



European Commission authorises the sale of Yondelis® for ovarian cancer

- **The European Commission has authorised the sale of Yondelis® (trabectedin) in combination with pegylated liposomal doxorubicin for relapsed platinum-sensitive ovarian cancer**
- **Yondelis® had already been approved by the European Commission in 2007 for treating soft tissue sarcoma**
- **Yondelis® will now be available for an indication which is four times more prevalent than soft tissue sarcoma**
- **Sales of the drug to treat relapsed ovarian cancer will commence in the UK, Germany, Austria, Denmark, Sweden, Finland and Norway**

Madrid, 2 November 2009: The European Commission (EC) has granted authorisation for PharmaMar, the biopharmaceutical subsidiary of Grupo Zeltia (ZEL.MC), to commercialise Yondelis® (trabectedin) in combination with pegylated liposomal doxorubicin to treat relapsed platinum-sensitive ovarian cancer in the 27 EU countries plus Norway, Iceland and Liechtenstein.

This authorisation comes one month after the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued by consensus a positive opinion recommending that marketing authorisation be granted in the EU for Yondelis® (trabectedin) in combination with pegylated liposomal doxorubicin to treat patients with relapsed platinum-sensitive ovarian cancer.

After receiving EC authorisation, Yondelis® sales are commencing in the UK, Austria, Germany, Denmark, Sweden, Finland and Norway, where prices do not need to be negotiated with the health authorities. In the remaining countries, the company will commence the paperwork for obtaining licenses and price negotiations with the health authorities.



Yondelis® is a new antitumour agent authorised in September 2007 by the European Union to treat advanced and metastatic soft tissue sarcoma (STS). The drug currently has approval for the treatment of soft tissue sarcoma in 46 countries.

About Yondelis

Yondelis® is a new antitumour agent originally derived from the Caribbean tunicate *Ecteinascidia turbinata* ("ascidia"). The compound is currently produced synthetically. Yondelis® binds to the minor groove of DNA, interfering with cell division and genetic transcription processes and the DNA repair machinery.

Under a licensing agreement with PharmaMar SA, Centocor Ortho Biotech Products, L.P. has the rights to market trabectedin worldwide except in Europe, where the drug is marketed by PharmaMar SA as YONDELIS®, and in Japan, where PharmaMar SA and Taiho Pharmaceutical Co., Ltd. have a licensing agreement to develop and market Yondelis®.

About ovarian cancer

In the West, epithelial ovarian cancer represents 4% of all cancers among women and ranks fifth as a cause of female deaths from cancer (American Cancer Society [ACS], Cancer Reference Information, 2005).

According to 2009 clinical data from the European Society for Medical Oncology (ESMO), ovarian cancer in the European Union affects 18 out of every 100,000 women per year, and the mortality rate is 12 per 100,000 women per year. The average age of diagnosis is 63, and the incidence increases with age, particularly above the age of 70; however, it may also occur in younger women, especially in those with a family history of the disease. 70% of women with ovarian cancer are diagnosed late, when the disease is already advanced (Stages III and IV). The 5-year survival rate for these women is only 15%-20%, whereas the 5-year survival rate is nearly 90% for patients in Stage I of the disease (i.e. the earliest stage) and 70% for Stage II (intermediate).

About soft-tissue sarcoma (STS)

Soft tissue sarcomas are a heterogeneous group of more than 50 types of tumours that arise in adipose, muscle or nerve tissue, tendons, blood and the lymph vessels. Almost half of these tumours affect the limbs. Soft tissue sarcomas affect around 4 out of every 100,000 people per year and account for 2% of the overall cancer mortality rate. STS is most common among people in their 50s. The 5-year survival rate of patients with STS is around 90% when it is detected early (Phase I), i.e. when the tumour is small and has not metastasised, but only 10-20% if the disease has metastasised. The life expectancy in patients with metastasis is 8-12 months after having received first-line therapy.

About PharmaMar

PharmaMar, a subsidiary of Grupo Zeltia (ZEL.MC), is the world-leading biopharmaceutical company in the discovery and development of marine-derived medicines to fight cancer. Yondelis® is Spain's first anti-cancer drug. In 2007, it was approved for sale in the European Union to treat soft tissue sarcoma. In 2009, the European Commission authorised the sale of Yondelis® (trabectedin) in combination with pegylated liposomal doxorubicin for relapsed platinum-sensitive ovarian cancer.

Phase II clinical trials with Yondelis® are also under way on prostate, breast and paediatric cancers. PharmaMar has four other compounds undergoing clinical trials: Aplidin®, Irvalec®, Zalypsis® and PM01183. PharmaMar also has a rich pipeline of pre-clinical candidates and a major R&D programme.



Important note

PharmaMar, which is headquartered in Madrid (Spain), is a subsidiary of Zeltia, S.A. (Spanish stock exchange: ZEL), which has been listed on the Spanish Stock Exchange since 1963 and on Spain's Electronic Market since 1998. This document is a press release, not a prospectus. This document does not constitute or form part of an offering or invitation to sell or a solicitation to purchase, offer or subscribe shares of PharmaMar or Zeltia. Moreover, no reliance should be placed upon this document for any investment decision or contract and it does not constitute a recommendation of any type with regard to the shares of PharmaMar or Zeltia.

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