



## ASCO Abstracts Highlight Late-stage Sanofi Oncology Pipeline

*- Progress on Jevtana<sup>®</sup>, Zaltrap<sup>™</sup> and JAK2 inhibitor featured -*

**Paris, France – May 16, 2012** - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today abstracts spanning the company's innovative marketed and late-stage development compounds will be featured at the 2012 American Society of Clinical Oncology Annual Meeting in Chicago, Ill., June 1-5. Sanofi products are noted in more than 170 abstracts to be presented at the meeting.

This year's meeting theme – *Collaborating to Conquer Cancer* – aligns with Sanofi Oncology's approach to drug discovery and development through external partnerships that complement internal expertise. Diverse collaborations with leading scientists, academic institutions and other industry partners have brought forth numerous compounds to be highlighted in poster and oral presentations at the meeting, including investigational agents Zaltrap<sup>™</sup> (afibercept) and the JAK2 inhibitor, SAR302503.

*"The data to be presented at ASCO underscore the commitment of Sanofi Oncology to the patient and focus on innovative scientific discovery to develop cancer therapies that meet patient needs,"* said Debasish Roychowdhury, M.D., Senior Vice President and Head, Sanofi Oncology. *"I thank the investigators and our partners for their strong collaboration in helping realize this progress."*

### **Zaltrap<sup>™</sup> (afibercept)**

Zaltrap<sup>™</sup> is a novel investigational recombinant human fusion protein that binds VEGF-A, VEGF-B and PlGF. A Biologics License Application (BLA) for Zaltrap for use in combination with irinotecan-fluoropyrimidine-based chemotherapy in patients with metastatic colorectal cancer (mCRC) previously treated with an oxaliplatin-containing regimen is under review at the U.S. Food and Drug Administration (FDA). A marketing authorization application for Zaltrap for the same indication is also under review at the European Medicines Agency (EMA). Abstracts to be presented at ASCO include:

- Effects of prior bevacizumab use on outcomes from the VELOUR study: a Phase III study of afibercept and FOLFIRI in patients with metastatic colorectal cancer after failure of an oxaliplatin regimen.
  - Presenter: Carmen Allegra M.D., University of Florida Shands Cancer Center, USA
  - Oral presentation #3505; Sunday, June 3, 11:15 am CT, E Hall D1
- A randomized Phase II trial of weekly topotecan with and without AVE0005 (afibercept) in patients with platinum-treated extensive stage small cell lung cancer
  - Presenter: Jeffrey W. Allen, M.D., University of Tennessee Cancer Institute, USA
  - Oral Presentation #7005; Monday, June 4, 9:30 am CT, E Hall D2
- Afibercept versus placebo in combination with FOLFIRI in previously treated metastatic colorectal cancer: Mean overall survival estimation from a Phase III trial
  - Presenter: Florence Joulain, MSc, Sanofi, France
  - Poster Presentation #3602; Monday, June 4, 8:00 am – 12:00 pm CT, S Hall A2, Poster Board #34G

### **Jevtana<sup>®</sup> (cabazitaxel)**

Jevtana<sup>®</sup>, a novel, semisynthetic second-generation taxane, has been approved by the FDA, the EMA and other national health authorities in combination with prednisone for the treatment of



patients with metastatic hormone-refractory prostate cancer who were previously treated with a docetaxel-containing treatment regimen. Abstracts accepted for presentation at ASCO include:

- Prostate-specific antigen decline is not a surrogate for overall survival in patients with metastatic castrate-resistant prostate cancer who failed first line chemotherapy
  - Presenter: Susan Halabi, Ph.D., Duke University, USA
  - Oral Presentation #4515, Saturday June 2, 11:30 am CT, E Arie Crown Theater
- Firstana Study: First-line use of cabazitaxel in chemotherapy-naive patients with metastatic castration-resistant prostate cancer: A three-arm study in comparison with docetaxel
  - Presenter: Stephane Oudard, M.D., Ph.D., Descartes University, France
  - TPS4696, Sunday June 3, 8:00am - 12:00pm CT, S Hall A2, Poster Board 16G
- Proselica study: Comparison of two doses of cabazitaxel + prednisone in patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing regimen
  - Presenter: Mario Eisenberger, M.D., Johns Hopkins Medical Institutions, USA
  - TPS4692, Sunday June 3, 8:00am - 12:00 pm CT, S Hall A2, Poster Board #16B
- Phase II trial of cabazitaxel in patients with advanced or metastatic transitional cell carcinoma of the urothelial tract who have progressed within less than 12 months after cisplatin-based chemotherapy: A Spanish Oncology Genitourinary Group (SOGUG) study
  - Presenter: Jose Angel Arranz Arija, M.D., Hospital General Universitario Gregorio Maranon, Spain
  - TPS4672, Sunday June 3, 8:00am - 12:00pm CT, S Hall A2, Poster Board #13G

### **SAR302503 (JAK2 inhibitor) and ombrabulin**

The Sanofi Oncology pipeline portfolio has more than 15 investigational compounds in clinical development, including small molecules and biological agents. Selected abstracts to be presented at ASCO include:

- JAKARTA: A phase III, multicenter, randomized, double-blind, placebo-controlled, three-arm study of SAR302503 in patients with intermediate-2 or high-risk primary myelofibrosis, post-polycythemia vera MF, or post-essential thrombocythemia MF with splenomegaly
  - Presenter: Aminesh Pardani, MBBS, Ph.D., Mayo Clinic, USA
  - TPS6639; Monday June 4, 1:15pm – 5:15pm CT, S Hall A2, Poster Board #30C
- A randomized phase II, open-label trial of orally administered SAR302503 in patients with polycythemia vera or essential thrombocythemia who are resistant or intolerant to hydroxyurea
  - Presenter: Ayalew Tefferi, M.D., Mayo Clinic, USA
  - TPS6641, Monday, June 4, 1:15pm – 5:15pm CT, S Hall A2, Poster Board #31B
- OPSALIN: A phase II placebo-controlled randomized study of ombrabulin in patients with platinum-sensitive recurrent ovarian cancer treated with carboplatin and paclitaxel
  - Presenter: Eric Pujade-Lauraine, M.D., Ph.D., Hopital Hotel-Dieu, France
  - TPS5112, Sunday, June 3, 8:00am – 12:00 pm CT S Hall A2, Poster Board #30A
- A phase I study of ombrabulin combined with bevacizumab in patients with advanced solid tumors
  - Presenter: Gianluca Del Conte, MD, Fondazione IRCCS Istituto Nazionale dei Tumori, Italy
  - Poster Presentation #3080, Monday June 4, 8:00am - 12:00pm CT, S Hall A2, Poster Board #17F

### **About Zaltrap™ (aflibercept) and the Clinical Development Program**

Zaltrap™ (aflibercept), also known in the scientific literature as VEGF Trap, is an investigational angiogenesis inhibitor with a unique mechanism of action. This fusion protein binds all forms of Vascular Endothelial Growth Factor-A (VEGF-A), as well as VEGF-B and placental growth factor



(PIGF), additional angiogenic growth factors that appear to play a role in tumor angiogenesis and inflammation. Zaltrap is being jointly developed under a global collaboration agreement between Sanofi Oncology and Regeneron Pharmaceuticals, Inc.

#### **About Jevtana® (cabazitaxel)**

Jevtana® (cabazitaxel) is a taxane chemotherapy approved in combination with prednisone for the treatment of patients with metastatic hormone-refractory prostate cancer previously treated with a docetaxel-containing treatment regimen.

#### **About SAR302503 (JAK2 Inhibitor)**

JAK2 is a key enzyme for blood cell development. SAR302503 is a novel, investigational, selective JAK2 inhibitor that has shown activity in preclinical studies against two activating mutations (JAK2V617F and MPLW515L) of JAK2. Dysregulated JAK2 signaling is thought to be a cause of MF and related disorders. SAR302503 is being investigated in multiple hematologic and solid tumor types.

#### **About ombrabulin**

Ombrabulin is an investigational small-molecule vascular-disrupting agent currently in Phase III clinical trials in patients with advanced soft tissue sarcoma, a disease with high unmet medical need, who have not responded to prior treatments and in phase II trials in NSCLC & ovarian cancer. In 2011, ombrabulin was granted orphan drug status for soft tissue sarcoma by the FDA because it is intended to treat a disease in a small patient population.

#### **About Sanofi Oncology**

Based in Cambridge, Massachusetts, USA and Vitry, France, Sanofi Oncology is dedicated to translating science into effective therapeutics that address unmet medical needs for cancer and organ transplant patients. Starting with a deep understanding of the disease and the patient, Sanofi Oncology employs innovative approaches to drug discovery and clinical development, with the ultimate goal of bringing the right medicines to the right patients. We believe in the value of partnerships that combine our internal scientific expertise with that of industry and academic experts. Our commitment is to help patients live healthier and longer lives through novel science and innovative therapies, with a portfolio that includes 10 marketed products and more than 15 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, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

#### **Sanofi 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'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 labelling and other matters that could affect the availability or commercial potential of such product*



*candidates, the absence of guarantee that the product 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, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding 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, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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