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# Cabazitaxel Increased Survival for Patients with Advanced Hormone-Refractory Prostate Cancer

- Results observed in patients treated with cabazitaxel plus prednisone whose disease progressed despite prior docetaxel-based chemotherapy -
- Data from large international Phase 3 study to be presented at the 2010 Genitourinary Cancers Symposium in San Francisco -

Paris, France - March 4, 2010 - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today results from a Phase 3 trial which demonstrated cabazitaxel, an investigational compound, plus prednisone/prednisolone significantly improved overall survival and progression-free survival in patients with metastatic (advanced) hormone-refractory prostate cancer whose disease progressed following treatment with docetaxel-based chemotherapy. The TROPIC trial compared the combination of cabazitaxel plus prednisone/prednisolone to the active agent mitoxantrone plus prednisone/prednisolone.

For many patients with metastatic hormone-refractory prostate cancer, their disease continues to progress despite prior chemotherapy. Currently, there are no approved therapies to treat these patients.

"These are significant results in the development of this investigational drug," said Dr. Oliver Sartor, North American principal investigator, Piltz Professor for Cancer Research at Tulane Medical School, New Orleans. "Improved overall survival was demonstrated in this trial – and these are the first data to show a statistical improvement in overall survival in patients with this difficult-to-treat and aggressive form of prostate cancer."

TROPIC was designed to assess patients with metastatic hormone-refractory prostate cancer whose disease had progressed following treatment with docetaxel-based chemotherapy. Results showed that the combination of cabazitaxel and prednisone/prednisolone significantly reduced the risk of death by 30% [HR=0.70 (95% CI: 0.59-0.83); P<0.0001] with a clinically meaningful improvement in the median overall survival of 15.1 months in the cabazitaxel combination arm vs. 12.7 months in the mitoxantrone combination arm. Patients who received the combination treatment with cabazitaxel also experienced a significant increase in median progression-free survival [2.8 months vs. 1.4 months [HR=0.74 (95% CI: 0.64 - 0.86); P<0.0001].

The most frequent grade 3/4 hematological adverse events with cabazitaxel included neutropenia (81.7%), febrile neutropenia (7.5%) and infections (10.2%); the most frequent grade 3/4 non-hematological adverse events included nausea (1.9%), vomiting (1.9%) and diarrhea (6.2%). Most frequent treatment-emergent adverse events leading to discontinuation with the cabazitaxel arm were neutropenia (2.4%), hematuria (1.3%), diarrhea (1.1%) and fatigue (1.1%). Grade 3/4 peripheral neuropathy occurred in 0.5% patients in



the cabazitaxel arm vs. 0.3% in the mitoxantrone arm. Deaths due to adverse events were 4.9% in the cabazitaxel arm (predominantly due to neutropenia and its complications) vs. 1.9% in the mitoxantrone arm.

"These are compelling results which we are looking forward to sharing with the health care and oncology community," said Debasish Roychowdhury, M.D., Senior Vice President, Global Oncology, sanofi-aventis. "Providing new options and hope for patients with serious diseases, such as metastatic hormone-refractory prostate cancer, is what drives our ongoing commitment to researching and exploring novel anti-cancer compounds and to bringing these medicines to patients."

Results will be presented by Dr. Sartor in San Francisco, CA on March 5 at the 2010 Genitourinary Cancers Symposium sponsored by the American Society for Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO) and the Society of Urologic Oncology (SUO).

### **About the TROPIC Trial**

TROPIC was conducted in 146 trial sites in 26 countries throughout the world, including the U.S. The multi-center Phase 3 randomized registrational trial assessed 755 metastatic hormone-refractory prostate cancer patients whose disease had progressed despite previous docetaxel-based chemotherapy.

The primary endpoint was overall survival. Secondary endpoints included progression-free survival, tumor response rate, tumor progression, prostate-specific antigen (PSA) response, (PSA) progression, pain response, pain progression. Disease progression in this trial was defined as tumor progression, PSA progression or pain progression. Patients were randomly assigned to receive cabazitaxel plus prednisone/prednisolone or mitoxantrone plus prednisone/prednisolone (378 and 377 patients, respectively). Patients were to receive either regimen for up to a maximum of 10 cycles.

### **About Cabazitaxel**

Cabazitaxel is a novel investigational taxane compound that may be active in cell lines refractory to taxanes. Cabazitaxel has been shown to inhibit cell division and tumor cell proliferation by binding to and stabilizing tubulin, a protein in the microtubules of cells which provides a skeleton for maintaining cell shape.

Cabazitaxel recently received fast track designation from the U.S. Food and Drug Administration (FDA) – a process designed to expedite the review of drugs being developed for serious diseases with the potential to address an unmet medical need. The rolling submission has already started and allows for completed sections of a New Drug Application to be submitted on an ongoing basis.

# **About Prostate Cancer**

Worldwide, prostate cancer ranks third in cancer incidence and sixth in cancer mortality in men. In the U.S., prostate cancer remains the second most common cause of cancer death among men after lung cancer. In 2009, an estimated 192,000 new cases were anticipated in the U.S., while 27,000 were expected to have died from the disease.

Metastatic prostate cancer indicates that the cancer has spread, or metastasized, to the lymph nodes or other parts of the body, mostly to the bones; castration resistant/hormone-refractory prostate cancer means that the cancer has continued to grow despite the suppression of male hormones that fuel the growth of prostate cancer cells. More than 80% of all prostate cancer cases are discovered when the disease is limited to the prostate and surrounding organs, while 10-20% of patients are diagnosed when the cancer has already metastasized.

# **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: <a href="https://www.sanofi-aventis.com">www.sanofi-aventis.com</a>

# 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 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 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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