



EUROPE GIVES GREEN LIGHT TO YONDELIS[®] FOR THE TREATMENT OF RELAPSED PLATINUM-SENSITIVE OVARIAN CANCER

This is the second EMEA recommendation to approve Yondelis[®], a drug already marketed for the treatment of soft tissue sarcoma in adults

Madrid, 25 September 2009: PharmaMar, a biopharmaceutical company subsidiary of Zeltia, SA, has been informed by the European Medicines Agency (EMA) that the EMA's Committee for Medicinal Products for Human Use (CHMP) has issued by consensus a Positive Opinion recommending to grant the Marketing Authorization for Yondelis[®] (trabectedin) with Caelyx/DOXIL[®] (pegylated liposomal doxorubicin) for the treatment of relapsed platinum-sensitive ovarian cancer in the European Union.

Yondelis[®] will be now proposed for Final Approval by the European Commission for the referenced indication and the Marketing Authorization could be granted in short.

The Committee for Medicinal Products for Human Use (CHMP) of the EMA reviewed data from the multicenter, randomized, phase III trial with 672 patients that established the superiority of trabectedin in combination with Caelyx/DOXIL[®] over Caelyx/DOXIL[®] alone in patients with ovarian cancer in relapsed after standard platinum therapy.

PharmaMar submitted the registration dossier in December 2008. The recommendation of the experts committee is based on the favorable efficacy and safety of the trabectedin combination in patients with relapsed ovarian cancer after standard platinum therapy.

Many European patients are expected to have access to Yondelis[®] by the end of the year. This will be the only non-platinum, non-taxane combination for patients who suffer a relapse after initial chemotherapy.

"We are pleased with the positive recommendation from the EMA, which again supports PharmaMar research and development efforts and provides a new treatment option for patients with a disease where few effective treatment alternatives are available such as relapsed ovarian cancer", said José Maria Fernandez Sousa - Faro, President of PharmaMar.



PharmaMar continues with the development of its portfolio of compounds, one with the greatest potential in oncology, which makes PharmaMar a key player in the European pharmaceutical industry.

About Yondelis®

Yondelis® is a new antitumour agent that was originally derived from the Caribbean tunicate *Ecteinascidia turbinata*. The compound is now produced synthetically. Yondelis® binds the minor groove of the DNA, interfering with cell division and gene transcription processes and DNA repair machinery.

Under licensing agreement with PharmaMar SA, Centocor Ortho Biotech Products, LP has global marketing rights for trabectedin, except in Europe where the product 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®.

Ovarian Cancer

Epithelial ovarian cancer accounts for 4% of cancers in women and is the fifth leading cause of death by cancer in the female population of developed countries (according to American Cancer Society [ACS], Cancer Reference Information, 2005). It is estimated that 205,000 new cases of ovarian cancer were diagnosed in 2006 in the world and that more than 125,000 women will die from this disease (Globocan 2005). According to the World Health Organization, the highest rates occur in the United States, Canada, Scandinavia, and Eastern Europe.

The mortality rate has not changed substantially over the past 50 years. This is the first cause of death by gynecological cancer. The median age of women with ovarian cancer is 60, although it can occur in younger women, especially where there is a family history of the disease. Some 70% of women with ovarian cancer are diagnosed late when the disease is already in advanced stages (III and IV). Only 15% -20% of patients survive five or more years.

Soft Tissue Sarcoma

STS are a diverse group of more than 50 types of tumours of the fatty tissue, muscle, nerve tissue, tendons and blood and lymph vessels. Nearly half of them affect the extremities. Soft tissue sarcomas (STS) have an incidence of around 3/100,000 new cases per year, which represents 2% of the overall mortality from cancer. The highest incidence is situated in patients around 50 years of age. The five-year survival of patients with STS is around 90% when detected early (stage I), that is, when the tumour is small and with no metastases. However, the five-year survival rate in patients with



metastatic disease is 10-20%. The estimated life expectancy in metastatic patients is 8-12 months after receiving the first line of cytotoxic therapy.

About PharmaMar

PharmaMar is the world leader biopharmaceutical company of the Zeltia Group, committed to advancing the treatment of cancer through the discovery and development of new marine-derived medicines. PharmaMar's first product, Yondelis®, is currently being commercialised for the treatment of advanced or metastatic soft tissue sarcoma since September 2007. In 2008 a registration dossier was submitted to the European Medicines Agency (EMA) and Food and Drug Administration (FDA, USA) for Yondelis® when administered in combination with DOXIL®/Caelyx™ (pegylated liposomal doxorubicin) for the treatment of women with relapsed ovarian cancer. It is also in phase II clinical trials for prostate, breast, and lung cancers. Three other PharmaMar compounds, Aplidin®, Irvalec®, Zalypsis® and, PM01183 are in various stages of clinical development.

Important note

PharmaMar, based in Madrid, Spain, is a subsidiary of Grupo Zeltia (Spanish Stock Exchange, ZEL) that has been quoted on the Spanish Stock Exchange since 1963. Grupo Zeltia is currently part of the Ibex Nuevo Mercado (New Market). This document is a press release, not a brochure. This document does not constitute nor is part of any offer or invitation to sell or issue any application of purchase, offer, or shares subscription of the Company. Likewise, neither this document nor its distribution is part or can be of base for any contract or investment decision and does not constitute any kind of recommendation in relation with the shares of the Company.

For more information:

Media Relations (tel. +34 91 846 60 00)

Fernando Mugarza
Carlos Martínez de la Serna
Carolina Lanzas Otazu

Capital Markets (Ph: +34 91 444 45 00)

José Luis Moreno
Florencia Radizza

This press release is also available at Pharmamar web site: www.pharmamar.com