Soligenix Investor Relations

Soligenix Announces Appointment of Timothy R. Coté, M.D. to its Board of Directors

Strengthens regulatory and orphan drug development expertise

PRINCETON, N.J., May 3, 2023 /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 the appointment of Timothy R. Coté, M.D., M.P.H. to its Board of Directors.

Dr. Coté is a leading national regulatory expert in orphan drug development. With 23 years of Federal service at the U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), and the Centers for Disease Control (CDC), Dr. Coté served as the Director of the FDA Office of Orphan Products Development (OOPD) from September 2007 to May 2011. In this role, he implemented the U.S. Orphan Drug Act and personally signed decisions on more than 1,400 orphan drug designation applications. After leaving FDA, Dr. Coté founded Cote Orphan (with a consultancy of 450 clients), where he served as Chief Executive Officer (CEO) until its sale in 2017 to IQVIA for $20 million. He is currently CEO of Only Orphans Cote LLC, a regulatory affairs consulting firm leveraging his expertise and commitment to delivering drugs for rare diseases. He also serves as the CEO of Silk Road Therapeutics, a privately held rare disease company from which Soligenix recently acquired an exclusive option to purchase a novel topical formulation of Pentoxifylline (PTX), a non-biological anti-TNF-alpha inhibitor, for the treatment of mucocutaneous ulcers in patient's suffering from Behçet's Disease.

Dr. Coté received his bachelor's degree from Syracuse University, a medical doctorate from the Howard University College of Medicine and a master's degree in Public Health from Harvard School of Public Health. An anatomic pathologist and medical epidemiologist, he has published 80 peer-reviewed articles on areas as diverse as HIV/AIDS-related malignancies, typhoid fever epidemics, and the impact of bicycle helmet laws on injury statistics.

"I am eager to be joining the Soligenix Board of Directors at such an important time for the Company," stated Dr. Coté. "Having spent over 20 years at the FDA, NIH, and CDC, I am confident that my experience will assist Soligenix in navigating the path forward for HyBryte™ and their other rare disease programs. I look forward to collaborating with the Board and management team to further this diverse pipeline."

"We are pleased to welcome Dr. Coté to the Soligenix Board," stated Christopher J. Schaber, PhD, President and CEO of Soligenix. "As Soligenix works with the FDA to advance its rare disease pipeline, including HyBryte™ (synthetic hypericin sodium) for the treatment of early stage cutaneous T-cell lymphoma (CTCL), a rare cancer, where it successfully demonstrated statistically significant results in a Phase 3 clinical trial, we aim to leverage Dr. Coté's extensive regulatory and orphan drug development expertise. We believe his knowledge will add significantly to our already experienced Board of Directors and management team."

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 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 sodium (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 healthcare practice, third party reimbursement limitations and Federal and/or state healthcare 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. HyBryte™ potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this information. While the Company has determined this potential market size based on assumptions that its believes are reasonable, there are a number of factors that could cause expectations to change or not be realized. 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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