Chicago (USA), 7 June 2012: PharmaMar, a biopharmaceutical company owned by Grupo Zeltia (ZEL.MC), presented new trials with marine-based anti-tumour drug Yondelis® (trabectedin) at the 2012 Annual Meeting of the American Society of Clinical Oncology (ASCO), held in Chicago on 1-5 June.

The ASCO Annual Meeting, one of the world's main events in cancer research, brings together over 30,000 oncology professionals to discuss the latest developments in this therapeutic area.

The first publication, “Association between body weight and efficacy outcomes during trabectedin therapy for recurrent advanced soft tissue sarcoma (STS)”, is based on findings in a number of preclinical trials that Yondelis® acts on the tumour's specific micro-environment by reducing the level of cytokine IL-6, which is involved in the appearance of cachexia (wasting syndrome) in patients. This retrospective exploratory analysis assesses the association between patient weight gain during treatment and efficacy results in 319 patients with recurrent STS. The analysis suggests that weight gain is associated with favourable efficacy results when patients are treated with Yondelis®. Further research is required to assess the weight change prognosis as a supplementary variable for assessing long-term outcomes and the drug's impact on the tumour's micro-environment.

The second abstract, “Growth modulation index (GMI) as a metric of clinical benefit assessment among advanced soft tissue sarcoma (ASTS) patients receiving trabectedin as salvage therapy”, addresses Dr. Von Hoff’s proposal that a GMI over 1.33 in clinical trials in cancer is a sign of drug activity. The broad conclusion is that around 30% of patients treated with Yondelis® attained a GMI over 1.33, independently of histological subtype, degree and number of lines of chemotherapy administered previously.
The third publication, “Rechallenge with trabectedin in patients with locally advanced or metastatic soft tissue sarcoma following drug holiday: the experience of the French Sarcoma Group (FSG)”, assesses the clinical benefit of Yondelis® to treat soft tissue sarcoma following first-line treatment with ifosfamides and/or anthracyclines when treatment resumes following withdrawal due to decision by the doctor or the patient. These studies were performed with data collected at 6 centres of the FSG that stated they had followed this approach with their patients. The conclusion is that, because of the lack of cumulative toxicity in the case of Yondelis®, re-exposure to the drug in patients who are responsive to Yondelis® should be considered as an option in treating STS.

Another study, entitled “Randomized multicenter phase III trial of trabectedin (T) versus doxorubicin-based chemotherapy as first-line therapy in patients with translocation-related sarcoma (TRS)”, was presented in the "Trials in progress" session. One-third of sarcoma subtypes present a specific chromosome translocation that leads to an abnormal transcription factor. This factor ultimately produces a malignant phenotype. There is in vitro evidence that Yondelis® is capable of interfering with the aberrant transcription factor. It has also been found that patients with this type of translocation, such as myxoid cell liposarcoma (FUS-CHOP translocation), benefited from long-term tumour control in response to Yondelis®. This Phase III multicenter randomised trial will evaluate the most appropriate first-line treatment: trabectedin or doxorubicin, by comparing progression free survival rates with each drug.

Further abstracts (independently) presented were:

“Preclinical study of trabectedin (TR) and Poly (ADP-ribose) polymerase 1 (PARP-1) inhibitor combination in soft tissue sarcoma (STS)”, combined Yondelis® in vitro with Olaparib, a PARP-1 inhibitor whose action mechanism involves disabling mechanisms for repairing DNA base-pair excision, leading to an accumulation of faults in the double helix; it arises due to the considerable interest in enhancing the activity of Yondelis® by combining it with other anti-tumour drugs. The results validate the biological justification for combining Yondelis® with PARP-1 inhibitors in STS and suggest that this drug combination should be evaluated in a clinical setting.

Another abstract presented: "Trabectedin in pretreated pediatric patients with relapsed or progressive advanced sarcomas: Toxicity and efficacy", aims to describe the toxicity and efficacy of Yondelis® in a group of pediatric patients with recurring sarcoma, as there is little information about these properties of the drug
in this specific population. The conclusion is that Yondelis® is generally well tolerated.

Further 2 abstracts presented: “Analysis of Hohn (HC) and porth-a-cath (PAC) central venous catheters (CVC) adverse events (AEs) and related costs in advanced soft tissue sarcomas (STS) treated with trabectedin (TR) 24-hour (24-h) infusion therapy” and “Whole-body PET/MR in soft tissue sarcoma (STS) patients.”

About PharmaMar

PharmaMar is a biotechnology subsidiary of Grupo Zeltia; it is a world leader in discovering, developing and selling marine-based drugs to treat cancer. Yondelis® is Spain’s first antitumour drug. It is currently approved for soft tissue sarcoma (STS) in 39 countries outside the EEA, and for platinum-sensitive relapsed ovarian cancer (ROC) in 25 of those countries plus Brazil. Yondelis® is approved for STS and platinum-sensitive ROC in all 30 countries of the EEA. Yondelis® is also undergoing Phase II trials on breast and paediatric cancers. PharmaMar has five other compounds in clinical development: Aplidin®, Irvalec®, Zalypsis®, PM01183 and PM060184. 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 diseases of the central nervous system; Genomica, 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 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 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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