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## Sanofi Pasteur initiates phase II trial of cell culture-based seasonal influenza vaccine

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, announced today that it has initiated Phase II testing of its cell culture-based seasonal influenza vaccine in the U.S.

The initiation of Phase I was announced on Sept 25, 2006. This project is part of a contract awarded in 2005 by the U.S. Department of Health and Human Services (HHS) aimed at accelerating the development of a new cell culture-based influenza vaccine. Phase II trials involving healthy adult volunteers in the U.S. will focus further on the safety profile and immunogenicity of the cell-based vaccine.

This vaccine was developed using the PER.C6<sup>®</sup> cell line, licensed from Dutch biotechnology company, Crucell N.V.

PER.C6 Cell technology offers Sanofi Pasteur a promising and reliable production method for seasonal and pandemic influenza vaccines in addition to traditional, proven egg-based production. The production scale potential of the PER.C6 cell line has been demonstrated in a successful bioreactor run of 20,000 liters, suggesting robustness of PER.C6 technology and further showing that this may be a suitable cell line for large-scale manufacturing of its influenza vaccine. This scale-up process was achieved under a subcontracting agreement between Sanofi Pasteur and Lonza Biologics plc (Lonza Group).

As the world leader in the research, development and manufacture of influenza vaccines, Sanofi Pasteur is actively involved in other projects in the U.S. and Europe with the goal of developing new influenza vaccines.

### Seasonal Influenza Overview

Influenza is a highly infectious virus that spreads easily from person to person, primarily when an infected individual coughs or sneezes. According to the World Health Organization (WHO), 5-15% of the population is affected with upper respiratory tract infections in annual influenza epidemics. Hospitalization and deaths mainly occur in high-risk groups (elderly, people with chronic conditions/illness). Although difficult to assess, these annual epidemics are thought to result in between three and five million cases of severe illness and between 300 000 and 500 000 deaths every year around the world<sup>1</sup>. Most deaths currently associated with influenza in industrialized countries occur among the elderly over 65 years of age.

### Reference:

1. [www.who.int/vaccine\\_research/diseases/ari/en/print.html](http://www.who.int/vaccine_research/diseases/ari/en/print.html)



### **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)

### **About Lonza Group**

Lonza Biologics plc, is a biotechnology contract manufacturer and biologics service provider, which is a business sector of the Lonza Group, a chemical and biotechnology company driven by the life sciences. Lonza is headquartered in Basel, Switzerland, and is listed on the SWX Swiss Exchange. In 2006, Lonza had sales of CHF 2.91 billion. Further information can be found at [www.lonza.com](http://www.lonza.com).

### **About Crucell**

Crucell N.V. is a Dutch biotechnology company (Euronext, NASDAQ: CRXL; Swiss Exchange: CRX) focused on research, development and worldwide marketing of vaccines and antibodies that prevent and treat infectious diseases. Crucell's vaccines are sold in public and private markets worldwide. The company licenses its PER.C6<sup>®</sup> production technology and other technologies to the biopharmaceutical industry. Crucell is headquartered in Leiden (The Netherlands) and 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 as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

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