



PRESS RELEASE

Aeras and Crucell Announce Start of Phase II TB study in South Africa

Leiden, the Netherlands (April 14, 2010) – Dutch biopharmaceutical company Crucell N.V. (NYSE Euronext, NASDAQ: CRXL; Swiss Exchange: CRX) and the Aeras Global TB Vaccine Foundation today announced the start of a Phase II clinical trial of the jointly developed tuberculosis (TB) vaccine candidate AERAS-402/Crucell Ad35 in HIV infected adults.

The Phase II study is designed to test the safety and efficacy of AERAS-402/Crucell Ad35 in adults infected with HIV and will be conducted by the Aurum Institute in Klerksdorp, South Africa. All Aeras-sponsored TB vaccine candidates have been or will be tested for safety in people living with HIV. Among people living with HIV in Africa and Asia, TB is a leading cause of death. People with HIV living in countries with high TB prevalence are 20 times more likely to develop TB than those who are HIV-negative. According to the World Health Organization's (WHO) 2009 TB surveillance report, one in four TB deaths globally is HIV-related, twice as many as previously recognized. In 2007, there were an estimated 1.4 million new cases of TB among people living with HIV and 456 000 deaths. Seventy-one percent of people with TB in South Africa are co-infected with HIV.

"With the support of Crucell's innovative technologies, we are on a joint mission with Aeras to develop a next generation vaccine against TB," said Dr. Jaap Goudsmit, Crucell's Chief Scientific Officer. "As there are many potential uses of the new TB vaccine, it is crucial to test the safety and immune responses in those who have been infected with HIV. That is why we are extremely pleased with the initiation of this Phase II study, an important next step towards our ambition of reducing the global burden of this fatal disease."

Enrollment of study volunteers for the first stage of the Phase II trial has started. This is the first study testing the AERAS-402/Crucell Ad35 TB vaccine candidate among this study population.

In 2004, Aeras and Crucell began jointly developing this vaccine candidate using Crucell's AdVac[®] vaccine technology and PER.C6[®] manufacturing technology. Data from all AERAS-402/Crucell Ad35 trials support the immunogenicity and acceptable safety profile of the TB vaccine candidate at all dose levels evaluated.

AERAS-402/Crucell Ad35 trials

In October 2008, the first Phase II study in adults who have had active TB started in South Africa. In this ongoing study, AERAS-402 has demonstrated an acceptable safety profile. Preliminary data indicate that the candidate vaccine induces CD8-cell immune responses in patients who have completed TB treatment.



To date, seven Phase I studies have been conducted in populations including healthy adults and infants and adult tuberculosis patients:

- A trial in healthy adults not previously immunized with Bacille Calmette-Guérin (BCG), the traditional TB vaccine, demonstrated that the candidate vaccine had an acceptable safety profile in this population.
- A South African study showed CD8 T cell immune responses that are much higher than those seen in humans in any previous TB vaccine study.
- US studies in healthy adults, focusing on the immunogenicity and safety of two boost doses after BCG priming, showed that two injections of the candidate vaccine are immunogenic, with an acceptable safety profile, when used in combination with a BCG prime, regardless of the boosting interval. This immune response is greater than that detected in the absence of BCG prime, supporting the possible utility of AERAS-402/Crucell Ad35 as a booster vaccine. BCG prime alone shows limited efficacy.
- Testing of the candidate vaccine's safety in BCG-vaccinated adults with or without latent TB has been completed in Kenya, with ongoing analysis. The vaccine had an acceptable safety profile in this study.
- A trial in South Africa is testing the safety of the candidate vaccine in infants previously vaccinated with BCG vaccine. The study is fully enrolled and dosing is ongoing. To date, the vaccine appears to have an acceptable safety profile in this study.
- Currently a US trial has started for more detailed analysis of the immune response to AERAS-402/Crucell Ad35, using a known immunogenic regimen of BCG and the candidate vaccine in healthy adults, followed by collection of large numbers of immune cells.

About Tuberculosis

Tuberculosis is the world's second deadliest infectious disease, with nearly 9.3 million new cases diagnosed in 2007. According to the 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 6–9 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 reemerging 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 preexisting 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 do not regularly occur 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.

About Aeras

The Aeras Global TB Vaccine Foundation is a non-profit product development partnership dedicated to the development of effective TB vaccine regimens that will prevent tuberculosis in all age groups and will be affordable, available and adopted worldwide. Aeras partners with academic, biotechnology, pharmaceutical research institutes throughout the world to ensure rapid development and ample vaccine distribution to eliminate TB. Aeras receives funding from foundations and government aid agencies and has six TB vaccine candidates in its product development pipeline. It operates from its headquarters in Rockville, Maryland, and an office in Cape Town, South Africa. For more information, please visit www.aeras.org.

About Aurum Institute

Aurum is an internationally recognized, specialist research and health systems management organization. The focus is TB and HIV prevention, treatment and care. The negative impact of the poor understanding and management of these epidemics is vast, affecting individuals, communities and economies. The recognition of the huge advantages of controlling these diseases is Aurum's motivation. Aurum has an international reputation for its work in the fields of tuberculosis, HIV/AIDS and is the recipient of research and other grants from South African and international agencies and institutions for this work. For more information, please visit www.auruminstitute.org.

About Crucell

Crucell N.V. (NYSE Euronext, NASDAQ: CRXL; Swiss Exchange: CRX) is a global biopharmaceutical company focused on research development, production and marketing of vaccines, proteins and antibodies that prevent and/or treat infectious diseases. Its vaccines are sold in public and private markets worldwide. Crucell's core portfolio includes a vaccine against hepatitis B, a fully-liquid vaccine against five important childhood diseases and a virosome-adjuvanted vaccine



against influenza. Crucell also markets travel vaccines, such as the only oral anti-typhoid vaccine, an oral cholera vaccine and the only aluminum-free hepatitis A vaccine on the market. The Company has a broad development pipeline, with several product candidates based on its unique PER.C6[®] production technology. The Company licenses its PER.C6[®] technology and other technologies to the biopharmaceutical industry. Important partners and licensees include Johnson & Johnson, DSM Biologics, sanofi-aventis, Novartis, Wyeth, GSK, CSL and Merck & Co. Crucell is headquartered in Leiden, the Netherlands, with subsidiaries in Argentina, China, Italy, Korea, Spain, Sweden, Switzerland, UK and the USA. The Company employs over 1200 people. For more information, please visit www.crucell.com.

Forward-looking statements

This press release contains forward-looking statements that involve inherent risks and uncertainties. We have identified certain important factors that may cause actual results to differ materially from those contained in such forward-looking statements. For information relating to these factors please refer to our Form 20-F, as filed with the US Securities and Exchange Commission on April 7, 2010, in the section entitled 'Risk Factors'. The Company prepares its financial statements under International Financial Reporting Standards (IFRS).

For further information please contact Crucell:

Oya Yavuz
Vice President Corporate Communications & Investor Relations
Tel. +31 (0)71 519 7064
ir@crucell.com
www.crucell.com