Health Canada (Canadian regulatory authority) issues marketing authorization of Yondelis® for the treatment of ovarian cancer

Madrid, 20 May 2010: Centocor Ortho Biotech Products has informed PharmaMar SA (Grupo Zeltia, ZEL.MC) that the regulatory authority in Canada has issued a marketing authorizations of Yondelis® in combination with CAELYX (pegylated liposomal doxorubicin hydrochloride) for the treatment of patients with platinum-sensitive ovarian cancer for whom one first-line platinum-based chemotherapy regimen, including adjuvant therapy, has failed and who are not expected to benefit, are ineligible or not willing to receive retreatment with platinum-based chemotherapy. Approval of Yondelis® in combination with CAELYX is based on progression-free survival (PFS) benefit in patients with relapsed ovarian cancer.

In view of the new marketing authorization, across all indications, Yondelis® now has authorization in 57 countries, 26 of them outside the European Economic Area (EEA). The European Commission approved Yondelis® for platinum-sensitive ovarian cancer in September 2009. Since then, the commercialization has started progressively in Europe and other territories where Yondelis® has been approved. In 2007 the European Commission approved Yondelis® for soft tissue sarcoma.

Clinical trials are under way to expand the use of Yondelis® in sarcoma, including a trial as first-line treatment in patients with translocation-associated tumours and in Ewing's sarcoma, rhabdomyosarcoma and other forms of STS. Yondelis® is also undergoing trials in solid tumours, such as prostate, breast and lung cancer.

Yondelis® has orphan drug status for soft tissue sarcoma and ovarian cancer in the European Union, the United States, and Switzerland, and for soft tissue sarcoma in South Korea.

According to the licensing agreement between PharmaMar (Zeltia, S.A. subsidiary) and Centocor Ortho Biotech Products, L.P., PharmaMar has the marketing rights to Yondelis® in Europe (including Eastern Europe), while Centocor Ortho Biotech

Products, L.P. has the marketing rights to the drug everywhere else, except in Japan, where Taiho Pharmaceutical Co., Ltd. has a licensing agreement for the development and sale of 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), 18 new cases f ovarian cancer are detected each year in the European Union per 100,000 women, 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%, compared with nearly 90% for patients in Stage I of the disease (i.e. the earliest stage) and 70% for Stage II (intermediate).

About PharmaMar

PharmaMar is Grupo Zeltia's biotechnology subsidiary; it is a world leader in discovering, developing and selling marine-based drugs to treat cancer. Yondelis® is Spain's first anti-cancer drug. It is currently approved for STS in 25 countries outside the EEA, and in 5 of those countries for platinum-sensitive ROC as well. Yondelis® is approved for STS and platinum-sensitive ROC in all 30 countries of the EEA; in Switzerland it is approved for STS. Phase II clinical trials with Yondelis® are also under way on prostate, breast, lung and paediatric cancers. PharmaMar has four other compounds in clinical development: 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 Grupo Zeltia (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 the company. 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 the company.

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This note is also available at PharmaMar website: www.pharmamar.com