

## Australia Leads the World in Funding Treatment for 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>

Australia – 16 March 2010 – Sanofi-aventis announced today that all Australian women\* will be able to access government funded Taxotere<sup>®</sup> (docetaxel) in combination with cyclophosphamide,<sup>1</sup> a chemotherapy combination shown to benefit women's chances of surviving early-stage breast cancer.<sup>2,3</sup> This follows a government decision to include Taxotere in combination with cyclophosphamide for this group of women on the Pharmaceutical Benefits Scheme (PBS) as of 1 April 2010.<sup>1</sup>

Dr Richard de Boer, Medical Oncologist at the Royal Melbourne and Western Hospitals, welcomed the government's decision to fund Taxotere in combination with cyclophosphamide, saying it represents an important advancement in the management of early-stage breast cancer.

Commenting on the decision to list this treatment option on the PBS, Dr de Boer said: *"The government's decision to fund a treatment that has been shown to benefit long-term survival is exciting news for Australian women with early-stage breast cancer. From April 1 Australian women will be able to access a treatment that is affordable, accessible and has been shown to improve their chances of surviving breast cancer in the long-term."*

The new listing means that Taxotere-based chemotherapy will be available for the cost of a PBS script for Australian women with operable breast cancer<sup>1,4</sup> – the only country in the world where this is the case.\*

The Therapeutic Goods Administration (TGA) approved the use of Taxotere in combination with cyclophosphamide for women with early-stage breast cancer in August 2009.<sup>5</sup> Prior to the government's decision, women with this stage of cancer who wished to access the treatment paid approximately \$8,000 - \$9,000 for four treatment cycles.

Approximately one in nine Australian women will be diagnosed with breast cancer during her lifetime,<sup>6</sup> and the number of women diagnosed with breast cancer is expected to increase. In fact, Australian Government projections estimate the number of women diagnosed with breast cancer will reach 15,440 cases each year by 2015, which equates to 42 women being diagnosed with breast cancer every day in 2015.<sup>6</sup>

*"Breast cancer is the most common form of cancer affecting Australian women and is a significant cause of death, so any decision to fund additional treatments which benefits survival is very welcome as it provides women with further choice,"* said Assoc Prof Eva Segelov, Medical Oncologist at a major Sydney teaching hospital.

Dr Arlene Chan, Medical Oncologist at Perth's Mount Hospital, explained that the new PBS reimbursement is particularly exciting as research has found that Taxotere in combination with cyclophosphamide improves survival of women with early-stage breast cancer and reduces the risk of cancer recurrence, a serious concern for many women battling the disease.<sup>2,3</sup>

Dr Chan commented on the new PBS reimbursement: *"Having an effective non-anthracycline chemotherapy treatment is an important therapy advance, particularly for women with an underlying heart problem."*

*"With Taxotere in combination with cyclophosphamide soon available on the PBS for early-stage breast cancer we have a treatment option that will help women reduce the chance of cancer recurrence,"* said Dr Chan. *"This is a significant development given approximately one in five women with early-stage node-negative breast cancer will have their cancer return within 10 years."*

Like all other chemotherapy medications that treat cancer, Taxotere may have side effects. Common side effects may include infections, fluid retention, muscle pain or tenderness, joint pain, hair loss and tiredness.<sup>5</sup>

*"Not all chemotherapy treatments are suitable for everyone, and different treatments affect individual women in different ways. It is important that women who are commencing chemotherapy treatment discuss the potential side effects and how these can be managed with their doctor,"* said Dr Chan.

— ENDS —

**PBS information as of 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® (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:**

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY). For more information, please visit: [www.sanofi-aventis.com](http://www.sanofi-aventis.com)

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.

## If you would like any further information or to arrange an interview please contact:

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

## References

1. Data on file – sanofi-aventis. Correspondence from Pharmaceutical Evaluation Branch. 2010
2. Jones SE, Savin ME, Holmes FA *et al.* Phase III trial comparing doxorubicin plus cyclophosphamide with docetaxel plus cyclophosphamide as adjuvant *therapy* for operable breast cancer. *JCO* 1 December 2006; **24**(34):5381-5387
3. Jones SE, Holmes FA, O'Shaughnessy J *et al.* Doxetaxel with cyclophosphamide is associated with an overall survival benefit compared with doxorubicin and cyclophosphamide: 7-year follow-up of US oncology research trial 9735. *JCO* 10 March 2009;**27**(8):1177-1183
4. UBM Media Australia. *MIMS Australia*. Dec 09/Jan 10;**46**(6):310-311
5. sanofi-aventis. *Taxotere (docetaxel) Product Information*. August 2009
6. Australian Institute of Health and Welfare and the National Breast and Ovarian Cancer Centre. *Series 50 Breast cancer in Australia, an overview 2009*. Canberra: AIHW October 2009