



Phase 3 Trial of Aflibercept in Metastatic Pancreatic Cancer Discontinued

Phase 3 studies in colorectal cancer, non-small cell lung cancer, and prostate cancer continue with over 70 percent enrollment completed

PARIS and TARRYTOWN, N.Y., Sept 11, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Sanofi-aventis (Euronext: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced the discontinuation of the Phase 3 trial that evaluated aflibercept (VEGF Trap) plus gemcitabine versus placebo plus gemcitabine for the first-line treatment of metastatic pancreatic cancer (VANILLA), based on the recommendations by an Independent Data Monitoring Committee (IDMC). As part of a planned interim efficacy analysis, the IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported on the combination arm with aflibercept were generally as anticipated.

With the closure of the study, a detailed analysis of the efficacy and safety results will be conducted by the companies and results will be presented at a future medical meeting. Sanofi-aventis and Regeneron have notified the study investigators and appropriate regulatory authorities of the decision to discontinue the study. Patients in the study will continue to be provided access to aflibercept at the determination of the study investigators in consultation with the patients.

Metastatic pancreatic cancer is among the most intractable cancers. Clinical development of new therapies, including anti-VEGF agents, has been generally characterized by a failure to achieve significant incremental clinical benefit over existing treatments.

"We are disappointed with the result of this study and we will continue our efforts to bring new and effective treatments for these patients," said Dr. Marc Cluzel, Senior Vice President, Research and Development sanofi-aventis. "We remain committed to the other ongoing Phase 3 trials of aflibercept in colorectal cancer, non-small cell lung cancer, and hormone-refractory metastatic prostate cancer."

Three Phase 3 studies continue, each of which is currently over 70 percent enrolled:

- VELOUR study: 2nd-line metastatic colorectal cancer in combination with fluorouracil, leucovorin, and irinotecan (FOLFIRI)
- VITAL study: 2nd-line non-small cell lung cancer in combination with docetaxel
- VENICE study: 1st-line hormone-refractory metastatic prostate cancer in combination with docetaxel and prednisone

About Pancreatic Cancer

Each year in the United States, more than 42,000 individuals are diagnosed with pancreatic cancer and over 35,000 die. The prognosis is generally poor; less than five percent of those diagnosed are still alive five years after diagnosis. Gemcitabine is considered the standard backbone of first-line treatment in patients with first-line metastatic pancreatic cancer.

About Aflibercept

Aflibercept is an anti-angiogenesis inhibitor with a unique mechanism of action. This fusion protein binds all forms of Vascular Endothelial Growth Factor-A (VEGF-A), as well as VEGF-B and placental growth factor (PlGF), additional angiogenic growth factors that appear to play a role in tumor angiogenesis and inflammation. Aflibercept has been shown to bind VEGF-A, VEGF-B, and PlGF with higher affinity than their natural receptors.

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 PARIS: SAN) and in New York (NYSE: SNY).

About Regeneron Pharmaceuticals, Inc.

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to

ARCALYST(R) (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

Forward Looking Statement - sanofi-aventis

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 labeling 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 sanofi-aventis' 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.

Forward Looking Statement - Regeneron Pharmaceuticals, Inc.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of aflibercept, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize aflibercept, competing drugs that may be superior to aflibercept, uncertainty of market acceptance of aflibercept, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2008 and Form 10-Q for the quarter ending June 30, 2009. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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