



## **PharmaMar shows new clinical data with Yondelis® in different sarcoma subtypes at CTOS 2016**

**Madrid, November 10<sup>th</sup>, 2016.**- Within the framework of the 21<sup>st</sup> Annual Meeting of the Connective Tissue Oncology Society (CTOS), that is taking place from the 9<sup>th</sup> of November until the 12<sup>th</sup> of November at Lisbon (Portugal), PharmaMar (MSE:PHM) is going to present the clinical data for the treatment of sarcomas obtained from various studies carried out with Yondelis® (trabectedin).

In this sense, it will be published, among others, the data from the Phase II randomized, non-comparative, TAUL study, that assess the activity of Yondelis® in patients with metastatic or locally relapsed uterine leiomyosarcoma; the TR1US study that evaluates trabectedin as first line treatment, in advanced soft tissue sarcoma (STS) patients unfit to receive standard anthracycline-based chemotherapy; and the YonLife trial that studies the quality of life reported by the patients with STS who receive Yondelis®. All of these studies have received financial support from PharmaMar.

*"PharmaMar continues to support the clinical development of trabectedin for the treatment of soft tissue sarcomas and to generate data on the efficacy and safety of Yondelis® in almost all subtypes, which are mainly rare and difficult to treat", explains Dr Nadia Badri, VP of Medical Affairs of the Oncology Business Unit at PharmaMar. "The role of trabectedin to treat patients with STS is still increasing as well as preclinical research to better understand the unique mechanism of action of the compound. It is important to note that there will be more than 20 presentations of studies with our drug in the meeting", she adds.*

As well as the clinical evidence, PharmaMar will present an abstract on pharmacoeconomics that evaluates, in Spain, the benefit-cost ratio of trabectedin versus pazopanib for the treatment of patients with advanced, metastatic soft tissue sarcoma, after receiving one or two prior lines of chemotherapy.

To finalize, in the symposium entitled *'Rising options in advanced STS: present and future treatment sequences'*, the Company will gather a group of oncologists of international prestige to discuss on the necessities of defining the most convenient treatment sequences with the current drugs and for those to come, for patients with advanced STS, with the aim of improving their prognosis and quality of life.

## Main studies to be present at CTOS 2016

### Yondelis® (trabectedin)

- **A phase II randomized – non comparative – study on the activity of trabectedin or gemcitabine + docetaxel in metastatic or locally relapsed uterine leiomyosarcoma pretreated with conventional chemotherapy (TAUL Study) (abstract #2570383 / Paper 025)**

Oral presentation. Soft Tissue Sarcomas - Uterine Sarcomas. Friday, 11th of November 4:20 pm a 5:05 pm. Floriana room.

Lead author: F. Grosso et al. SC Oncologia, ASO SS Antonio e Biagio e C Arrigo, Alessandria, Italy.

- **Trabectedin as first line in advanced soft tissue sarcoma (STS) patients unfit to receive standard chemotherapy: safety and efficacy from TR1US study (abstract #2567652 / poster 107)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: Federica Grosso et al. Azienda Ospedaliera Nazionales SS Antonio e Biagio e C Arrigo, Alessandria, Italy.

- **Incremental benefit-cost ratio of trabectedin vs pazopanib for the treatment of advanced, metastatic, soft tissue sarcoma in Spain. (Abstratct #2554229 / poster 103)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead authors: José Miguel Fernandez<sup>1</sup>; Roberto Diaz Beveridge<sup>2</sup>. <sup>1</sup>Health Economics, PharmaMar, Colmenar Viejo, Madrid, Spain; <sup>2</sup>Hospital Universitario La Fe, Valencia, Spain.

- **Trabectedin in well differentiated versus dedifferentiated liposarcoma (abstract # 2569845 / poster 101)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11th of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: Roberta Sanfilippo et al. Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy.

- **Patient-directed intervention to improve quality of life for patients with soft tissue sarcoma undergoing palliative treatment: a multicenter, cluster-randomized, controlled trial of the German Interdisciplinary Sarcoma Group (YonLife trial) (abstract #2540447/ Poster 193)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 6:15 pm – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 a.m. – 4:00 p.m. Foyer room.

Lead author: Leopold Hentschel et al. University Cancer Center, University Hospital Carl Gustav Carus, Technische Universität Dresden, Dresden, Germany.

- **Impact of supervised physical exercise on fatigue and quality of life in adult sarcoma patients (abstract #2541168/ Poster 192)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: Leopold Hentschel et al. University Cancer Center, University Hospital Carl Gustav Carus, Dresden, Germany.

- **Trabectedin with prophylactic N-acetylcysteine co-treatment in patients with recurrent soft tissue sarcoma and reduced liver and renal function (abstract # 2565733 / poster 099)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: Salvatore Grisanti et al. Medical Oncology, University of Brescia, Brescia, Italy.

- **BMI as a risk factor for toxicities in advanced STS patients treated with trabectedin (abstract #2565859 / Poster 212)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: B. Vincenzi et al. Oncology, Campus Bio-Medico, Rome, Lazio, Italy.

- **M1 macrophages as predictor of poor response to trabectedin treatment in myxoid liposarcoma (Abstract #2561280 / Poster 130)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: Marco Fioramonti et al. Translational Oncology Laboratory, University Campus Bio-Medico of Rome, Rome, Italy.

- **Relationship between monocyte reduction and radiological tissue modification in STS patients treated with trabectedin (abstract #2566640 / Poster 105)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: Bruno Vincenzi et al. Medical Oncology, University Campus Bio Medico of Rome, Roma, Italy.

### **PM1183 (lurbinectedin)**

- **A phase II multi-strata study of PM1183 as a single agent or in combination with conventional chemotherapy in metastatic and/or unresectable soft tissue sarcoma (abstract #2558960 / Poster 097)**

Poster session 2 – Soft Tissue Sarcomas. Friday, 11<sup>th</sup> of November 10:40 am – 7:00 pm and Saturday 12<sup>th</sup> of November 7:00 am – 4:00 pm. Foyer room.

Lead author: Gregory M. Cote, et al. Hematology/Oncology, Massachusetts General Hospital, Boston, MA, USA.

### **About YONDELIS® (trabectedin)**

YONDELIS® (trabectedin) is a multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The drug exerts its activity by targeting the transcriptional machinery and impairing DNA repair. It is approved in close 80 countries in North America, Europe, South America and Asia for the treatment of advanced soft tissue sarcomas as a single-agent and for relapsed ovarian cancer in combination with DOXIL®/CAELYX® (doxorubicin HCl liposome injection) in the European Union. Under a licensing agreement with PharmaMar, Janssen Products, L.P. has the rights to develop and sell YONDELIS® globally except in Europe, where PharmaMar holds the rights, and in Japan, where PharmaMar has granted a license to Taiho Pharmaceuticals.

### **About PM1183 (lurbinectedin)**

PM1183 is a compound under clinical investigation. It is an inhibitor of RNA polymerase II. This enzyme is essential for the transcription process that is over-activated in tumors with transcription addiction. The antitumor efficacy of lurbinectedin is being investigated in various types of solid tumors, including a Phase III study for platinum-resistant ovarian cancer, a Phase II study for BRCA 1 and BRCA 2-associated metastatic breast cancer and a Phase III study for small cell lung cancer.



### **About PharmaMar**

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has three other clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom, Belgium and the United States. PharmaMar fully owns other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and two other chemical enterprises, Zelnova Zeltia and Xylazel. To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://www.pharmamar.com).

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### **Media Contact:**

Paula Fdez. Alarcón – Media Relations Manager

[pfalarcon@pharmamar.com](mailto:pfalarcon@pharmamar.com)

Phone: +34 918466000 / +34 638796215



### **Investor Relations:**

Phone: +34 914444500

Or please visit our website at [www.pharmamar.com](http://www.pharmamar.com)