Soligenix Investor Relations

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

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

PRINCETON, N.J., April 15, 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 MarVax™, the subunit protein vaccine of recombinantly expressed *Marburg marburgvirus* (MARV) glycoprotein, for "the prevention and post-exposure prophylaxis against MARV 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.

"*Marburg marburgvirus* causes Marburg Virus Disease, a highly related disease to the more commonly known Ebola Virus Disease. Although MARV has caused fewer outbreaks, they remain highly fatal and a significant risk in continental Africa, with the most recent outbreak occurring in 2023. There is no approved vaccine for MARV, and the only approved vaccines for filovirus type disease is specific to *Zaire ebolavirus*. Unlike the approved vaccines, which depend on using a different inactive or attenuated virus to stimulate the immune system, MarVax™ is a heat stable subunit vaccine with adjuvant. Subunit vaccines are a gold standard technology for safety and are also broadly applicable across the population, especially when combined with an effective adjuvant," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Elements of this subunit vaccine platform have been utilized in our ricin toxin, filovirus and COVID-19 vaccine candidates, indicating its broad applicability. We have also demonstrated the ability to package more than one vaccine antigen in a single vaccine, particularly against MARV and *Sudan ebolavirus* where there are currently no available vaccines. The FDA's decision to grant orphan drug designation to both the MARV and *Sudan ebolavirus* vaccine candidates 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 and the filovirus program."

About MarVax™

MarVax™ is a subunit protein vaccine of recombinantly expressed *Marburg marburgvirus* (MARV) 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 MARV, 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. Stability studies have demonstrated that MarVax™ is heat stable for at least 2 years at temperatures of at least 40 degrees Celsius (104 degrees Fahrenheit). MarVax™ has demonstrated 100% protection of non-human primates exposed to a lethal injection of MARV.

Manufacture of the recombinant protein utilized in MarVax™ 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. MarVax™ can also be expressed as part of a multivalent vaccine, in combination with antigens against *Sudan ebolavirus* for example.

About Marburg marburgvirus Infection

Marburg Virus Disease is caused by MARV, a member of the Filoviridae family that also includes *Sudan ebolavirus* (causing Sudan Virus Disease) and *Zaire ebolavirus* (causing Ebola Virus Disease). 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 MARV outbreaks occurring in February – June 2023 in Equatorial Guinea and in March – May 2023 in Tanzania, with no relationship between the two

outbreaks, according to the Centers for Disease Control and Prevention (CDC). Cases of Marburg Virus Disease were also recorded in Ghana in 2022 and 2021.

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 *Zaire ebolavirus*, there are no available treatments or vaccines available for Marburg Virus Disease. The approved vaccines for Ebola virus (*Zaire ebolavirus*) 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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For further information: Company CONTACT: 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
