

Submitted by:

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NCCN Guidelines Panel: Prostate Cancer

On behalf of Sanofi-Genzyme, we respectfully request the *NCCN Prostate Cancer Panel* members to review the enclosed data for inclusion of the findings of the CARD Study (NCT02485691) into the guidelines for the management of metastatic castration-resistant prostate cancer (mCRPC), PROS-18.

Specific Changes: Recommend that reference to 'cabazitaxel' (as subsequent therapy to docetaxel) on PROS-18 of the NCCN Guidelines Version 4.2019) be cited with the results from the CARD Study as presented at the European Society of Medical Oncology (ESMO) 2019 Meeting and as published online on September 30, 2019 in the New England Journal of Medicine (NEJM.org). A summary of results is included in the 'Rationale' section below.

FDA Clearance: "JEVTANA®(cabazitaxel) injection, is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." Jevtana Prescribing Information 2018

Rationale: In support of the specific request for the guideline update/change,

- The multicenter CARD study, a randomized, open-label clinical trial of 62 sites across 13 European countries compared cabazitaxel (n=129) with an androgen-signaling-targeted inhibitor (abiraterone or enzalutamide) (n=126) in patients with mCRPC who had previously received docetaxel and progressed within 12 months while receiving an androgen-signaling-targeted inhibitor
 - Patients received cabazitaxel 25 mg/m² intravenously every 3 weeks, plus prednisone daily and G-CSF from cycle 1
 - Patients received either abiraterone 1000 mg (plus prednisone daily), or enzalutamide 160 mg daily
- CARD met its primary objective; cabazitaxel more than doubled radiographic PFS (rPFS) vs abiraterone or enzalutamide (8.0 vs 3.7 months, HR=0.54, p<0.0001)
- Cabazitaxel reduced the risk of death by 36% vs abiraterone or enzalutamide (13.6 vs 11.0 months, HR=0.64, p=0.008)
- Adverse events of grade 3 or higher occurred in 56.3% of patients receiving cabazitaxel and in 52.4% of those receiving an androgen signaling–targeted inhibitor
- No new safety signals were observed

A copy of the online publication of the CARD study is submitted with this request and in support of the proposed updates to the NCCN Prostate Cancer Guidelines, PROS-18:

deWit r et al. Cabazitaxel versus abiraterone or enzalutamide in metastatic prostate cancer. N Engl J Med. Published on September 30, 2019 at NEJM.org DOI: 10.1056/NEJMoa1911206

Sincerely,

Marian Ibrahim, PharmD