# Sanofi-aventis and Biotechnology company Exelixis enter into an Exclusive Global Alliance for Novel Targeted Oncology Therapies

- Alliance includes a Global License Agreement for XL147 & XL765 and an Exclusive Collaboration for discovery of PI3K Inhibitors -

Paris, France - May 28, 2009 - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and Exelixis, Inc. (Nasdaq: EXEL) announced today a *global license agreement* for *XL147* and *XL765* and an *exclusive collaboration for the discovery* of inhibitors of phosphoinositide-3 kinase (PI3K) for the management of solid malignancies. Activation of the PI3K pathway is a frequent event in human tumors, promoting cell proliferation and cell survival, as well as resistance to chemotherapy and radiotherapy.

**Under the license agreement**, sanofi-aventis will have an exclusive worldwide license to **XL147**, an oral PI3K inhibitor, and **XL765**, an oral dual inhibitor of PI3K and mTOR (mammalian target of rapamycin); both are currently in phase 1 clinical trials. Sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, manufacturing and commercial activities. Exelixis will participate in ongoing and potential future clinical trials.

**Under the exclusive discovery collaboration**, sanofi-aventis and Exelixis will combine research efforts to establish several preclinical programs related to isoform-selective inhibitors of PI3K. Sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of the products that result from the collaboration. However, Exelixis may be responsible for conducting certain clinical trials.

"We are very excited about integrating such novel targeted therapies with high therapeutic potential in our portfolio," said Marc Cluzel, Senior Vice-President R&D, sanofi-aventis. "We look forward to combining our efforts with Exelixis to develop innovative drugs in the best interest of patients suffering from cancers. This alliance is aligned with our strategy to create value through strategic partnerships that deliver new therapeutic options".

Under the terms of the agreements, sanofi-aventis will pay Exelixis an upfront cash payment as well as development and regulatory milestone payments that could reach over \$1 billion in aggregate for existing and future programmes under both agreements. In addition, Exelixis will be entitled to receive royalties and commercial milestones on sales when products are commercialized.

The license agreement is subject to antitrust clearance under the *Hart-Scott-Rodino Antitrust Improvements Act*.

\*\*\*



#### **About PI3K inhibitors**

The phosphoinositide-3-kinase (*PI3K*) pathway is triggered in normal cells upon exposure to growth factors. It regulates a cascade of proliferation and survival signals. The PI3K pathway is one of the primary deregulated signaling pathways in human cancer. Activation of the PI3K pathway is a frequent event in human tumors, promoting cell proliferation, survival, and resistance to chemotherapy and radiotherapy. Novel therapeutics impacting the PI3K pathway, alone or in combination, are therefore considered to have a high therapeutic potential.

### About XL147 and XL765

XL147 is an orally available small molecule inhibitor of phosphoinositide-3-kinase (PI3K). XL765 is an orally available small molecule, dual inhibitor of PI3K and mTOR (mammalian target of rapamycin). mTOR can be activated via upregulation of PI3K, or via PI3K-independent mechanisms. mTOR is frequently activated in human tumors, and plays a central role in tumor cell proliferation.

#### **About Exelixis**

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its fully integrated drug discovery platform to fuel the growth of its development pipeline, which is primarily focused on cancer. Currently, Exelixis' broad product pipeline includes investigational compounds in Phase III, Phase II and Phase I clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb, GlaxoSmithKline, Genentech, Wyeth Pharmaceuticals and Daiichi-Sankyo. For more information, please visit the company's website at http://www.exelixis.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).

## 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 product development, product potential 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 among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMEA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as 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 sanofiaventis' annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.