Soligenix Investor Relations

Soligenix Applying for Vaccine Development Funding for Bundibugyo Ebola Vaccine

Thermostability, immunogenicity and efficacy data against related viruses provides firm starting point for rapid vaccine development

PRINCETON, N.J., June 8, 2026 /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, noted today that the Coalition for Epidemic Preparedness Innovations (CEPI) has announced a call for proposal for vaccine development for Bundibugyo virus (BDBV) with applications due June 12, 2026. Soligenix, in collaboration with Axel Lehrer, PhD, Professor in the Department of Tropical Medicine, Medical Microbiology and Pharmacology at the John A. Burns School of Medicine, University of Hawai'i at Mānoa, has previously developed bivalent and trivalent thermostable vaccines, constructed from antigens against Ebola virus, Sudan virus and Marburg virus and the CoVaccine HT™ adjuvant, demonstrating thermostability, immunogenicity and durable efficacy in non-human primates. This work, combined with previous and ongoing work in Dr. Lehrer's laboratory that has demonstrated platform compatibility of the key Bundibugyo virus antigen, will form the basis of an application to CEPI enabling rapid development of a protein-based thermostable subunit vaccine for BDBV.

"Our filovirus vaccines have demonstrated broad and robust immune responses in mice and up to 100% protection in non-human primates," stated Dr. Lehrer. "Further, we have developed thermostable vaccine formulations in collaboration with Soligenix, demonstrating extended stability that is particularly relevant for the use of these vaccines in virus-endemic countries in Africa, as well as in the context of strategic national stockpiles and preparations for potential larger outbreaks and pandemics. A single-vial subunit vaccine that can be shipped at ambient temperatures and then needs to only be reconstituted with sterile water immediately prior to use has the potential to improve vaccination efforts globally by simplifying storage and distribution logistics not only as a stand-alone vaccine, but also as a practical add-on booster broadening immunity in persons previously or concurrently vaccinated with other vaccines. We look forward to submitting this application with the aim of rapidly advancing the BDBV vaccine and the multivalent platform in general."

"Our ThermoVax® platform has successfully thermostabilized vaccines for ricin toxin, for filoviruses such as Ebola, Sudan and Marburg, and for COVID, and as such is a well-established thermostabilization strategy that enhances the long-standing protein subunit vaccination technology. We believe this enhancement makes protein subunit vaccines, the gold standard for safe vaccines, competitive with other vaccine technologies, which have much more stringent cold-storage requirements," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The ability of these vaccines to rapidly induce broad immune coverage, even when administered after other primary vaccination series, is another marked advantage. Moreover, the use of subunit vaccines that has been built on years of proven vaccine technology may also provide a very safe option for people of all ages. We continue to evaluate potential opportunities to advance the vaccine platform and hope to have additional opportunities to apply for funding in the context of the Bundibugyo virus in particular"

About CEPI

The Coalition for Epidemic Preparedness Innovations (www.cepi.net) is a global partnership focused on addressing vaccines and therapeutics for epidemic and pandemic threats. CEPI has had $3.6 billion committed investments since its launch, with over 30 investors and 470 global research, development and manufacturing partners.

About Filovirus Vaccines

The proprietary platform encompasses a suite of highly efficacious subunit protein vaccines formulated using recombinantly expressed *Orthoebolavirus sudanense* glycoprotein, *Orthoebolavirus zairense* glycoprotein and *Orthomarburgvirus marburgense* glycoprotein developed in partnership with Dr. Axel Lehrer at the University of Hawai'i at Mānoa. Dr. Lehrer's team has also previously used the same expression platform to produce glycoprotein of *Orthoebolavirus bundibugyoense,* which has already found application in collaborative seroepidemiology studies conducted in the Democratic Republic of the Congo (DRC). All filovirus vaccines include a protein found on the surface of each virus, 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 vaccines. The resulting products are manufactured as a heat stable powder in a vial which is reconstituted with widely available water for injection immediately prior to use. Alone or in combination, these heat stable protein subunit vaccines, have protected up to100% of non-human primates exposed to a lethal injection of the corresponding virus. Stability studies have demonstrated that these vaccines are heat stable for at least 2 years at temperatures of at least 40 degrees Celsius(104 degrees Fahrenheit).

Manufacture of the recombinant proteins 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.

Soligenix has been granted Orphan Drug Designation by the United States Food and Drug Administration (FDA) for the prevention and post-exposure prophylaxis against *Orthoebolavirus sudanense* and *Orthomarburgvirus marburgense* infection. In addition to providing a seven-year term of market exclusivity upon final FDA approval, orphan drug designations also position 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.

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, *Orthoebolavirus zairense* (Ebola virus), with *Orthoebolavirus sudanense* being the second-most common cause of human infection in this family. Other known human pathogenic viruses include *Orthoebolavirus bundibugyoense* and *Orthoebolavirus taiense*. All species of orthoebolavirus 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, Sudan, Bundibugyo and Marburg Virus Disease outbreaks since 1967. The most recent SUDV outbreak occurred in January – April, 2025 in Uganda according to the Centers for Disease Control and Prevention (CDC). The most recent MARV outbreaks occurred in January – March 2025 in Tanzania, according to the CDC. Most recently, the Bundibugyo virus has been identified as responsible for the ongoing outbreak in the Democratic Republic of Congo and Uganda, with 65 confirmed deaths, and 397 confirmed cases as of June 4, 2026. This outbreak was declared a Public Health Emergency of International Concern by the World Health Organization on May 16, 2026 and is ongoing.

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 currently are limited treatment options for Ebola Virus Disease and no available treatments for Sudan, Bundibugyo or Marburg Virus Disease, although steady progress has also been made in development of immunotherapeutics for filoviruses beyond *Orthoebolavirus zairense*. There are approved vaccines for Ebola virus, requiring stringent ultra-low cold-chain storage, but no efficacious and approved vaccines are available for Sudan, Bundibugyo, or Marburg virus.

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

Established in 1965, the John A. Burns School of Medicine (JABSOM) is one of the degree-granting schools of the University of Hawai'i at Mānoa. Named in honor of the visionary former governor, JABSOM trains the next generation of outstanding physicians, scientists, medical technologists, and speech pathologists to improve the health and wellness of our diverse communities throughout Hawai'i and the Pacific. Our impactful research focuses on understanding and addressing health disparities, particularly in Native Hawaiian, Pacific Islander, and Filipinos. JABSOM is home to the first clinical department in an accredited medical school in the nation that is focused on health disparities of an indigenous population, Native Hawaiians.

About Soligenix, Inc.

Soligenix is a 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 synthetic hypericin for the treatment of psoriasis (SGX302), and our first-in-class Innate Defense Regulator (IDR) technology, dusquetide, for the treatment of inflammatory diseases, including aphthous ulcers in Behçet's Disease (BD) (SGX945) and oral mucositis in head and neck cancer (SGX942). We were developing HyBryte™ (SGX301 or synthetic hypericin sodium), a photodynamic therapy utilizing visible light, for the treatment of cutaneous T-cell lymphoma (CTCL) in a Phase 3 study called "FLASH2" (Fluorescent Light Activated Synthetic Hypericin 2). The Data Monitoring Committee completed its interim efficacy analysis of the FLASH2 trial during April 2026, and under the terms of the interim analysis, the study was recommended to halt for futility. We are in the process of analyzing the data to better determine why the study did not meet expectations.

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 athttps://www.soligenix.com and follow us on LinkedIn and X 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 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 timing and results of clinical trials and the expected timing of regulatory submissions and approvals. The Company's submission of an application for funding from CEPI for Bundibugyo virus vaccine development is preliminary in nature and there can be no assurance that CEPI will select the Company's application for funding, that the Company will receive any funding from CEPI, or that any such funding, if received, will be sufficient to advance the Company's vaccine development programs. The Company does not intend to provide updates regarding the status of its CEPI application unless and until a material development occurs, such as the receipt of a funding award. The failure to receive CEPI funding would not, standing alone, constitute a material event requiring further disclosure, as the Company has not previously received the CEPI funding and would not be losing an existing funding source. In light of the discontinuation of the FLASH2 study, the Company's ability to continue as a going concern will be dependent upon its ability to develop and commercialize its remaining pipeline assets, including dusquetide for the treatment of Behçet's Disease, to identify and acquire or in-license additional product candidates or technologies, and to raise sufficient capital to fund such development and any such acquisitions. There can be no assurance that the Company will be able to obtain financing on acceptable terms, if at all, that suitable acquisition or in-licensing opportunities will be available, or that any of its remaining or future development programs will be successful. If the Company is unable to raise sufficient capital or otherwise advance its remaining assets, it may be required to significantly curtail or cease its operations, sell or otherwise dispose of its assets, or pursue dissolution and liquidation. 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 or any other studies (including the open-label, investigator-initiated study) and the overall blinded study response rate observed in the second HyBryte™ (SGX301) Phase 3 clinical trial, notwithstanding any prior observations regarding such blinded response rate, the second HyBryte™ (SGX301) Phase 3 clinical trial did not demonstrate sufficient efficacy at the interim analysis to support continuation of the study, and no assurance can be given that any further development of HyBryte™ (SGX301) will be pursued or that a marketing authorization from the FDA or EMA will be sought or granted. Notwithstanding the result of HyBryte™ (SGX301) in the first Phase 3 clinical trial (or any other studies) 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. Additionally, despite the biologic activity observed in aphthous ulcers induced by chemotherapy and radiation, 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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