



## **PRESS RELEASE**

### **Aeras and Crucell Announce Start of a Tuberculosis Vaccine Clinical Trial in the United States. Aeras commits a further USD 5 million to the development of the tuberculosis vaccine**

**Leiden, The Netherlands, December 21, 2007** – Dutch biotechnology company Crucell N.V. (Euronext, NASDAQ: CRXL; Swiss Exchange: CRX) today announced it will receive up to USD 5 million from Rockville, Maryland-headquartered Aeras Global TB Vaccine Foundation to support the advanced development of the candidate AdVac<sup>®</sup>- and PER.C6<sup>®</sup>-based tuberculosis vaccine.

Crucell and Aeras also announced the launch of a new Phase I BCG-Ad35 prime boost clinical trial of the unique AdVac<sup>®</sup>-based tuberculosis vaccine, weeks sooner than expected. The trial will be conducted in St. Louis, Missouri, USA under the direction of Dr. Daniel F. Hoft at the Saint Louis University Center for Vaccine Development.

“We are very proud that Crucell’s technologies are playing a key role in the search and development of a much-needed TB vaccine,” said Dr. Jaap Goudsmit, Chief Scientific Officer at Crucell. “We also feel honored to collaborate with Aeras on this important mission.”

Aeras and Crucell began jointly developing this vaccine candidate, called AERAS-402, in 2004 using Crucell’s AdVac<sup>®</sup> vaccine technology and PER.C6<sup>®</sup> manufacturing technology. A Phase I clinical trial launched in October 2006 in the United States, indicates that the vaccine candidate is safe in healthy adults in the US. A second study in progress in healthy adults in South Africa appears to be showing safety, tolerability and immunogenicity of AERAS-402.

The main parameters under examination in the St. Louis study will be the immunogenicity and safety of BCG prime followed by two AERAS-402 boost doses administered at three to six month intervals after BCG in healthy adults.

The trial will be conducted as double-blind, randomized, placebo-controlled study in 32 healthy adult volunteers.

#### **About Tuberculosis**

Tuberculosis is the world’s second deadliest infectious disease, with 8 to 9 million new cases diagnosed each year. According to the World Health Organization (WHO), an estimated 1.6 million people died from TB in 2005. 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 Bacillus 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. TB is changing and evolving, making new vaccines more crucial to controlling the pandemic. Tuberculosis is now the leading cause of death for people with AIDS, particularly in Africa. Multi-drug resistant TB (MDR-TB) and extremely 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 adenovirus vectors that do not regularly occur in the human population, such as Ad35. In contrast to the AdVac® vectors, 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 ([www.aeras.org](http://www.aeras.org)) 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. Dr. Jerald C. Sadoff, President and CEO of Aeras, has worked in vaccine development for more than 30 years. He led efforts to develop and obtain licensure for nine currently licensed vaccines and has been involved in the research and development of numerous other vaccines. Aeras is primarily funded by the Bill and Melinda Gates Foundation, and also receives important support from the Dutch Ministry of Foreign Affairs, the Danish International Development Agency, and the U.S. Centers for Disease Control and Prevention. Aeras is based in Rockville, Maryland, where it operates a state-of-the-art manufacturing and laboratory facility.

### **About Crucell**

Crucell N.V. (Euronext, NASDAQ: CRXL; Swiss Exchange: CRX) is a biotechnology company focused on research, development and worldwide marketing of vaccines and antibodies that prevent and 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 Crucell products based on its unique PER.C6<sup>®</sup> production technology. The Company licenses this and other technologies to the biopharmaceutical industry. Important partners and licensees include DSM Biologics, sanofi aventis, GSK and Merck & Co. Crucell is headquartered in Leiden (the Netherlands), with subsidiaries in Switzerland, Spain, Italy, Sweden, Korea and the US. The Company employs over a 1000 people. For more information, please visit [www.crucell.com](http://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 June 13, 2007, and the section entitled "Risk Factors". The Company prepares its financial statements under generally accepted accounting principles in the United States (US GAAP) and Europe (IFRS).*

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