



Results of VEGF Trap (Aflibercept) Highlighted at ASCO 2007 Annual Meeting

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Results of VEGF Trap (Aflibercept) Highlighted at ASCO 2007 Annual Meeting CHICAGO, June 2 /PRNewswire-FirstCall/ -- Sanofi-aventis (Euronext: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced encouraging preliminary results from two Phase II studies in advanced ovarian cancer and lung cancer with aflibercept (VEGF Trap), an anti-angiogenic agent targeting Vascular Endothelial Growth Factor. Aflibercept (VEGF Trap) is being developed by Regeneron in collaboration with sanofi-aventis. The companies will present data from the lung cancer study tomorrow.

These are the first reported results from a late-stage development program consisting of single-agent studies and planned Phase III trials in combination with common chemotherapy regimens in several different solid tumor types. The presentation reviewing the advanced ovarian cancer trial and the poster describing the lung cancer trial will be available on the Regeneron website (www.regeneron.com on the Events page, under the Investor Relations heading) later, after they are presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO).

The first study selected for an oral presentation at ASCO is an interim analysis of a Phase II randomized, double-blind, multi-center trial investigating two doses of single-agent aflibercept (VEGF Trap) in patients with recurrent platinum-resistant epithelial ovarian cancer. While the study remains blinded with regards to dose, the combined preliminary results of the two dose levels demonstrated anti-tumor activity as evidenced by an 8 percent partial response rate and 77 percent achievement of stable disease in heavily pre-treated patients who have failed multiple other treatments. Aflibercept (VEGF Trap) has been well tolerated with the typical class effect of anti-angiogenic agents (hypertension and proteinuria were the most common adverse events).

"For this refractory group of advanced ovarian cancer patients who have already received three or more previous courses of treatment, there are few therapeutic options available. These interim results indicate that the VEGF Trap may offer an acceptable safety profile, and the VEGF Trap has shown encouraging signs of activity not only in terms of response rate but also durable stable disease, lowering of a biochemical marker of ovarian cancer, and improvement in ascites," stated Robert L. Coleman, M.D., Professor and Director, Clinical Research, University of Texas, M.D. Anderson Cancer Center Department of Gynecologic Oncology. "The VEGF Trap may one day represent a new treatment regimen for these seriously ill patients with few available alternatives."

The second study is presented as a poster at ASCO and is a Phase II single-arm study conducted in patients with platinum-resistant and erlotinib-resistant adenocarcinoma of the lung (the most common type of non-small cell lung cancer).

Regeneron and sanofi-aventis plan to meet with the U.S. Food and Drug Administration (FDA) to discuss these Phase II results and determine the next steps in the development program for the aflibercept (VEGF Trap). The ongoing single-agent studies of aflibercept (VEGF Trap) will be complemented by a large Phase III program combining aflibercept (VEGF Trap) with standard chemotherapy regimens in five different advanced solid tumors: colorectal, non-small cell lung, prostate, pancreas and gastric cancer.

Sanofi-aventis plans to make a first registration submission to regulatory agencies as early as 2008 for the VEGF Trap.

"We are encouraged with the results we are seeing with the aflibercept (VEGF Trap), especially the evidence of biologic activity and the preliminary safety results in both trials," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "We are further pleased with the commitment by sanofi-aventis, whose capabilities in oncology drug development will play an important role in completing the broad development of aflibercept (VEGF Trap)."

"Our interest for VEGF-Trap is driven by its unique characteristics and its high potential in most tumor types. Our alliance with Regeneron and the ambitious development program we are moving forward are reflecting the increasing commitment we have to Oncology," said Dr Marc Cluzel, Senior Vice President, Science and Medical Affairs of sanofi-aventis. "We have a great aspiration for this product, for the further development of our company in oncology, and for improving the care of patients with cancer."

About the Ovarian Study

This study is a Phase II randomized, double-blind, multi-center trial investigating two doses of single-agent aflibercept (VEGF Trap) in patients with recurrent platinum-resistant or refractory epithelial ovarian cancer. The primary endpoint is a comparison of the objective response rate of two different doses of the aflibercept (VEGF Trap): 4.0 milligrams per kilogram (mg/kg) and 2.0 mg/kg delivered by intravenous injection every two weeks. Secondary endpoints are time to progression (TTP), progression-free survival (PFS), overall survival (OS), CA-125 protein level reduction, and time to CA-125 progression, as well as safety, pharmacokinetics, immunogenicity and health-related quality of life measures.

From June 2006 to April 2007, 162 patients were randomized and evaluated for efficacy from 44 centers in 12 countries (Europe,

Canada, and the United States). A total of 13 partial responses have been observed (8 percent). Disease has been assessed as stable in 77 percent of patients at 4 weeks with 41 percent of patients demonstrating durable stable disease at 14 weeks. CA-125 protein levels, a surrogate marker for disease activity in ovarian cancer used to measure response to treatment, have been reduced by more than 50 percent in 21 patients (13 percent of the 162 patients evaluated). Of the 24 patients with advanced ovarian cancer who experienced ascites, 7 patients (29 percent) have experienced complete disappearance of the ascites, and 13 patients (54 percent) have experienced no increase in ascites during treatment. Tolerability has been similar to other molecules of the same class, hypertension being the most common grade 3/4 side effect (16 percent). Notably, only 2 of the 162 patients (1.2 percent) experienced bowel perforation, both of whom have recovered. Recruitment in this trial is continuing, and the companies expect to enroll approximately 200 patients in total. The study remains blinded.

About the Lung Cancer Study

This study is a Phase II open-label, single-arm, multi-center trial. This trial is evaluating aflibercept (VEGF Trap) dose of 4.0 mg/kg delivered every two weeks to patients with platinum-resistant and erlotinib-resistant adenocarcinoma of the lung. The primary endpoint is response rate. Secondary endpoints are safety, duration of response, progression free survival, overall survival and quality of life.

About Ovarian Cancer

Most ovarian cancers are either ovarian epithelial carcinomas (cancer that begins in the cells on the surface of the ovary) or malignant germ cell tumours (cancer that begins in egg cells).

More than 28000 new cases in the US and 22400 in Europe were diagnosed in 2004 and almost 14400 patients in the US and 18500 patients in Europe died.

About Lung Cancer

Lung cancer has been the most common cancer globally since 1985 and, in 2002, 1.35 million new cases of lung cancer were diagnosed, which represents about 12.4% of all newly diagnosed cancers. Lung cancer accounts for 29% of all cancer deaths and causes more deaths than breast, colorectal and prostate cancer combined. There are an estimated 1.18 million lung cancer deaths annually.

In the US, the most recently available figures from 2002 show that 100,099 men and 80,163 women were diagnosed with lung cancer. In the European Union (EU), lung cancer is the third most commonly diagnosed cancer, with 243,600 people diagnosed in the year 2000. Lung cancer does not only affect developed nations; nearly 50% of lung cancer cases in 2002 were reported in developing countries.

Among US men, incidence rates have significantly declined since 1984 from 102.0 per 100,000 in 1984 to 77.8 per 100,000 in 2002. Since 1998, the lung cancer rates in women have stabilised after a long period of increase.

About aflibercept (VEGF Trap) in Oncology

The VEGF Trap is a fully human soluble VEGF receptor fusion protein with a unique mechanism of action. It is a potent angiogenesis inhibitor, which binds VEGF-A more tightly than monoclonal antibodies. It blocks all VEGF-A isoforms plus placental growth factor (PlGF), another angiogenic growth factor that appears to play a role in tumor angiogenesis. The VEGF Trap has a relatively long half-life of approximately two weeks. Other anti-VEGF drugs have been approved for certain cancer indications and neovascular age-related macular degeneration.

About sanofi-aventis

Sanofi-aventis is one of the world's leading pharmaceutical companies, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. 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 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.

About Regeneron Pharmaceuticals

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates for the potential treatment of cancer, eye diseases, and inflammatory diseases and has preclinical programs in other diseases and disorders.

Additional information about Regeneron and recent news releases are available on Regeneron's worldwide web site at www.regeneron.com

Forward-looking statement

This news release discusses historical information and includes forward- looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our 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-Q for the quarter ended March 31, 2007. 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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