

ZELTIA NEWS

PharmaMar Presented Data from Five Ongoing Trials at ESMO 2012

- PharmaMar presented preliminary Phase II results of PM01183 in a platinum-resistant/refractory ovarian cancer study, showing that 73% of patients achieved general control of the disease and 27% of Overall Response Rate (ORR).
- PharmaMar also reported the activity shown in the preliminary results Phase Ib on PM01183 in several tumours in combo with Gemcitabine, highlighting the activity in NSCLC.
- Additional presentations included Yondelis data in ovarian cancer and first line STS treatments.

Madrid, 1st October 2012. PharmaMar, a biotechnology subsidiary of Grupo Zeltia (MC:ZEL), presents five trials with its compounds of marine origin at the 37th Congress of the European Society for Medical Oncology (ESMO 2012).

The most notable of the communications presented at ESMO was titled, "Lurbinectedin (PM01183) activity in platinum-resistant/refractory ovarian cancer patients. Preliminary results of an ongoing two-stage Phase II study". The ESMO scientific committee selected this study for a special oral presentation.

The trial recruited 22 patients, and evaluated the compound's efficacy for treating platinum-resistant/refractory ovarian cancer. Initial analyses of the data showed that general control of the disease was achieved in 73% of the cases, while demonstrating manageable safety and tolerability. The second phase of the trial which commenced in April is ongoing and will accrue an additional 60 patients randomized to receive PM01183 or Topotecan.

Another report on PM01183, "Lurbinectedin (PM01183) in combination with gemcitabine (GEM). Preliminary results of an ongoing Phase Ib study", evaluated the combination of PM01183 with gemcitabine, which is showing promising anti-tumour activity with acceptable safety profile below the maximum tolerated dose. Notable activity, including complete and partial responses, was observed with this combination in non-small cell lung cancer, among others tumour types.

Two papers on Yondelis were presented at ESMO 2012. The first was “Conservative sensitivity analysis of progression-free survival (PFS) of trabectedin plus pegylated liposomal doxorubicin (PLD) vs. PLD alone in patients with relapsed ovarian cancer: OVA-301 study”. Sensitivity analyses are essential for understanding the importance of the outcome of the primary analysis of clinical trials.

The OVA-301 Phase III trial compared the efficacy of trabectedin with PLD against PLD alone, the primary endpoint being progression-free survival (PFS), assessed by radiological review. The analysis presented this year at ESMO evaluated patients from both arms of the trial using two different analyses; the positive effect of the combined treatment was found to persist after the sensitivity analysis, which strengthens the methodology, the reliability and interpretability of the conclusions drawn from the Phase III trial.

The “GEIS-20 study”: this “Randomized, open, multicenter, prospective, phase II clinical trial of doxorubicin (Doxo) vs. Trabectedin plus doxorubicin in the first-line treatment of patients (pts) with advanced non-operable and/or metastatic soft tissue sarcomas (STS): GEIS-20 study” is headed by the Spanish Sarcoma Research Group (GEIS). The trial, being conducted at 27 centres, will assess radiological PFS in the two arms of the trial. In the experimental arm patients are being treated with trabectedin in combination with doxorubicin, while the control arm involves patients treated with doxorubicin as monotherapy. Efficacy and safety will be evaluated in both arms, along with pharmacogenomic aspects.

The fifth communication presented at ESMO 2012 deals with Zalypsis: “Phase II clinical and pharmacokinetic (PK) trial of Zalypsis (Z) in patients with urothelial carcinoma (UC) progressing after a first-line platinum-based regimen”. This compound, of marine origin, was studied in urothelial tumours that have progressed after first-line platinum-based treatment.

The European Society for Medical Oncology (ESMO) is the leading European professional organization, committed to advancing the specialty of medical oncology and promoting a multidisciplinary approach to cancer treatment and care. ESMO’s mission is to advance cancer care and cure through fostering and disseminating good science that leads to better medicine and determines best practice, by evaluating the most relevant innovations arising each year in the field of oncology.

About PharmaMar

PharmaMar is a biopharmaceutical subsidiary of Grupo Zeltia; it is a world leader in discovering, developing and marketing 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 four other compounds in clinical development: Aplidin®, 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.

For more information +34 91 444 4500

This note is also available on the PharmaMar web site: www.pharmamar.com and at Zeltia's website: www.zeltia.com