



PRESS RELEASE

Aeras and Crucell Announce Start of TB Infant Study in South Africa

Leiden, The Netherlands / Rockville, MD, USA - April 28, 2009 – Dutch biopharmaceutical company Crucell N.V. (Euronext, Nasdaq: CRXL; Swiss Exchange: CRX) and the Aeras Global TB Vaccine Foundation today announced the start of a Phase I clinical trial in infants of the jointly developed tuberculosis (TB) vaccine candidate, AERAS-402/Crucell Ad35. This is the first clinical trial designed to test this vaccine candidate in infants.

The Phase I study of AERAS-402/Crucell Ad35 will be conducted by the South African Tuberculosis Vaccine Initiative (SATVI) in the Western Cape region of South Africa. The main objective of the study will be to test the safety 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 AERAS-402/Crucell Ad35 vaccine candidate has previously been tested for safety in healthy adults in the United States and South Africa, and adults exposed to TB in South Africa and Kenya.

“BCG is the most widely administered vaccine globally, yet there is more TB now than ever before,” said Dr. Jerald C. Sadoff, President and CEO of the Aeras Global TB Vaccine Foundation. “We are testing AERAS-402/Crucell Ad35 as a booster vaccine to BCG or to a recombinant BCG to stimulate the body’s immune response and improve protection against TB. The AERAS-402/Crucell Ad35 vaccine is inducing the highest CD8 T cell responses in humans we have seen with any TB vaccine.”

Fifty-four healthy infants who have not been exposed to TB or HIV will be enrolled in the study.

“We are very pleased that the collaboration with Aeras and SATVI enables us to enter into this new trial,” said Dr. Jaap Goudsmit, Crucell’s Chief Scientific Officer. “Using Crucell’s technologies, we are on a joint mission to develop a new vaccine against TB that could increase the number of people protected from infectious diseases worldwide.”

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

A first Phase I clinical trial launched in October 2006 in Kansas, USA indicated that the vaccine candidate is safe in healthy adults who have not previously been immunized with BCG in the USA.



Results of a second study, launched in May 2007 in South Africa, were presented at the 'TB Vaccines for the World' conference in April 2008. Preliminary data demonstrated induction of both critical arms of the cellular immune system, CD4 and CD8 immune T-cells, and showed that in those participants who responded, CD8 immune responses were much higher than had ever previously been seen in a TB vaccine study.

A third phase I study in healthy adults in St. Louis, Missouri, USA was launched in December 2007 focusing on the immunogenicity and safety of two AERAS-402/Crucell Ad35 boost doses administered at three to six month intervals after BCG priming in healthy adults. Data from this study indicate that two injections of AERAS-402/Crucell Ad35 are immunogenic; these responses and those seen in South African adult volunteers given BCG around birth are some of the highest CD8 T cell responses ever seen in a TB vaccine study. 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 immunogenicity.

An ongoing study in St. Louis, Missouri, USA is evaluating a longer prime-boost interval. The study has been fully enrolled and has discovered no safety issues. Immunological data are expected to be available in the first half of 2009.

A Phase I clinical trial of the jointly developed TB vaccine was started in Kenya in October 2008. The study is being conducted by the KEMRI/Walter Reed Project-Kisumu at their Kombewa Clinical Trials Center near Kisumu, in Western Kenya. Its main objective will be to test the safety of the candidate vaccine in BCG-vaccinated adults with or without latent tuberculosis. This study is fully enrolled and is now in its follow-up segment, with no safety issues identified.

In October 2008, enrollment for the first Phase II study of AERAS-402/Crucell Ad35 was started in Cape Town, South Africa. The study is being conducted by the University of Cape Town Lung Institute in conjunction with SATVI. The candidate is being tested in 82 adults who have had active TB. No evidence of an unacceptable safety issue has been found in the study's dose escalation design.

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 6–9 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 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 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 organization working as a Product Development Partnership to develop new tuberculosis vaccines and ensure that they are distributed to all who need them around the world. Aeras' major funders include the Bill & Melinda Gates Foundation, the Netherlands Ministry of Foreign Affairs, the Danish International Development Agency, the Research Council of Norway and the U.S. Centers for Disease Control and Prevention. Aeras, with more than 130 employees, is based in Rockville, Maryland, USA, where it operates a state-of-the-art manufacturing and laboratory facility. In 2008, the Aeras Africa Office was opened in Cape Town, South Africa. For more information, please visit www.aeras.org.

About SATVI

The South African Tuberculosis Vaccine Initiative is located in the Institute of Infectious Disease and Molecular Medicine at the University of Cape Town (UCT). Since 1999, with funding largely from the Aeras Global TB Vaccine Foundation, SATVI has developed the capacity to conduct registration standard vaccine trials at a site in Worcester, some 110km outside of Cape Town, where rates of tuberculosis are among the highest in the world. SATVI has a state-of-the-art



immunology laboratory located at UCT, where the complex assays needed for TB vaccine studies can be performed. In the last six years, SATVI has conducted a number of very large field trials and epidemiological cohort studies of the type that will be necessary to test the efficacy of new tuberculosis vaccines, involving thousands or tens of thousands of participants, as well as a number of smaller Phase I and II trials of new TB vaccines. In addition, SATVI conducts cutting edge basic science research aimed at better understanding the human immune response to tuberculosis and to tuberculosis vaccines. For more information, please visit www.satvi.uct.ac.za.

About Crucell

Crucell N.V. (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 DSM Biologics, sanofi-aventis, Novartis, Wyeth, GSK, CSL and Merck & Co. Crucell is headquartered in Leiden, the Netherlands, with subsidiaries in Switzerland, Spain, Italy, Sweden, Korea and the U.S. The Company employs over 1000 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 U.S. Securities and Exchange Commission on April 22, 2009, in the section entitled 'Risk Factors'. The Company prepares its financial statements under International Financial Reporting Standards (IFRS).

For further information please contact:

Crucell N.V.

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

Aeras Global TB Vaccine Foundation

Annmarie Leadman
Director of Communications
Tel: +1 240 599 3018
aleadman@aeras.org
www.aeras.org