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## Fact Sheet: Taxotere® (docetaxel) in early stage breast cancer

- Australia will be the first country in the world to fund Taxotere in combination with cyclophosphamide for women with early-stage breast cancer,\* as of 1 April<sup>1</sup> -

### What is Taxotere?

- Taxotere (docetaxel) is a chemotherapy medicine used to treat different types of cancer. It is part of a group of chemotherapy medicines called taxanes, which can improve outcomes for people with breast cancer.<sup>2-4</sup>
- In Australia Taxotere can be used to treat breast cancer, ovarian cancer, some types of lung cancer, head and neck cancer and prostate cancer.<sup>5</sup>

### How does Taxotere work?

- Taxotere stops cancer cells from growing and multiplying,<sup>5</sup> thereby resulting in the death of cancer cells.
- Taxotere like other chemotherapy treatments helps prevent cancer returning by destroying cancer cells that may have spread to other parts of the body, before they are detected.<sup>6</sup>
- Depending on the cancer, Taxotere may be used alone or in combination with other medicines to treat cancer.<sup>5</sup>
- For the treatment of early stage node negative (cancer that has not spread to the lymph nodes) breast cancer, Taxotere in combination with cyclophosphamide (referred to as TC) is available through the Pharmaceutical Benefits Scheme (PBS).<sup>1</sup>

### Benefits of Taxotere in combination with cyclophosphamide in treating early stage breast cancer

- A phase III multicentre, randomised, clinical trial involving 1,016 patients with early stage breast cancer, found that women who received treatment with Taxotere in combination with cyclophosphamide (TC) benefitted from a lower risk of cancer returning and improved survival:
  - 81 percent of women did not have their cancer return after seven years post treatment.<sup>4</sup>
  - After seven years post treatment the overall survival of women was improved, with 87 percent of women still alive.<sup>4</sup>
  - The survival benefits for women who received TC treatment was irrespective of age.\*\* The reduced risk of cancer recurrence with TC was observed among younger women was similar to that of women aged >65 years.<sup>4</sup>

## Taxotere in combination with cyclophosphamide available on the PBS

- Taxotere in combination with cyclophosphamide for women with early stage node negative breast cancer will become available through the PBS from 1 April 2010.<sup>1</sup>
- The government funding means that Taxotere-based chemotherapy is available for the cost of a PBS script for Australian women with operable breast cancer<sup>1,7</sup> – the only country in the world where this is the case.\*

## How is Taxotere in combination with cyclophosphamide administered?

- Chemotherapy is usually given in 'cycles' with rest periods between cycles to give your body a chance to recover between treatments. Each cycle involves a short period of treatment followed by a rest period in which you do not have treatment.<sup>6</sup>
- The number of cycles, the length of the treatment period and the length of the rest period depends on the type of chemotherapy.<sup>6</sup>
- Taxotere in combination with cyclophosphamide is administered as an infusion (drip through the veins) over one and a half hours every three weeks, under the supervision of a qualified oncologist.<sup>5</sup> For the treatment of early stage breast cancer four treatment cycles with TC is required.<sup>4</sup>

## What are the side effects of Taxotere?

- As with all medications Taxotere can have side effects in some people. Common side effects may include infections, fluid retention, muscle pain or tenderness, joint pain, hair loss and tiredness.<sup>8</sup>

— ENDS —

### PBS information from 1 April 2010:

**PBS Information:** Adjuvant treatment of operable breast cancer in combination with cyclophosphamide. NOTE: A maximum of four cycles of treatment will be authorized under this restriction.

For full Consumer Medicine Information please visit: <http://www.pbs.gov.au/cmi/swctaxot10309.pdf>

### TAXOTERE (docetaxel) Minimum Product Information

**INDICATIONS:** TAXOTERE is indicated for the treatment of patients with locally advanced or metastatic breast cancer in whom previous chemotherapy has failed; or (in combination with capecitabine) after failure of prior anthracycline containing chemotherapy. TAXOTERE in combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumours over express HER2 and who previously have not received chemotherapy for metastatic disease. TAXOTERE in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with node-positive breast cancer. *\*Doxorubicin and cyclophosphamide followed by TAXOTERE in combination with trastuzumab (AC-TH) is indicated for the adjuvant treatment of patients with operable breast cancer whose tumours overexpress HER2. \*TAXOTERE in combination with carboplatin and trastuzumab (TCH) is indicated for the adjuvant treatment of patients with operable breast cancer whose tumours overexpress HER2. \*TAXOTERE in combination with cyclophosphamide is indicated for the adjuvant treatment of operable breast cancer with a primary tumour of  $\geq 1\text{cm}$  and  $< 7\text{cm}$ .* TAXOTERE is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer, including those who have failed platinum-based chemotherapy. TAXOTERE is indicated for the treatment of metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy. TAXOTERE is indicated for the treatment of patients with androgen independent (hormone refractory) prostate cancer. TAXOTERE in combination with cisplatin and fluorouracil, is indicated as induction treatment prior to chemoradiotherapy, for the treatment of patients with locally advanced, squamous cell carcinoma of the head and neck, who have low probability of surgical cure, require organ preservation or where the tumour is technically unresectable.

**CONTRAINDICATIONS:** Contraindicated in patients with a history of severe hypersensitivity reactions to TAXOTERE or polysorbate 80; a baseline neutrophil count of  $< 1.5 \text{ cells} \times 10^9/\text{L}$ ; severe liver impairment; who are pregnant (**Pregnancy Category D**) or in breast-feeding women.

**PRECAUTIONS:** confined to units specialised in the administration of cytotoxic chemotherapy and for administration under the supervision of a qualified oncologist. Patients should be pre-medicated prior to each TAXOTERE administration to minimise fluid retention and hypersensitivity reactions. Patients should be closely observed for hypersensitivity reactions (especially during the first and second infusions). Frequent monitoring of complete blood counts and liver function should be conducted on all patients during treatment with TAXOTERE (baseline and before each cycle) – refer to full Product Information for further details. Neutrophil nadirs occurred at a median of 7 days but this interval may be shortened in heavily pre-treated patients. Prophylactic G-CSF may be used to mitigate the risk of haematological toxicities. Cutaneous Reactions, hearing disorders, neurotoxicity and cardiac toxicity (when used with trastuzumab, particularly following anthracycline (doxorubicin and epirubicin)-containing chemotherapy) have been reported with TAXOTERE and should be monitored for. Interactions – Exercise caution with strong cytochrome P450-3A inhibitors. *\*In vivo investigations show that caution should be exercised when administering ketoconazole to patients as concomitant therapy since there is a potential for a significant interaction. \*Docetaxel should be*

administered with caution in patients concomitantly receiving protease inhibitors (e.g., ritonavir) which are inhibitors and substrates of cytochrome P450-3A.

**ADVERSE REACTIONS:** Haematological - neutropenia, anaemia, febrile neutropenia, infection, thrombocytopenia, acute myeloid leukaemia, myelodysplastic syndrome, \*disseminated intravascular coagulation (DIC), often associated with sepsis, or multiorgan failure. Neurologic - neuropathy, confusion, seizures, loss of consciousness. Hepatic - elevated transaminases, bilirubin & alkaline phosphatase, hepatitis. \*Hypersensitivity – Rare: cases of anaphylactic shock; Very rare: these cases resulted in a fatal outcome in patients who received premedication. Cutaneous – rash, \*cutaneous lupus erythematosus and bullous eruptions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and scleroderma-like changes, nail disorders. Gastrointestinal – stomatitis, diarrhoea, nausea, vomiting, duodenal ulcer, \*ileus and intestinal obstruction, gastrointestinal perforation, neutropenic enterocolitis, colitis including ischemic colitis. Cardiovascular – hypertension, hypotension, arrhythmia, heart failure, chest pain. Other –acute respiratory distress syndrome, dyspnoea, alopecia, fluid retention, \*acute pulmonary/neurosensory/peripheral oedema, dehydration, interstitial pneumonia, and renal insufficiency/\*failure, ototoxicity, hearing disorders and/or hearing loss, amenorrhea, fever, infection and asthenia. Heart failure has been observed in patients receiving TAXOTERE in combination with trastuzumab, particularly following anthracycline-containing chemotherapy – sometimes resulting in death. When TAXOTERE is used in combination with other products, the effects of each may be exacerbated. Refer to full PI for further adverse reactions. **DOSAGE AND administration:** Always review the full PI (available on request from sanofi-aventis) before prescribing or administering Taxotere. Patients should be premedicated to minimise fluid retention and hypersensitivity reactions. The recommended dosage for Taxotere is 75 to 100mg/m<sup>2</sup> every 3 weeks, depending on the indication. The use of other agents in combination with Taxotere is recommended for some indications. The safety and effectiveness of TAXOTERE in children has not been established. **Preparation for the intravenous administration:** Refer to PI for detailed instructions for preparing Taxotere for administration. TAXOTERE solution for infusion should be visually inspected prior to use, and solutions containing a precipitate should be discarded.

**SPONSOR:** sanofi-aventis australia pty ltd, 12-24 Talavera Road, Macquarie Park NSW 2113 Freecall No:1800 818 806. Full Product Information is available from sanofi-aventis Australia Pty Ltd.

#### Notes to the editor:

\* Australia is the first country to register and reimburse Taxotere<sup>®</sup> (docetaxel) in combination with cyclophosphamide for the treatment of early-stage node-negative breast cancer. The treatment has also been reimbursed in one Canadian state (Ontario). However the treatment is currently not funded or registered for use in any other parts of Canada.

#### About sanofi-aventis:

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For further information on Taxotere and breast cancer please refer to separate fact sheets.

#### Forward Looking Statements

This press release contains forward-looking statements as defined in the U.S. Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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-aventis’ 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-aventis, 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 products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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*Disseminated by Burson-Marsteller on behalf of sanofi-aventis.*

#### References

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