Cabazitaxel Accord for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC) previously treated with a docetaxel containing regimen

**General information [1]**

<table>
<thead>
<tr>
<th>Drug description</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabazitaxel is an antineoplastic agent that acts by disrupting the microtubular network in cells.</td>
<td>Cabazitaxel Accord in combination with prednisone or prednisolone is indicated for the treatment of adult patients with mCRPC previously treated with a docetaxel containing regimen.</td>
</tr>
</tbody>
</table>

**Current treatment [2]**

For men with mCRPC who have received prior taxane chemotherapy (Docetaxel), NICE recommends:
- Abiraterone in combination with prednisone or prednisolone is recommended as an option for the treatment of mCRPC in adults, in which the disease has progressed on or after one docetaxel-containing chemotherapy regimen.
- Enzalutamide is recommended as an option for treating metastatic hormone-relapsed prostate cancer in adults whose disease has progressed during or after docetaxel-containing chemotherapy.
- Cabazitaxel in combination with prednisone or prednisolone is recommended as an option for treating metastatic hormone-relapsed prostate cancer in people whose disease has progressed during or after docetaxel chemotherapy, only if: the person has an ECOG performance status 0 or 1; the person has had ≥225 mg/m² or more of docetaxel; treatment with cabazitaxel is stopped when the disease progresses or after a maximum of 10 cycles (whichever happens first).

**Regulatory status**

<table>
<thead>
<tr>
<th>EMA [1]</th>
<th>FDA [3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval status for this indication: On 30 April 2020, the CHMP adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cabazitaxel Accord. Cabazitaxel Accord will be available as a 20 mg/ml concentrate for solution for infusion. Cabazitaxel Accord is a hybrid medicine of Jevtana® which has been authorised in the EU since 17 March 2011. Cabazitaxel Accord contains the same active substance as Jevtana, but it is available in a different formulation. The full indication is: Cabazitaxel Accord in combination with prednisone or prednisolone is indicated for the treatment of adult patients with mCRPC previously treated with a docetaxel containing regimen.</td>
<td>Approval status for this indication: 09/2017: Jevtana® is indicated in combination with prednisone for treatment of patients with mCRPC previously treated with a docetaxel-containing treatment regimen. Recommended Dose: Jevtana® 20 mg/m² administered every three weeks as a one-hour intravenous infusion in combination with oral prednisone 10 mg administered daily throughout Jevtana® treatment. A dose of 25 mg/m² can be used in select patients at the discretion of the treating healthcare provider. Other indications: none</td>
</tr>
</tbody>
</table>

**Costs**

Currently no cost information available.

**Study characteristics [4, 5]**

<table>
<thead>
<tr>
<th>Trial name</th>
<th>n</th>
<th>Intervention (I)</th>
<th>Comparator (C)</th>
<th>PE</th>
<th>Characteristics</th>
<th>Biomarker</th>
<th>Funding</th>
<th>Publication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROSELICA NCT01308580</td>
<td>1,200</td>
<td>Cabazitaxel 20 mg/m² intravenously (Day 1) every 3 weeks + prednisone 10 mg orally given daily</td>
<td>Cabazitaxel 25 mg/m² intravenously (Day 1) every 3 weeks + prednisone 10 mg orally given daily</td>
<td>OS</td>
<td>phase III, randomized, open-label, noninferiority</td>
<td>-</td>
<td>Sanofi</td>
<td><a href="#">Link</a></td>
</tr>
</tbody>
</table>

**Efficacy (I vs. C)**

- Median OS: 13.4 vs. 14.5 months (HR, 1.024)
- Median OS in a secondary analysis of the per-protocol population (including only patients who had received at least three doses of cabazitaxel): 15.1 vs. 15.9 months (HR, 1.042)
- Median PFS: 2.9 vs. 3.5 months (HR, 1.10; 95% CI, 0.974-1.240)

**Safety (I vs. C)**

- Any TEAE of grade ≥3: n=230/580 (39.7%) vs. n=324/595 (54.5%)
- Serious TEAEs: n=177/580 (30.5%) vs. n=257/595 (43.2%)
- Death: 2.1% vs. 3.2%
- Discontinuation: n=95/580 (16.4%) vs. n=116/595 (19.5%)

1 Death a result of AEs within 30 days of last treatment dose
2 TEAEs possibly related to study treatment leading to permanent treatment discontinuation
Tumor response rate: no significant difference between both groups (18.5% vs. 23.4%, p=.1924)

Median time to tumor progression: was 9.0 months vs. 9.3 months (HR, 1.096; 95% CI, 0.902-1.33)

PSA response rates: were significantly higher in I n=160/543 (29.5%) vs. C n=231/538 (42.9%)

Median time to PSA progression: 6.8 v 5.7 months (HR for I vs. C, 1.195; 95% CI, 1.025-1.393)

The rate of pain progression: 39.8% vs. 40.9%

The median time to pain progression: 6.2 vs. 6.4 months

HRQoL: the median time to definitive deterioration did not differ between the two doses of cabazitaxel for any of the well-being subscales or for prostate-specific concerns.

**References:**

5. Eisenberger M, Hardy-Bessard A, Soo Kim C, G’eczi L, Ford D, Mourey L, et al. Phase III Study Comparing a Reduced Dose of Cabazitaxel (20 mg/m2) and the Currently Approved Dose (25 mg/m2) in Postdocetaxel Patients With Metastatic Castration-Resistant Prostate Cancer—PROSELICA. J Clin Oncol 35:3198-3206.