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Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

New England Journal of Medicine publishes data showing improved survival with Jevtana® (cabazitaxel) over second androgen receptor-targeted agent in metastatic castration-resistant prostate cancer

- CARD is a treatment sequencing trial investigating the efficacy and safety of Jevtana versus abiraterone or enzalutamide after disease progression following initial androgen receptor-targeted agent therapy and docetaxel
- Jevtana more than doubled radiographic progression free survival (primary endpoint) and significantly reduced risk of death (key secondary endpoint) by 36%
- Study results presented during Presidential Symposium at the 2019 European Society of Medical Oncology Congress

PARIS – September 30, 2019 – Data published today in the *New England Journal of Medicine* showed that patients with metastatic castration-resistant prostate cancer (mCRPC) previously treated with docetaxel and who progressed within 12 months on an androgen receptor (AR)-targeted agent (abiraterone or enzalutamide) experienced significantly longer radiographic progression free survival (rPFS) with Jevtana® (cabazitaxel) plus prednisone compared with abiraterone plus prednisone or enzalutamide. Overall survival (OS) with Jevtana was also significantly longer. These findings from the CARD study were presented today in the Presidential Symposium of the 2019 European Society of Medical Oncology (ESMO) Congress in Barcelona, Spain.

> *"In this study, treatment with Jevtana significantly improved radiographic progression free survival and overall survival compared with enzalutamide or abiraterone,"* said Professor Ronald de Wit from Erasmus MC University Hospital, Rotterdam, The Netherlands, and the lead investigator of the CARD study. *"These results are exciting as they have the potential to impact treatment guidelines for metastatic prostate cancer and current clinical practice."*

CARD is a randomized, open-label, treatment sequencing clinical study involving 62 sites across 13 European countries, enrolling 255 patients (median aged 70 years, 31% aged over 75 years) with mCRPC who were previously treated with docetaxel and who progressed within 12 months on an AR-targeted agent, in any order. These patients were randomized 1:1 to Jevtana (25 mg/m^2 intravenously every three weeks, daily prednisone, and granulocyte colony-stimulating factor) versus abiraterone (1,000 mg plus prednisone, daily) or enzalutamide (160 mg daily; patients received abiraterone if they were previously

treated with enzalutamide, or enzalutamide if they were previously treated with abiraterone).

CARD study met primary and secondary endpoints

The study's primary endpoint was rPFS, which more than doubled with Jevtana treatment (N=129) compared to abiraterone or enzalutamide (N=126; median 8.0 vs 3.7 months; HR=0.54; 95% CI,0.40–0.73; p<0.0001). Patients treated with Jevtana experienced an improvement in rPFS in all pre-specified subgroups, irrespective of the timing of the previous alternative AR-targeted agent, before or after docetaxel. Jevtana also significantly improved a key secondary endpoint, OS (median 13.6 vs 11.0 months; HR=0.64; 95% CI, 0.46–0.89; p=0.0078), reducing the risk of death from any cause by 36% compared with abiraterone or enzalutamide. Other key secondary endpoints all favored Jevtana: progression free survival (PFS) (median 4.4 vs 2.7 months; p<0.0001); confirmed prostate specific antigen (PSA) (35.7% vs 13.5%; p=0.0002) and tumor responses (36.5% vs 11.5%; p=0.004). Pain response (45.0% vs 19.3%; p<0.0001) and time to symptomatic skeletal events (not reached vs 16.7 months; p=0.0499) were also significantly improved with Jevtana treatment.

The incidence of grade ≥3 adverse events (AEs) was 56.3% with Jevtana vs 52.4% with AR-targeted agents. Key grade ≥3 treatment-emergent AEs with Jevtana versus AR-targeted agents were renal disorders (3.2% vs 8.1%), infections (7.9% vs 7.3%), musculoskeletal pain/discomfort (1.6% vs 5.6%), cardiac disorders (0.8% vs 4.8%), asthenic conditions (4.0% vs 2.4%), diarrhea (3.2% vs 0), peripheral neuropathy (3.2% vs 0) and febrile neutropenia (3.2% vs 0). Serious AE rates of any grade were similar for Jevtana treatment (38.9%) and treatment with an AR-targeted agent (38.7%). AEs led to death in 7 vs 14 patients (5.6% vs 11.3%) for Jevtana compared to AR-targeted agents. No new safety signals were observed.

About Prostate Cancer

Prostate cancer is a very heterogenous disease and one of the most common types of cancer in men.[1] Prostate cancer is the second leading cause of cancer related death among men in the United States[2] and the third in Europe.[3]

Metastatic castration-resistant prostate cancer (mCRPC) is prostate cancer that has spread beyond the prostate gland and progressed despite androgen deprivation therapy.

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[1] https://www.who.int/en/news-room/fact-sheets/detail/cancer

2. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. CA Cancer J Clin. 2019;69(1):7-34.

3. Malvezzi M, Carioli G, Bertuccio P, et al. European cancer mortality predictions for the year 2019 with focus on breast cancer. Ann Oncol. 2019;30(5):781-787

About Jevtana (cabazitaxel)

Jevtana is a semi-synthetic taxane chemotherapy. Jevtana is a microtubule inhibitor that binds to tubulin. This leads to the stabilization of microtubules, which results in the inhibition of mitotic and interphase cellular functions.

Jevtana is indicated, in combination with prednisone, for the treatment of adult patients with mCRPC previously treated with a docetaxel-containing treatment regimen.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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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, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements