Soligenix Investor Relations

Soligenix Invited to Submit BARDA Contract Proposal for Development of Thermostabilized Subunit Vaccines for Sudan Ebola and Marburg Viruses

- **Emerging infectious diseases where no protective vaccines are currently available**
- **SuVax™ targets *Sudan ebolavirus,* origin of a current disease outbreak in Uganda**

PRINCETON, N.J. , Oct. 27, 2022 /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 Company has been invited by the Biomedical Advanced Research and Development Authority (BARDA) Division of Chemical, Biological, Radiological and Nuclear (CBRN) Medical Countermeasures to submit a full contract proposal for the development of single-vial, adjuvanted, heat stable subunit vaccines to prevent filovirus infection. This submission supports a potential multi-year, multi-million dollar contract to develop SuVax™ and MarVax™ vaccine candidates as medical countermeasures (MCM) for use in the event of a *Sudan ebolavirus* or *Marburg marburgvirus* outbreak.

Soligenix was invited to submit this proposal following a review of its white paper entitled, "SuVax™: A Safe and Thermostable Single-Vial Adjuvanted Subunit Vaccine with Rapid Onset Immunity to *Sudan ebolavirus*", which proposed development of SuVax™ through Phase 1 clinical studies in a $25 million program of work over 5 years. BARDA also requested that additional options be built into the full proposal including addressing a separate potential *Marburg marburgvirus* vaccine candidate, MarVax™, which has the potential to increase the value of the program. BARDA's mission is to develop and procure needed MCMs, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural or intentional in origin.

In a non-human primate model of Sudan viral disease, SuVax™ demonstrated 100% protection four weeks after vaccination with a 3-dose series of SuVax™. Similar potency has been demonstrated for MarVax™. The development of these vaccines is part of an ongoing long-term collaboration with Soligenix's academic partner, the University of Hawai'i at Mānoa. This work was partially supported by a $1.5 million Small Business Innovation Grant (#1R44AI157593-01) awarded to Soligenix and a grant to the University of Hawaii at Manoa (R01-AI132323) from the National Institute of Allergy and Infectious Diseases (NIAID).

"We are excited about the favorable review of our white paper by BARDA and by their invitation to submit a full contract proposal," stated Christopher J. Schaber, PhD, President & Chief Executive Officer of Soligenix. "Although a contract award is not guaranteed, we believe that we are well-positioned to receive BARDA development support for this indication allowing us to further demonstrate the growing body of compelling scientific evidence supporting our heat stable filovirus vaccine platform, including vaccine candidates directed towards *Sudan ebolavirus* and *Marburg marburgvirus*. This is particularly relevant given the outbreak of Sudan viral disease in Uganda for which there is no current protective vaccine available. We look forward to continued productive interactions with BARDA, NIAID and FDA as we move these programs forward."

The submission of a contract proposal is non-binding and does not guarantee the award of a BARDA contract. The contract award will require a favorable technical and scientific review by BARDA followed by negotiation of fair and reasonable contract terms.

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* (Sudan virus) 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 marburgvirus* (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, and involved over 26,000 confirmed/probable/suspected cases with an estimated death toll of over 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. Morbidity after viral infection is also significant, with surviving patients reporting symptoms including fatigue, memory problems, shortness of breath, sleep problems and joint pain for years after infection. Most recently, an outbreak of Sudan virus in Uganda has been declared, with containment activities underway.

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 Ebola virus. There are approved vaccines for Ebola virus, requiring stringent ultra-low cold-chain storage, but no efficacious vaccines are yet available for Marburg virus or Sudan virus.

Filoviruses are one of the virus families identified as having the ability to cause pandemics. On the heels of the COVID-19 pandemic the US 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 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 more than $40 million in extramural funds 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) 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 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).

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 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, 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. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 1/2 proof-of-concept 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, 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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