Investigational Cancer Drug BSI-201 Showed Clinical Benefit in 62% of Patients with Triple-Negative Metastatic Breast Cancer and Significantly Prolonged Survival

- Data Highlighted in Plenary Session of 2009 American Society of Clinical Oncology Annual Meeting -

Paris, France, and Brisbane, California, USA - May 31, 2009 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and its fully owned subsidiary, BiPar Sciences, today announced results from a randomized Phase 2 clinical trial of ***BSI-201***, a poly ADP-ribose polymerase (PARP) inhibitor, in combination with gemcitabine and carboplatin (GC) chemotherapy, in patients with metastatic triple-negative breast cancer (TNBC). BSI-201 is a novel investigational agent that acts by inhibiting PARP1, an enzyme that repairs DNA damage.

In this study, 116 women with metastatic TNBC, defined as tumors lacking expression of estrogen and progesterone receptors and without overexpression of HER2, were randomly assigned to receive GC in combination with the investigational agent BSI-201 or GC alone. Patients assigned to receive chemotherapy without BSI-201 were allowed to receive BSI-201 at the time of disease progression.

The primary study endpoint was the rate of clinical benefit, defined as complete or partial response or stable disease of at least 6 months. Secondary study endpoints included progression-free survival, overall survival and safety.

Approximately 62 percent of patients receiving BSI-201 in combination with GC showed clinical benefit, compared with 21 percent in the group receiving chemotherapy alone ($p= 0.0002$). Tumor response (complete or partial response) was observed in 48 percent of patients who received BSI-201 combined with chemotherapy, whereas patients receiving chemotherapy alone showed a response rate of 16 percent. Women who received BSI-201 had a median progression-free survival of 6.9 months and overall survival of 9.2 months compared with 3.3 and 5.7 months, respectively, for women who received chemotherapy alone. The hazard ratios for progression free survival and overall survival were 0.342 ($p< 0.0001$) and 0.348 ($p=0.0005$), respectively.

The most common severe (grades 3 and 4) side effects included neutropenia [25/57 in patients treated with GC and BSI-201; 31/59 patients treated with GC alone], thrombocytopenia and anemia. No febrile neutropenia was observed in patients receiving BSI-201 combined with chemotherapy. BSI-201 did not add to the frequency or severity of adverse events associated with chemotherapy.

"The improvement in overall survival and progression free survival together with the responses seen in this study are promising. We did not observe added toxicities. BSI-201 may provide a potential new treatment option for patients suffering from this disease," said Joyce O'Shaughnessy, M.D., co-director of the Breast Cancer Research Program at Baylor-Charles A. Sammons Cancer Center and Texas Oncology in Dallas, Texas.

"These results represent an important development for a disease that currently has no approved standard of treatment," said Barry Sherman, M.D., BiPar's Executive Vice President of Development. *"Further study of BSI-201 will help us determine its full therapeutic potential in triple negative breast cancer, as well as in other cancers"*.

BiPar Sciences and sanofi-aventis expect to begin a Phase 3 trial with BSI-201 in metastatic TNBC this summer.

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About ASCO

ASCO is the world's leading professional organization representing physicians who care for people with cancer. Approximately 30,000 cancer specialists from around the world are expected to gather at ASCO to discuss the latest advances in cancer care, treatment, prevention and survivorship. More than 4,000 abstracts have been accepted to the meeting, which will focus on the theme of "Personalizing Cancer Care", a practice focusing on caring for the individual – not just treating the disease – through the entire spectrum of care from prevention, diagnosis, and treatment to survivorship and end of life care. For information on abstract embargo schedules and other ASCO information and resources, visit www.asco.org/presscenter.

About BSI-201

Among other investigational PARP inhibitors in the industry, BSI-201 is the furthest along in clinical development in metastatic TNBC. BSI-201 is currently being evaluated for its potential to enhance the effect of chemotherapy-induced DNA damage. The clinical development of BSI-201 is supported by well documented safety profile based on studies of more than 200 patients.

About 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. Commonly used breast cancer therapies target these receptors; for example, tamoxifen for estrogen receptor and trastuzumab (Herceptin®) for HER2. However, 15-20% of all breast cancers lack over-expression of all three proteins, thus giving rise to the term "triple- negative breast cancer" or "TNBC."

TNBC can be an aggressive disease, with higher rates of metastases and poorer survival rates than other breast cancer subtypes. No treatment has been approved specifically for TNBC.

About BiPar Sciences

BiPar Sciences is a biopharmaceutical organization pioneering novel tumor-selective therapies designed to address urgent unmet needs of cancer patients. In addition to BSI-201, the company also has two additional compounds in preclinical development. BiPar Sciences, located in Brisbane, California, is a fully-owned subsidiary of sanofi-aventis, Inc. For more information, please visit www.biparsciences.com.

About sanofi-aventis

Sanofi-aventis is a leading global pharmaceutical company that discovers, develops and distributes therapeutic solutions to help improve the lives of patients. 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, 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.

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