



**Abstracts #1007, 5004, 5005**  
**Embargoed Until 6 June 2011, 11:15 am CT**

## **New Data in Breast and Ovarian Cancer Presented at ASCO Support Continued Development of Iniparib**

**Paris, France – June 6, 2011**– Sanofi (EURONEXT: SAN and NYSE: SNY) today announced new data for iniparib (BSI-201), an investigational agent, in metastatic triple-negative breast cancer (mTNBC), platinum-sensitive and platinum-resistant recurrent ovarian cancer. The data were presented at the 47<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

### **Metastatic Triple-negative Breast Cancer**

Results from the randomized, open-label, Phase III trial investigating the use of gemcitabine and carboplatin with or without iniparib in mTNBC were presented by Joyce O'Shaughnessy, MD, 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. The results showed that:

- The study did not reach statistical significance for the co-primary endpoints of Overall Survival (HR=0.88, 95% CI [0.69, 1.12]; p=0.28 [versus pre-specified at 0.04]) or Progression-free Survival (HR=0.79, 95% CI [0.65, 0.98]; p=0.027 [versus pre-specified at 0.01]).
- In a preplanned sub-group analysis of patients in the second- and third-line treatment settings, the median Progression-free Survival was 4.2 months in the iniparib arm, compared to 2.9 months in the chemotherapy alone arm (HR=0.67, 95% CI [0.5, 0.92]). The median Overall Survival was 10.8 months in the iniparib arm, compared to 8.1 months in the chemotherapy alone arm (HR=0.65, 95% CI [0.46, 0.91]).
- The most common adverse events (Grade 3/4, >5%) in the iniparib arm were neutropenia, thrombocytopenia, anemia, fatigue, increase in alanine aminotransferase and dyspnea. The addition of iniparib did not significantly add to the toxicity profile of gemcitabine and carboplatin.

*"Patients with metastatic triple-negative breast cancer have very few treatment options available to them," said Dr. O'Shaughnessy. "I am encouraged by the second- and third-line data from this trial and believe further investigation is warranted in an effort to alleviate this unmet medical need."*

### **Platinum-sensitive Recurrent Ovarian Cancer**

Data from a preliminary analysis of an ongoing multi-center, single-arm Phase II trial evaluating gemcitabine and carboplatin in combination with iniparib in platinum-sensitive recurrent ovarian cancer presented by Richard T. Penson, MD, Clinical Director, Medical Gynecologic Oncology, Massachusetts General Hospital in Boston demonstrated that:

- The Overall Response Rate (complete plus partial responses) was 65% in 40 evaluable patients.
- The most common adverse events (Grade 3/4, >5%) were: neutropenia, thrombocytopenia, diarrhea, and anemia.



## Platinum-resistant Recurrent Ovarian Cancer

Results from a preliminary analysis of a multi-center, single-arm Phase II trial evaluating gemcitabine and carboplatin in combination with iniparib in platinum-resistant recurrent ovarian cancer presented by Michael Birrer, MD, PhD, Director, Medical Gynecologic Oncology, Massachusetts General Hospital in Boston demonstrated that:

- The Overall Response Rate (complete plus partial responses) was 25% in 32 evaluable patients.
- The most common adverse events (Grade 3/4, >5%) were: neutropenia, thrombocytopenia, nausea, anemia, small intestinal obstruction, abdominal pain, and fatigue.

*“These results again demonstrate that iniparib is an active agent and can be combined with standard chemotherapy,”* said Debasish Roychowdhury, MD, Senior Vice President and Head of Sanofi Oncology. *“Sanofi is committed to further developing iniparib based on activity seen to date with this molecule.”*

## About the Studies

The randomized, open-label Phase III mTNBC study enrolled 519 women from 109 sites in the US. 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 iniparib (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 or Progression-free Survival.

The multi-center single-arm Phase II recurrent ovarian cancer studies evaluated the same treatment regimen of gemcitabine/carboplatin with or without iniparib used in the mTNBC study. The platinum-sensitive study included 41 patients whose disease recurred at least six months after completing treatment with a platinum-based chemotherapy agent, while the platinum-resistant study continues to enroll up to 48 patients whose disease recurred between two and six months following treatment with a platinum-based chemotherapy agent. The primary endpoint of both trials was Overall Response.

## About Iniparib (BSI-201)

BSI-201 is a novel, investigational oncology agent that is in Phase III trials for patients with squamous non-small cell lung cancer (NSCLC), as well as in Phase II trials for patients with breast, lung and other cancers. In addition, BSI-201 is the subject of an extensive translational program designed to identify biomarkers predictive of response both within and across tumor types. Iniparib is the United States Adopted Name (USAN) for BSI-201.

## About Sanofi Oncology Division

Based in Cambridge, Massachusetts, and Vitry, France, Sanofi 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 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

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### Forward Looking Statement

*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's 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, 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 labeling 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, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2010. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

---

### Contacts:

#### Oncology Division Communications

Lauren Musto

Tel: +1 (617) 665-4618

Mobile: +1 (781) 572-1147

E-mail: [lauren.musto@sanofi.com](mailto:lauren.musto@sanofi.com)

#### Corporate Media Relations

Marisol Péron

Tel: +33 (0) 1 53 77 45 02

Mobile: +33 (0) 6 08 18 94 78

E-mail: [marisol.peron@sanofi.com](mailto:marisol.peron@sanofi.com)