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BiPar Sciences Announces Update on the Clinical Development Progress of BSI-201 for Metastatic Triple-Negative Breast Cancer

- Phase 3 Trial Accrual Advances On-Schedule -
- Updated Phase Data Presented at San Antonio Breast Cancer Symposium -
- FDA Grants BSI-201 Fast Track Designation -

Paris, France, and San Francisco, California, USA – December 11, 2009 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and its wholly-owned subsidiary, BiPar Sciences, announced today that the clinical development program in metastatic triple-negative breast cancer (mTNBC) for the investigational PARP1 inhibitor, BSI-201, progresses as planned with the Phase 3 study meeting expectations on patient accrual and trial site coverage in the United States. Study investigators have enrolled 214 of the target number of 420 patients.

BSI-201 entered a Phase 3 clinical trial in the United States in July 2009 and is being evaluated in combination with chemotherapy in patients with mTNBC, a condition defined by tumors lacking expression of estrogen, progesterone receptors and without overexpression of HER2. BSI-201 is a novel investigational targeted therapy that inhibits poly (ADP-ribose) polymerase (PARP1), an enzyme involved in DNA damage repair.

The decision to commence with the Phase 3 study in July was based on the encouraging Phase 2 study results presented at ASCO on May 31, 2009. In the Phase 2 clinical trial, women with mTNBC who were randomly assigned to receive gemcitabine and carboplatin (GC) in combination with the investigational agent BSI-201 or GC alone. Updated Phase 2 data – including overall survival – were presented today, Friday, December 11, at 5:30 pm CST, at a poster session at the 32nd Annual San Antonio Breast Cancer Symposium (SABCS).

The addition of BSI-201 to GC improved median overall survival from 7.7 months to 12.2 months. (HR=0.5, p=0.005). BSI-201 did not add to the frequency or severity of adverse events associated with chemotherapy. This is not a final analysis of the Phase 2 data, but rather an updated analysis of overall survival. Median survival has not yet been reached in the BSI-201 arm, therefore the data cut-off period for the Phase 2 trial from September to November.

"The updated analysis from the Phase 2 program, including data on overall survival, are consistent with the positive results presented earlier this year at ASCO," declared Marc Cluzel, Executive Vice President, R&D, sanofi-aventis. *"We are very encouraged by the fast recruitment of patients in Phase 3 trial. We hope the findings will lead to emerging strategy that may help women with metastatic triple negative breast cancer."*

The U.S. Food and Drug Administration (FDA) granted Fast Track designation to BSI-201 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 medical need.

For more information about the BSI-201 Phase 3 clinical trial, please go to: www.clinicaltrials.gov or www.biparsciences.com, or call the BiPar Sciences Call Center at +1 866 668 2232.

About the BSI-201 Phase 3 Trial

The Phase 3 trial is a multi-center, randomized trial designed to evaluate the safety and efficacy of BSI-201 when combined with gemcitabine and carboplatin (GC) in women with mTNBC. A total of 420 mTNBC patients, who have received 0-2 prior therapies in the metastatic setting will be randomized to receive GC with or without BSI-201.

The co-primary objectives of the Phase 3 study are to assess improvement in progression-free survival and overall survival. The secondary objectives are to assess objective response rate and safety. The trial encompasses an estimated 94 sites in the United States. Importantly, this trial will have a crossover provision that will ensure that all patients enrolled in the BSI-201 Phase 3 clinical trial have the potential opportunity to receive BSI-201 (patients randomly assigned to the control arm may receive BSI-201 upon disease progression).

About BSI-201

BSI-201 is a potential first-in-class investigational targeted therapy designed to inhibit poly (ADP-ribose) polymerase (PARP1), an enzyme involved in DNA damage repair. Among other investigational PARP inhibitors in the industry, BSI-201 is the farthest along in clinical development in the mTNBC setting. BSI-201 is currently being evaluated for its potential to enhance the effect of chemotherapy-induced DNA damage on cancer cells where PARP hyperactivity was demonstrated. BSI-201 is in Phase 3 for mTNBC, as well as in Phase 2 trials in patients with ovarian, uterine, brain and lung cancers.

About Triple-Negative Breast Cancer

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 for HER2. However, 15-20 percent 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 dedicated to 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 South San Francisco, California, is an independent, wholly owned subsidiary of sanofi-aventis, Inc. For more information, please visit www.biparsciences.com.

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, 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 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 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 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.

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