18 February 2010
EMA/CHMP/54045/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Docefrez

docetaxel

On 18 February 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Docefrez, 20 mg and 80 mg, powder and solvent for concentrate for solution for infusion intended for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, head and neck cancer.

The applicant for this medicinal product is Sun Pharmaceutical Industries Europe B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Docefrez is docetaxel, an antineoplastic medicinal product (*L01CD 02)* that disrupts intracellular structures necessary for the replication and survival of cells (cytotoxic activity).

The benefits with Docefrez are its broad clinical anti-tumour activity against various tumour types. The most common side effects are neutropenia, anaemia, alopecia, nausea, vomiting, stomatitis, diarrhoea and asthenia.

The approved indication is:

- Breast cancer
  - Docefrez in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node- positive breast cancer.
  - Docefrez in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition.
  - Docefrez monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent.
  - Docefrez in combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who previously have not received chemotherapy for metastatic disease.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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  - Docefrez in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.
- Non-small cell lung cancer
  - Docefrez is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy.
  - Docefrez in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition.
- Prostate cancer
  - Docefrez in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer.
- Gastric adenocarcinoma
  - Docefrez in combination with cisplatin and 5-fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease.
- Head and neck cancer
  - Docefrez in combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

It is proposed that Docefrez should only be administered under the supervision of a physician qualified in the use of anticancer chemotherapy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Docefrez and therefore recommends the granting of the marketing authorisation.