of the second HyBryte™ (SGX301) Phase 3 clinical trial, no assurance can be given that the Company will be able to modify the development path to adequately address the FDA's concerns or that the FDA will not require a longer duration comparative study. Notwithstanding the result in the first 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, the Company's preliminary prospectus (Registration No. 333-271049) filed with the SEC on May 4, 2023, and 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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