



## **PRESS RELEASE**

### **Crucell Enters Agreement with Sanofi Pasteur for Next-generation Biologicals against Rabies**

#### ***Exclusive agreement for rabies monoclonal antibodies to fight fatal disease***

**Leiden, The Netherlands, 3 January 2008** - Dutch biotechnology company Crucell N.V. (Euronext, NASDAQ: CRXL, Swiss Exchange: CRX) today announced that it has signed an exclusive collaboration and commercialization agreement with sanofi pasteur, the vaccines division of sanofi-aventis Group, for Crucell's rabies monoclonal antibodies, the next-generation rabies biologicals to be used in association with rabies vaccine for post-exposure prophylaxis against this fatal disease.

Under the terms of the agreement, Crucell will continue to perform the development activities. Crucell will be responsible for the manufacturing of the final product and will retain exclusive distribution rights in Europe, co-exclusive distribution rights in China and the rights to sell to supranational organizations such as UNICEF. Crucell will receive a payment of € 10 million following the execution of the agreement, will be eligible for milestone payments of up to € 66.5 million and will receive an undisclosed percentage on sales of the final product by sanofi pasteur.

Crucell has developed a combination of two rabies monoclonal antibodies that has shown favorable results comparable to current immunoglobulin products. Phase I clinical trials demonstrated that the antibody product is well tolerated, provides the expected immediate passive neutralizing activity and that it can be safely administered in combination with a rabies vaccine without interfering with the vaccine's ability to induce an active immunity. The program has been granted a Fast Track designation by the Food and Drug Administration's (FDA) Department of Health and Human Services. Crucell expects to enter phase II clinical trials in the first half of 2008. Peak sales for Crucell's rabies antibody cocktail are expected to exceed US\$ 300 million.

Sanofi pasteur is the worldwide market leader in providing biologicals for pre- and post-exposure prophylaxis against rabies. In the last 20 years, over 20 million people in 100 countries have been treated with sanofi pasteur's rabies products.

"Sanofi pasteur is the global leader in providing rabies vaccine and immunoglobulin, and the only international company to offer a full range of rabies biologicals. Adding a next generation rabies treatment to our well-established rabies product range will further position the company as a leading force to help prevent this fatal disease," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. "Louis Pasteur's first human rabies immunization in 1885 was a founding milestone for modern vaccination and we are proud to build on his legacy with innovative treatments."

"We are pleased that sanofi pasteur selected our rabies antibodies to be used in combination with their rabies vaccine," said Ronald H.P. Brus, Crucell's Chief



Executive Officer. "Today, millions of people are exposed to rabies and often no life-saving treatment is available for this fatal disease. This agreement further validates our PER.C6<sup>®</sup> production technology and our MAbstract<sup>®</sup> technology for generating monoclonal antibodies."

### **About rabies**

Rabies is a viral disease of mammals most often transmitted through the bite of a rabid animal. The virus infects the central nervous system, causing encephalitis (inflammation of the brain) and ultimately death if medical intervention is not sought promptly after exposure. There is no proven treatment for rabies once symptoms of the disease have appeared. Lethal rabies is prevented by post-exposure prophylaxis (PEP) via the combined administration of a rabies vaccine and RIG (rabies immunoglobulin) following the bite of a rabid animal.

Rabies is prevalent in Europe, Asia, North and South America as well as Africa. Every year, approximately 10 million people are vaccinated worldwide. An estimated 40,000 to 70,000 people die of the disease each year, mainly in Asia.

### **About Crucell's rabies antibody cocktail program**

Crucell develops the antibody cocktail using its PER.C6<sup>®</sup> technology, which offers large-scale manufacturing capabilities and production under serum-free culture conditions. Crucell's rabies monoclonal antibody cocktail offers the potential for replacing the traditional serum-derived products that are currently still used for the treatment of rabies.

Crucell's cocktail is a combination of two human monoclonal antibodies, generated with the use of Crucell's MAbstract<sup>®</sup> technology and produced with the use of Crucell's PER.C6<sup>®</sup> technology. Phase I clinical studies (conducted in the US and India) recently showed that the antibody cocktail can be safely co-administered with rabies vaccine in line with standard therapy and that it provides the expected immediate passive neutralizing activity. The program has been granted a Fast Track designation by the Food and Drug Administration's (FDA) Department of Health and Human Services. The Fast Track program facilitates the development and expedites the review of new drugs that are intended to treat serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs. Peak sales for Crucell's rabies antibody cocktail are expected to exceed US\$ 300 million.

### **About PER.C6<sup>®</sup> technology**

Crucell's PER.C6<sup>®</sup> technology is a cell line developed for the large-scale manufacture of biopharmaceutical products such as recombinant proteins including monoclonal antibodies. Compared to conventional production technologies, the strengths of the PER.C6<sup>®</sup> technology lie in its excellent safety profile, scalability and productivity under serum-free culture conditions.

### **About MAbstract<sup>®</sup> technology**

Crucell's proprietary MAbstract<sup>®</sup> technology can be used to discover drug targets, such as cancer markers or proteins from infectious agents including bacteria and viruses, and identify human antibodies against those drug targets.



### **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 aluminium-free hepatitis A vaccine on the market. The Company has a broad pipeline, with several products based on its unique PER.C6<sup>®</sup> production technology in development. The Company licenses this and other technologies to the biopharmaceutical industry. Important partners and licensees include DSM Biologics, sanofi-aventis, Novartis, Wyeth 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)

### **About sanofi-aventis**

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, provided more than a billion doses of vaccine in 2006, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers the broadest range of vaccines protecting against 20 infectious diseases. The Company's heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR1 million in research and development. For more information, please visit: [www.sanofipasteur.com](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://www.sanofipasteur.us)

### **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 International Financial Reporting Standards (IFRS) with reconciliation to the generally accepted accounting principles in the United States (US GAAP).*

### **For further information please contact:**

#### **Media:**

Barbara Mulder  
Director Corporate Communications  
Tel: +31-(0)71-519 7346  
[press@cruCell.com](mailto:press@cruCell.com)

#### **Investors/Analysts:**

Oya Yavuz  
Director Investor Relations  
Tel. +31-(0)71-519 7064  
[ir@cruCell.com](mailto:ir@cruCell.com)