Soligenix Investor Relations

Soligenix Extends Patent Protection for its Filovirus Vaccine Platform to the United Kingdom and South Africa

- **Includes thermostabilized Ebola vaccines MarVax™ and SuVax™**
- **Includes nanoemulsion adjuvant compatible with lyophilization**

PRINCETON, N.J., April 25, 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 it has received notice of intent to grant additional patents based on its patent application titled "Compositions and Methods of Manufacturing Trivalent Filovirus Vaccines" in the United Kingdom and South Africa, with other international jurisdictions pending. The Company has previously announced multiple issued patents within the same patent family in the United States (U.S.). The allowed claims are directed to unique, proprietary compositions and methods related to combinations of glycoprotein antigens with nanoemulsion adjuvants comprising sucrose fatty acid esters prior to lyophilization. The described vaccine platform has previously been successfully applied to mono-, bi- and tri-valent candidates for *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg marburgvirus*, including monovalent vaccines SuVax™ (targeting *Sudan ebolavirus*) and MarVax™ (targeting *Marburg marburgvirus*).

The candidate filovirus vaccines have been previously shown to completely protect non-human primates (NHPs) from subsequent infection, and represent the only recombinant subunit vaccines that have demonstrated efficacy against *Zaire ebolavirus* and other filoviruses in NHPs. Lyophilization (i.e., freeze drying) of the antigens with bivalent vaccine formulations has also been demonstrated to thermostabilize the antigens at temperatures as high as 40 degrees Celsius (104 degrees Fahrenheit) for up to two years, enabling storage at ambient temperature. No currently licensed lyophilized vaccine that contains an adjuvant is presented in a single vial format and there are few reports of successfully using nanoemulsions in lyophilized formulations. Previous work has demonstrated the use of a single vial platform to co-lyophilize antigen(s) and a nanoemulsion adjuvant, CoVaccine HT™, maintaining key adjuvant stability characteristics including particle size and colloidal stability, as well as maintaining immunogenicity.

"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. There are no vaccines for either Sudan or Marburg viruses, while approved vaccines for *Zaire ebolavirus* are constrained by cold chain logistics. Availability of a single-vial, heat stable vaccine would significantly enhance global public health preparedness or 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, University of Hawai'i at Mānoa. "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 at temperatures exceeding 100 degrees Fahrenheit. Having a vaccine platform such as this available has the potential to accelerate worldwide vaccination campaigns addressing future health emergencies, including other global pandemics as seen with COVID-19."

"Our next generation combined vaccine platform includes three major components: a robust protein manufacturing process that has been demonstrated on multiple protein antigens, a novel nanoemulsion 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. "Elements of this vaccine platform have been utilized in our ricin toxin, filovirus and COVID-19 vaccine candidates, indicating its broad applicability. We continue to focus on vaccine development against *Sudan ebolavirus* and *Marburg marburgvirus* where there are currently no available vaccines."

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, significantly reduces logistical hurdles when vaccinating large groups of individuals as required for example when addressing a global pandemic or for the deployment of vaccines in outbreaks occurring in remote areas or with unreliable power supply.

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 has been supported by a National Institute of Health (NIH) grant R01-AI132323 (awarded to the University of Hawaii) and a Small Business Innovation Research grant (#1R44AI157593-01; awarded to Soligenix).

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.

Soligenix has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the prevention and post-exposure prophylaxis against *Sudan ebolavirus* infection. 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, and certain tax credits.

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 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.

Soligenix has been granted Orphan Drug Designation by the FDA for the prevention and post-exposure prophylaxis against *Marburg marburgvirus* infection.

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 family. 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 (both Sudan and Zaire) and Marburg Virus Disease outbreaks since 1967. The most recent SUDV outbreak occurred in August – October, 2022 in Uganda according to the Centers for Disease Control and Prevention (CDC). The most recent MARV outbreaks occurred in February – June 2023 in Equatorial Guinea and in March – May 2023 in Tanzania, with no relationship between the two outbreaks, according to the 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. 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 are yet available for Marburg virus (*Marburg marburgvirus*) or Sudan virus (*Sudan ebolavirus*).

Filoviruses are one of the virus families identified as having the ability to cause pandemics. On the heels of the COVID-19 pandemic, the U.S. government is accelerating its investment in pandemic preparedness, including having "the ability to rapidly make vaccines effective against any virus family." Specific initiatives have been spear-headed by the White House and Biden-Harris administration, as evidenced by the "American Pandemic Preparedness: Transforming Our Capabilities" white paper released in September 2021.

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

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 an 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

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 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's current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations, clinical trial enrollment, the expected timing for closing the offering described herein and the intended use of proceeds therefrom. 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. 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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