# Final Results from Phase II Study Confirm BSI-201 (Iniparib) Prolongs Survival in Metastatic Triple Negative Breast Cancer

***- Data presented at 35th European Society for Medical Oncology (ESMO) Congress -***

**Paris, France – October 10, 2010 –** Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and its fully owned subsidiary, BiPar Sciences, today announced that final results from a randomized Phase II clinical trial confirmed that treatment with BSI-201 (iniparib*) in combination with gemcitabine/carboplatin results in a significant improvement in overall survival and a high rate of clinical response in women with metastatic triple negative breast cancer (mTNBC). Findings from the study were presented today at an oral presentation at the 35th European Society for Medical Oncology (ESMO) Congress in Milan, Italy.

*"These results confirm that more than half of the patients treated with BSI-201 (iniparib) had substantial decrease in their tumor burden, and they lived significantly longer than women getting chemotherapy alone,"* said Joyce O'Shaughnessy, M.D., lead investigator of the study and co-chair of the Breast Cancer Research Program Baylor-Charles A. Sammons Cancer Center; Texas Oncology, US Oncology in Dallas. *"Iniparib appears to enhance the ability of chemotherapy to kill cancer cells without increasing the severity of adverse events."*

According to the study results, median overall survival among women who received BSI-201 (iniparib) in combination with the chemotherapy agents gemcitabine and carboplatin was 12.3 months compared with 7.7 months among women who received chemotherapy alone, translating to a 43 percent reduction in the risk of death (HR=0.57). Median progression-free survival in the BSI-201 (iniparib) group was 5.9 months compared to 3.6 months in the chemotherapy group (HR=0.59) . In addition, 55.7 percent of patients in the BSI-201 (iniparib) group showed a clinical benefit, defined as a complete or partial response or stable disease of at least six months, compared with 33.9 percent of patients in the chemotherapy group. There was no significant difference in adverse events between the two groups. The most common severe (grade 3 and 4) adverse events included neutropenia, thrombyocytopenia, anemia, fatigue, leukopenia and increases in the enzyme ALT. The study included 123 women with mTNBC.

*"BSI 201 (Iniparib) continues to demonstrate potential as a promising new treatment option for women with metastatic triple negative breast cancer, an aggressive disease that currently has no approved treatments,"* said Debasish Roychowdhury, M.D., Senior Vice President, Global Oncology, sanofi-aventis. *"The development of BSI 201 (iniparib) is progressing well and we hope iniparib can become the first treatment available specifically for this disease."*

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

The U.S. Food and Drug Administration (FDA) granted Fast Track designation to iniparib for mTNBC. As described by the FDA, the Fast Track process is designed to expedite the review of drugs being developed for serious diseases with the potential to address an unmet need. The regulatory submissions are planned for Q1 2011 in the U.S. and Q2 2011 in the European Union.



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## About BSI-201 (Iniparib)

IBSI-201 (Iniparib) is a novel investigational anti-tumor agent with poly (ADP-ribose) polymerase (PARP) inhibitory activity. Among other anti-tumor agents which inhibit PARP, iniparib is the only one that has demonstrated improved overall survival in a Phase II study of this aggressive and advanced form of breast cancer. PARP1 functions in the repair of DNA damage that occurs naturally in cancer cells, or that is induced by DNA-damaging chemotherapy. Inhibiting PARP may prevent cancer cells from repairing their DNA, therefore, enhancing the effectiveness of chemotherapy.

BSI-201 (Iniparib) is in Phase III trials for patients with mTNBC and squamous non-small cell lung cancer, as well as in Phase II trials for patients with ovarian, uterine and brain cancers. Iniparib is the United States Adopted Name (USAN) for the investigational agent BSI-201.

## About Triple Negative Breast Cancer (TNBC)

When patients 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, 15-20 percent of all breast cancers lack over-expression of all three proteins, therefore giving rise to the term “triple-negative breast cancer” or TNBC. TNBC continues to be associated with poorer outcomes than other types of breast cancer. Women with TNBC are not candidates for hormonal therapy such as tamoxifen or the targeted therapy 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 sanofi-aventis Oncology

Sanofi-aventis Oncology is targeting cancer on all fronts in an effort to address unmet medical needs for a broad range of patients. Starting with a deep understanding of the mechanisms by which cancer develops, grows and spreads, as well as identifying the right science early in the discovery process, the company employs innovative approaches to bring the right medicines to the right patients. There are currently more than 10 compounds in development across a broad scientific platform, including cytotoxic, antimitotic, anti-angiogenic agents, antivascular agents, monoclonal antibodies and cancer vaccines, as well as supportive care therapies. Four of these compounds are now being investigated in Phase III clinical studies aimed at multiple solid and hematologic tumors.

## 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.

## 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 wholly owned subsidiary of sanofi-aventis. For more information, please visit www.biparsciences.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.*

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