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Aeras and Crucell announce Phase II clinical trial start in Kenya

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Dutch biopharmaceutical company Crucell N.V. and the Aeras Global TB Vaccine Foundation today announced the start of a Phase II clinical trial in infants of the jointly developed tuberculosis (TB) vaccine candidate, AERAS-402/Crucell Ad35.

The main objective of the trial is to test the safety and efficacy of the TB vaccine candidate in infants previously vaccinated with the Bacille Calmette-Guérin (BCG) vaccine, which is currently the only vaccine licensed to help prevent TB. The first part of this clinical trial, which will be conducted in Kenya, will establish the optimal dosing regimen. The selected regimen will then be tested in the second part of the trial, which is planned to begin in 2011 in Kenya, Mozambique, South Africa and Uganda.

The Phase II study of AERAS-402/Crucell Ad35 is being led in Kenya by a joint research project of the Kenya Medical Research Institute and the US Centers for Disease Control and Prevention, called the KEMRI/CDC Research and Public Health Collaboration. Participants from the Siaya District in Nyanza Province of Western Kenya will be enrolled.

"Despite the availability of the BCG vaccine, two million men, women and children die from tuberculosis every year. We urgently need a new TB vaccine to ensure long-term and effective TB protection," said Jim Connolly, President and CEO of the Aeras Global TB Vaccine Foundation. "This clinical trial represents an important step in our

collaboration among a global network of researchers and the people of Kenya, who continue to be at high-risk for TB infection."

In 2004, Aeras and Crucell began jointly developing this vaccine candidate using Crucell's AdVac vaccine technology and PER.C6 manufacturing technology.

"I am extremely pleased at the pace in which our work to develop a next generation vaccine against TB is progressing. Our successful collaboration with Aeras, enabling the initiation of yet another Phase II study, is an important step towards our ambition of reducing the global burden of this fatal disease," said Jaap Goudsmit, Crucell's Chief Scientific Officer.

Kenya is ranked 13th on a list of 22 high-burden TB countries, according to the World Health Organization. In 2007, 24,000 Kenyans died from TB and there were 132,000 new cases.

"The communities in which we work are hard hit by both TB and HIV/AIDS, two leading causes of mortality," said Videlis Nduba, MD, MPH, Principal Investigator for the trial at KEMRI/CDC Research and Public Health Collaboration. "We are pleased to apply our research expertise at this stage in the development of this vaccine—a vaccine which has undergone considerable early-stage safety testing."

AERAS-402/Crucell Ad35 has been tested in seven early-stage clinical trials including a phase I clinical trial in infants in South Africa. A Phase II trial to test its safety and efficacy in adults living with HIV is ongoing in South Africa. To date, the candidate has been shown to have an acceptable safety profile in these populations.

About Tuberculosis

Tuberculosis is the world's second deadliest infectious disease, with nearly 9.3 million new cases diagnosed in 2007. According to the World Health Organization (WHO), an estimated 1.8 million people died from TB in 2007. One-third of the world's population has been infected with the TB bacillus and current treatment takes 6 months. The current TB vaccine, Bacille Calmette-Guérin (BCG), developed over 85 years ago, reduces the risk of severe forms of TB in early childhood but is not very effective in preventing pulmonary TB in adolescents and adults — the populations with the highest rates of TB disease. TB is changing and evolving, making new vaccines more crucial for controlling the pandemic. Tuberculosis is now the leading cause of death for people living with HIV/AIDS, particularly in Africa. Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) are hampering treatment and control efforts.

About AdVac technology and Ad35

AdVac® technology is a vaccine technology developed by Crucell and is considered to play an important role in the fight against emerging and re-emerging infectious diseases, and in biodefense. The technology supports the practice of inserting genetic material from the disease-causing virus or parasite into a 'vehicle' called a vector, which then delivers the immunogenic material directly to the immune system. Most vectors are based on an adenovirus, such as the virus that causes the common cold.

The AdVac technology is specifically designed to manage the problem of pre-existing immunity in humans against the most commonly used recombinant vaccine vector, adenovirus serotype 5 (Ad5), without compromising large-scale production capabilities or the immunogenic properties of Ad5. AdVac technology is based on adenoviruses that occur less frequently in the human population, such as Ad35. In contrast to for instance Ad35 antibodies, antibodies to Ad5 are widespread

among people of all ages and are known to lower the immune response to Ad5-based vaccines, thereby impairing the efficacy of these vaccines. All vaccine candidates based on AdVac are produced using Crucell's PER.C6 production technology.

About PER.C6 technology

Crucell's PER.C6 technology is a cell line developed for the large-scale manufacture of biopharmaceutical products including vaccines. The production scale potential of the PER.C6 cell line has been demonstrated in an unprecedented successful bioreactor run of 20,000 liters. Compared to conventional production technologies, the strengths of the PER.C6® technology lie in its excellent safety profile, scalability and productivity under serum-free culture conditions. These characteristics, combined with its ability to support the growth of both human and animal viruses, make PER.C6 technology the biopharmaceutical production technology of choice for Crucell's current and potential pharmaceutical and biotechnology partners.

Provided by Aeras Global TB Vaccine Foundation