



## **PharmaMar presents clinical studies for YONDELIS<sup>®</sup> (trabectedin) during the international congress CTOS**

*Madrid, November 6, 2015:* PharmaMar (MSE:PHM) has announced that the Company will showcase several clinical studies with YONDELIS<sup>®</sup> (trabectedin) in soft tissue sarcoma (STS) during the 20<sup>th</sup> anniversary CTOS (Connective Tissue Oncology Society) meeting that will be held in Salt Lake City, Utah, from the 4-7 November, 2015. This forum will gather oncologist experts and investigators to share new results and experiences to move forward basic and applied research on connective tissue-related cancers.

In addition to presenting several studies for YONDELIS<sup>®</sup> (trabectedin) in STS, PharmaMar has organized a stand-alone meeting in which Javier Martín Broto, MD, President of the Spanish Sarcoma Research Group and Peter Reichardt, MD, Professor and Head of the Hematology and Oncology Department, Sarcoma Center HELIOS Klinikum Bad Saarow, Germany, have discussed the clinical development story of YONDELIS<sup>®</sup> in STS.

During his presentation, Dr. Martín Broto has showcased the pivotal studies that led to the approval in the European Union and the U.S., the clinical trial STS-201<sup>i</sup> and the SAR-3007<sup>ii</sup>, respectively. To date, approximately 50.000 pacientes have been treated with YONDELIS<sup>®</sup> worldwide. The expert has pointed out how everything started with the authorization of commercialization of YONDELIS<sup>®</sup> for soft tissue sarcoma by the European Commission, resulting in the first anticancer drug of marine origin.

### **Trabectedin, an effective therapy in second line treatment**

Trabectedin is an anticancer drug that has shown to decrease tumor density and to induce tumor shrinkage, two clinical measurements that should be considered in patients treated with this drug when assessing tumor response<sup>iii</sup>. "Understanding how to correctly define tumor progression in patients treated with trabectedin is important for the decision making strategy to prevent interruption of a treatment that may provide clinical benefit after 6 cycles of treatment, in some cases" added Dr. Martín Broto. This is one of the main points that were concluded from the clinical trials carried out by the French sarcoma Group in 2015, which include the large retrospective study called Retrospectyon, and the prospective trial T-DIS. The

oncologist Dr. Martín Broto added that “when patients continued receiving trabectedin until disease progression, instead of stopping the treatment after 6 cycles, the next disease relapse is delayed.”

Since 2003 when the first clinical study started until now, trabectedin has demonstrated that it is the treatment of choice for patients with STS treated in the second-line setting as “this drug provides prolonged survival, has an optimal safety profile, has received approval for all subtypes of STS and it is currently included in the ESMO Clinical Guidelines and very soon will be also in the NCCN Clinical Practice Guidelines”.

#### **Main studies presented at CTOS**

- ***Y-IMAGE study: a non-interventional, prospective phase IV study of trabectedin in patients with advanced soft tissue sarcoma (STS).***  
Main author: Penel et al.
- ***Efficacy and safety of trabectedin as an early treatment for advanced STS: an interim analysis of a non-interventional, prospective Phase IV study.*** Main author: Mazzeo et al.
- ***Trabectedin in elderly patients with recurrent soft tissue sarcoma (STS): an interim analysis of a non-interventional, prospective Phase IV study.*** Main author: Buonadonna et al.
- ***Final results of two phase II studies, a randomized comparative study and a single arm study, of trabectedin in patients (PTS) with translocation-related sarcomas (TRS) - patrocinado por Taiho Pharmaceuticals.*** Main author: Kawai, A et al.
- ***Single-center experience of high-grade chondrosarcoma treated with trabectedin - patrocinado por Janssen Research & Development, LLC.*** Main author: Chawla.
- ***Final Overall Survival (OS) Analysis of the Randomized Phase 3 Study of Trabectedin (T) or Dacarbazine (D) for the Treatment of Patients (pts) with Advanced Leiomyosarcoma (LMS) or Liposarcoma (LPS) - patrocinado por Janssen Research &***



**Development, LLC.** Main author: Shreyaskumar R. Patel, Margaret von Mehren, Damon.

- ***Efficacy and Safety of Trabectedin (T) or Dacarbazine (D) in an Elderly Patient subgroup (+65 years) with Advanced Leiomyosarcoma (LMS) or Liposarcoma (LPS) after Prior Chemotherapy - patrocinado por Janssen Research & Development, LLC.*** Main author: Margaret von Mehren, George D. Demetri, Scott M Sc
- ***Efficacy and Safety of Trabectedin(T) or Dacarbazine (D) for Treatment of Patients (pts) with Advanced Leiomyosarcoma (LMS) or Liposarcoma (LPS) after Prior Chemotherapy - patrocinado por Janssen Research & Development, LLC.*** Main author: George D. Demetri, Shreyaskumar R. Patel, Samuel Th
- ***Trabectedin in patient with an abdominal small round cells desmoplastic tumour: a case report.*** Main author: J. Casanova, P. Tavares, R. Ferreira
- ***Analysis of trabectedin safety in teenage young adults with STS.*** Cambridge University Hospital-Addrnbrookes

#### **About YONDELIS® (trabectedin)**

YONDELIS® (trabectedin) is a novel, 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 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). 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 Soft Tissue Sarcoma**

Soft tissue sarcoma is a type of cancer originating in the soft tissues that connect, support and surround other body structures, such as muscle, fat, blood vessels, nerves, tendons and the lining of joints<sup>iv,v</sup>. In the United States, nearly 12,000 people will be diagnosed and approximately 4,870 are expected to die of soft tissue sarcomas in 2015<sup>vi</sup>.

#### **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 other three clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom 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 and Xylazel. To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://www.pharmamar.com).

#### **Disclaimer**

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.

#### **Media Inquiries:**

Carolina Pola – Communications Director

Paula Fdez. Alarcón – Media Relations

Phone: +34 91 846 6000

Mobile: +34 608 93 36 77

#### **Investor Relations:**

Phone: +34 914444500

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

###

---

<sup>i</sup> <http://jco.ascopubs.org/content/27/25/4188.long>

<sup>ii</sup> <http://jco.ascopubs.org/content/early/2015/09/14/JCO.2015.62.4734.full>

<sup>iii</sup> [http://www.ejcancer.com/article/S0959-8049\(14\)01115-0/abstract](http://www.ejcancer.com/article/S0959-8049(14)01115-0/abstract)

<sup>iv</sup> Mayo Clinic. Disease Conditions: Soft tissue sarcoma.

Available at: <http://www.mayoclinic.org/diseases-conditions/soft-tissue-sarcoma/basics/definition/con-20033386>. Accessed: May 2015.

<sup>v</sup> American Cancer Society. What is a soft tissue sarcoma? Available at:

<http://www.cancer.org/cancer/sarcoma-adultsofttissuecancer/detailedguide/sarcoma-adult-soft-tissue-cancer-soft-tissue-sarcoma>. Accessed May 2015.

<sup>vi</sup> American Cancer Society: Cancer Facts and Figures 2015. Atlanta, Ga: American Cancer Society, 2015 <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf>. Accessed: May 2015.