Sanofi-aventis Reports Top-line Results from Phase III Study with BSI-201 in Metastatic Triple-Negative Breast Cancer

Paris, France - January 27, 2011 - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and its subsidiary, BiPar Sciences, today announced that a randomized Phase III trial evaluating BSI-201 (iniparib*) in patients with metastatic triple-negative breast cancer (mTNBC) did not meet the pre-specified criteria for significance for co-primary endpoints of overall survival and progression-free survival.

Importantly, the results of a pre-specified analysis in patients treated in the second- and third-line setting demonstrate an improvement in overall survival and progression-free survival, consistent with what was seen in the Phase II study. The overall safety analysis indicates that the addition of BSI-201 did not significantly add to the toxicity profile of gemcitabine and carboplatin.

"While this trial did not meet its primary goal, we believe that the improvement in overall survival and progression-free survival in patients in the second- and third-line setting are important findings," said Dr. Debasish Roychowdhury, M.D. Senior Vice President and Head of sanofi-aventis Oncology. "We are conducting in-depth analysis to gain further insight into these Phase III results. Sanofi-aventis remains committed to improving outcomes for patients with triple negative breast cancer where there is high unmet medical need."

Sanofi-aventis plans to discuss these data with United States and European health authorities in the near future. Full study results will be presented at an upcoming major oncology conference. Patients with questions are encouraged to consult with their treating physicians. The current clinical development program for BSI-201 continues in breast, lung and other cancers.

* Iniparib is the United States Adopted Name (USAN) for the investigational agent BSI-201.

About the BSI-201 Phase III Study

The study enrolled 519 women with mTNBC from 109 sites in the United States. Patients were randomized to receive a standard chemotherapy regimen (gemcitabine and carboplatin) on days one and eight of each 21-day cycle, with or without BSI-201 5.6 mg/kg, which was administered on days one, four, eight and 11 of each 21-day cycle. Patients in the study had received up to two previous lines of chemotherapy in a metastatic setting. The co-primary endpoints were overall survival and progression-free survival.

About BSI-201

BSI-201 is a novel investigational anti-tumor agent with poly (ADP-ribose) polymerase (PARP) inhibitory activity in preclinical models. BSI-201 is in Phase III trials for patients with squamous non-small cell lung cancer, as well as in Phase II trials for patients with breast, lung and other cancers.

About Triple-Negative Breast Cancer (TNBC)

When women are diagnosed with breast cancer, their tumors are routinely tested for the presence of estrogen and progesterone receptors and for the over-expression of HER2. However, 15 to 20 percent of all breast cancers lack over-expression of all three proteins – giving rise to the term "triple-negative breast cancer" or TNBC. Research has shown TNBC continues to be difficult to treat and associated with poorer outcomes than



other types of breast cancer. Women with TNBC are not candidates for hormonal therapies such as tamoxifen or therapies targeting the human epidermal growth factor receptor 2, such as Herceptin, leaving chemotherapy as the standard treatment. Therefore, finding new strategies to enhance the effectiveness of chemotherapy in this population has become an important research focus.

About BiPar Sciences

BiPar Sciences is a biopharmaceutical organization dedicated to pioneering novel tumor-selective therapies designed to address urgent unmet needs of cancer patients. Located in South San Francisco, California, BiPar is a subsidiary of sanofi-aventis. For more information, please visit www.biparsciences.com.

About sanofi-aventis Oncology

Based in Cambridge, Massachusetts, and Vitry, France, sanofi-aventis Oncology is translating science into effective cancer therapeutics to address unmet medical needs for patients with cancer. Starting with a deep understanding of the mechanisms by which cancer develops, grows and spreads, the company employs innovative approaches in drug discovery, clinical development and partnerships to bring the right medicines to the right patients with the goal of helping cancer patients live healthier and longer lives.

Sanofi-aventis Oncology is committed to the pursuit of science and innovative cancer therapies. We believe in partnership with leading experts, and combining that expertise with our own internal scientific strength and heritage. There are currently more than 10 compounds in clinical development including small molecules and biological agents.

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). For more information, please visit www.sanofi-aventis.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 projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, 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 EMA, 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, the Group's ability to benefit from external growth opportunities 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, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts:

Megan Humphrey

Oncology Division Communications

Tel: 1 (617) 447-0258

E-mail: megan.humphrey@sanofi-aventis.com

Marisol Peron

Corporate Media Relations

Tel: +33 (0) 1 53 77 45 02; Mobile: +33 (0) 6 08 18 94 78

E-mail: marisol.peron@sanofi-aventis.com