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Streptococcus vaccine clinical trial to begin

SASKATOON – The Pan-Provincial Vaccine Enterprise Inc. (PREVENT), a national Centre of Excellence for Commercialization and Research (CECR) located at the University of Saskatchewan, and Vaxent in Memphis, Tennessee, are pleased to announce the initiation of a Phase 1 clinical trial of StreptAnova[®], a vaccine designed to prevent Group A streptococcal (GAS) infections. The trial will be conducted at the Canadian Center for Vaccinology in Halifax, Nova Scotia.

Group A streptococcal diseases are more common in children than adults. GAS infections cause substantial morbidity and mortality, with illnesses ranging from uncomplicated streptococcal pharyngitis (strep throat) to invasive infections, toxic shock syndrome, necrotizing fasciitis (flesh-eating disease), cellulitis, sepsis (blood infection), pneumonia and subsequent complications such as rheumatic fever and glomerulonephritis (acute inflammation of the kidney).

Worldwide each year, there are 616 million cases of pharyngitis caused by GAS. An estimated 663,000 cases of severe infection and 470,000 cases of acute rheumatic fever result in 517,000 deaths annually. In the U.S., there are 1,850 deaths each year from invasive Group A streptococcal disease. Necrotizing fasciitis kills close to 30% of patients and streptococcal toxic shock syndrome has a mortality rate of 30-70%.

StreptAnova[®] was invented by James B. Dale, M.D., Chief of the Division of Infectious Diseases, and Gene H. Stollerman, M.D., Endowed Professor in Medicine at the University of Tennessee Health Science Center (UTHSC), and Research Scientist at the Memphis Veterans Affairs Medical Center. It is being commercialized jointly by PREVENT and Vaxent, a company founded by Dr. Dale. StreptAnova[®] is composed of four recombinant proteins containing protective peptides from 30 streptococcal serotypes that account for the vast majority of infections in North America and Europe.

The main objective of the Phase I clinical trial is to demonstrate that the novel vaccine is safe and well tolerated in humans. Forty-five healthy adults will receive three injections over six months, with a one-year follow-up to assess the immune response to the vaccine. In addition to safety, the clinical trial protocol calls for a measurement of the immune responses generated by those vaccinated to determine if they are similar to the natural immunity that protects one from disease.

“This is an exciting milestone in the development of StreptAnova[®],” said Dr. Dale, Professor of Medicine at UTHSC and Chief Scientific Officer of Vaxent. “The safety and immunogenicity results from these studies will add to the growing body of clinical data from previous human studies of similar vaccines developed in our laboratories. With positive results, clinical development will move to examine the safety and immune response in adolescents and pre-school children, the ultimate target age for the vaccine.”

“We are very excited by this collaborative partnership with Vaxent to advance the development of this novel StreptAnova[®] multivalent vaccine,” said Dr. Andrew Potter, CEO of PREVENT and Director of VIDO-InterVac at the U of S. “It represents a significant milestone in PREVENT’s commercialization success working together with partners to accelerate the commercial development of innovative vaccine candidates. The availability of a safe and effective multi-valent GAS vaccine could address a huge unmet public health demand, preventing a wide variety of potentially life-threatening complications and diseases in humans worldwide attributable to this organism.”

About PREVENT:

Pan-Provincial Vaccine Enterprise Inc. (PREVENT) accelerates the development of promising early-stage vaccine candidates to address existing or potential human health issues. PREVENT's founding members include: the Vaccine and Infectious Disease Organization – International Vaccine Centre (VIDO-InterVac), the BC Centre for Disease Control (BC-CDC), and the Canadian Center for Vaccinology (CCfV) at Dalhousie University. By partnering with Canadian experts and shouldering the risk of early-stage vaccine development, PREVENT strengthens and advances Canada's vaccine industry, promoting growth and improved global competitiveness.

About Vaxent:

Vaxent is an early stage vaccine development company located in Memphis, Tennessee, whose lead product in development is a subunit vaccine against Group A streptococcus (GAS), earlier versions of which have been tested in early stage human clinical trials with no adverse events. The company plans to use its core competency in protein vaccine technology to advance its lead product in clinical testing, as well as develop other new vaccines against infectious diseases.

About The University of Tennessee Health Science Center:

As Tennessee's only public, statewide, academic health system, the mission of the University of Tennessee Health Science Center (UTHSC) is to bring the benefits of the health sciences to the achievement and maintenance of human health, with a focus on the citizens of Tennessee and the region, by pursuing an integrated program of education, research, clinical care, and public service. Founded in 1911, during its more than 100 years, UT Health Science Center has educated and trained more than 57,000 health care professionals in academic settings and health care facilities across the state. For more information, visit www.uthsc.edu.

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