PharmaMar presents new data on Yondelis® at the 35th annual meeting of the European Society for Medical Oncology (ESMO)

Madrid, 13 October 2010: PharmaMar SA (Grupo Zeltia, ZEL.MC) presents 6 abstracts on Yondelis® at the annual meeting of the European Society for Medical Oncology (ESMO), held in Milan (Italia), October 8-12.

Highlights of these presentations are summarized below.

Three analisis confirm Yondelis® (trabectedin) well characterized and manageable safety profile:

Tolerability of trabectedin plus pegylated liposomal doxorubicin (PLD) in platinum sensitive and platinum resistant patients with relapsed ovarian cancer (ROC) has been analyzed. Final safety data were evaluated in 663 treated patients who received one or more doses of trabectedin or PLD. This analysis showed that the combination of trabectedin plus pegylated liposomal doxorubicin was well tolerated and manageable. Disabling and/or unpleasant side effects such as peripheral neuropathy and alopecia were not associated to the combination therapy.

A comprehensive review of cardiac safety profile of Yondelis® in clinical trials as monotherapy or in combination with anthracyclines, and during post-marketing experience, indicates a low cardiac risk for trabectedin with a low overall incidence of cardiac events. Most of these events were tachycardia and palpitations, without associated LVEF changes or clinical sequelae. Other cardiac events were infrequent and relevant predisposing factors were identified in patient's baseline characteristics. This extensive data review confirms the low cardiac risk for trabectedin.

A pooled analysis of 19 phase II clinical trials with Yondelis® including 1,132 patients with solid tumours concluded that trabectedin commonly induces transient, self-limiting transaminase elevations, easily manageable and with

low discontinuation rates, reflecting an adaptive host response. Trabectedin has an acceptable overall benefit-risk ratio in the approved indications.

A retrospective analysis of trabectedin activity in 31 pre-treated advanced Ewing Sarcoma patients has shown clinical activity in this population, with a tumour control rate of 26%. The observed toxicity profile was acceptable, and antitumour activity support further evaluation of trabectedin in Ewing Sarcoma, being of interest the identification of the subgroup of patients which most benefits from the drug.

Data from preclinical evaluation of Trabectedin in patient derived tumor xenografts *in vitro* and *in vivo* have also been presented. A signature of 19 gene transcripts was identified to predict sensitivity towards trabectedin which significantly discriminated responsive from non-responsive tumors. Introducing the concept of predictive gene signature in clinical trials will identify subgroups of patients with higher response rates compared to unselected patients. Data was obtained through preclinical evaluation of trabectedin in patient derived tumor xenografts in vitro.

A study with tumour samples from myxoid liposarcoma patients analyzes neoadjuvant trabectedin treatment correlation to the expression of XPG, ERCC1 and BRCA1 genes, previously described as biomarkers of response to trabectedin in soft tissue sarcoma. With the caveat of the low number of patients studied, the response to trabectedin seems to be better in those patients with higher expression of XPG.

The European Commission approved Yondelis® in combination with PLD for platinum-sensitive ovarian cancer in September 2009. In 2007 the European Commission had approved Yondelis® for soft tissue sarcoma. Numerous clinical trials of Yondelis® are under way in sarcoma, including a trial as first-line treatment in patients with chromosome translocation-associated tumors and in children with Ewing sarcoma, rhabdomyosarcoma and other STS subtypes.

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 31 countries outside the EEA, and in 10 of those countries for platinum-sensitive ROC besides Brazil and Canada. Yondelis® is approved for STS and platinum-sensitive ROC in all 30 countries of the EEA; in Switzerland it is approved for STS. At the moment it is also approved for STS in 33 countries out of EEA and in 10 of these countries is also approved for platinum-sensitive ROC, besides Brasil and Canada. Phase II clinical trials with Yondelis® are also under way on solid tumors. 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.

About Zeltia

Zeltia S.A. is a world-leading biopharmaceutical company specialised in the development of marine-based drugs for use in oncology and central nervous system illnesses. Grupo Zeltia consists mainly of the following companies: **PharmaMar**, the world-leading biotechnology company in advancing cancer care through the discovery and development of innovative marine-derived medicines; **Noscira**, a biotech firm focused on discovering and developing new drugs against Alzheimer's disease and other neurodegenerative central nervous system diseases; Genómica, Spain's leading molecular diagnostics company; **Sylentis**, dedicated to researching therapeutic applications of gene silencing (RNAi); and a chemical division comprising **Zelnova** and **Xylazel**, two highly profitable companies that are leaders in their respective market segments.

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.

For more information (Tel. +34 91 444 4500)

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