

## ZELTIA NEWS:

### POSITIVE SURVIVAL DATA FROM A RANDOMIZED PHASE II TRIAL WITH PM1183 IN PLATINUM RESISTANT OVARIAN CANCER WILL BE PRESENTED AT ASCO

New clinical trial data from both Yondelis<sup>®</sup> and PM1183 have been selected by The American Society of Clinical Oncology (ASCO) for oral presentations

**Madrid, May 15 2014:** New trials with marine-based anti-tumour drug Yondelis<sup>®</sup> (trabectedin) and PM1183 will be presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO), to be held in Chicago (US) from 30 May to 3 June.

**Of the 13 trials reporting data, two have been accepted for oral presentations: a Phase II trial with PM1183 in patients with relapsed/refractory ovarian cancer, and a pivotal Phase II trial with Yondelis<sup>®</sup> in patients with sarcoma, presented by PharmaMar's partner Taiho Pharmaceutical, for patients with translocation-related sarcomas (TRS).**

#### **Oral Presentations**

**PM1183:** "Lurbinectedin (PM01183), PFS and OS results in a Phase II study in platinum-resistant/refractory ovarian cancer (PRROC) patients" will be presented at the conference as part of an oral presentation. It is a Phase II multicentre trial with PM1183 as monotherapy to treat patients with PRROC, compared with standard treatment with Topotecan. The primary endpoint, which was attained, was to determine the overall response rate, which was found to be higher—in statistically significant terms—than that obtained with Topotecan. The drug was also found to have an acceptable and manageable safety profile.

PharmaMar plans to initiate a Phase III trial for this indication in 2014.

**Yondelis®:** “A randomized phase II study comparing trabectedin (T) and best supportive care (BSC) in patients (pts) with translocation-related sarcomas (TRS)” will be presented in an oral presentation by Taiho Pharmaceutical Co., LTD., PharmaMar's partner for Yondelis® development and sales in Japan. Seventy-six patients with a range of TRS sub-types were treated with Yondelis®, which was compared with the BSC. The primary endpoint was to evaluate the efficacy of both treatments by comparing progression free survival (PFS). Both PFS and OS (overall survival) improved notably with Yondelis® in patients that had been pretreated with other options available for TRS.

**Other Poster Presentations:**

- “Results of the prospective T-DIS randomized phase II trial comparing interruption vs. continuation of trabectedin after 6 cycles of treatment in patients (pts) with advanced soft tissue sarcoma (ASTS)”
- “Prognostic/predictive biomarkers in advanced SOFT tissue sarcomas (STS): Translational research associated to randomized PHASE II trial comparing trabectedin-doxorubicin VS doxorubicin.
- “Trabectedin plus pegylated liposomal doxorubicin (PLD) prior to subsequent platinum chemotherapy in patients with platinum-resistant (PR) recurrent ovarian cancer (ROC): results from OVA-301 follow up.
- “Phase II prospective study on Trabectedin (T) in BRCA mutated and BRCAness phenotype advanced ovarian cancer (AOC) patients (pts): the MITO 15 trial”
- “Radiologic Adipocytic Maturation in Dedifferentiated Liposarcoma (ddLPS) Patients (pts) Treated with Trabectedin (Tdin)”
- “Predictive biomarkers of Trabectedin (TR) and Olaparib (OL) synergism in preclinical models of bone and soft tissue sarcoma (BSTS)”

- "Trabectedin-related Liver toxicity in soft tissue sarcoma patients: always a good reason to discontinue the treatment?"
- "Trabectedin and indole-3-carbinol combination in heavily pre-treated metastatic breast cancer.
- "A Phase 3 Study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus PLD for Treatment of Advanced Relapsed Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer": PharmaMar's US partner, Janssen, will present this pivotal trial in patients with platinum-sensitive ovarian cancer who relapse after receiving first-line platinum-based treatment. This trial has not yet concluded.
- "Effects of cytochrome P450 inducer and inhibitor coadministration on the pharmacokinetics of trabectedin in patients with advanced or metastatic solid tumor" (ET743-OVC-1002 and ET743-OVC-1003).
- "Low skeletal muscle density is predictive for febrile neutropenia in patients treated by doxorubicin/trabectedin/pegfilgrastim combination as a first-line treatment of advanced or metastatic leiomyosarcoma (LMS) (LMS02 study)"

#### **About ASCO**

The ASCO Annual Meeting, one of the world's foremost events in cancer research, brings together over 25,000 oncology professionals to discuss the latest developments in this therapeutic area. For more information, visit [www.asco.org](http://www.asco.org)

#### **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 the first marine-based antitumour drug. 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. 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; Genómica, Spain's leading company in molecular diagnostics based on DNA analysis; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi).



**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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This note is also available on the PharmaMar web site: [www.pharmamar.com](http://www.pharmamar.com) and at Zeltia's website: [www.zeltia.com](http://www.zeltia.com)