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/m² 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 States2 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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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

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