



*Abstracts: #11061, #11064, #11060, #11018, #8006, #TPS5597*

## **PharmaMar announces new data on Yondelis<sup>®</sup>, Aplidin<sup>®</sup> and PM1183 to be presented at 2016 ASCO Annual Meeting**

- *Results from a Phase I study of Aplidin<sup>®</sup> (plitidepsin) in combination with bortezomib and dexamethasone in patients with multiple myeloma will be presented in an oral session*

**Madrid, May 19<sup>th</sup>, 2016** – PharmaMar (MSE:PHM) announced today that data obtained from various clinical studies carried out with three of its antitumoral compounds of marine origin - Yondelis<sup>®</sup>, Aplidin<sup>®</sup> and PM1183 - will be presented during the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, June 3 – 7.

The studies have been selected either for oral or poster presentations or poster debates. In addition, PharmaMar will present the results of a Phase I study of Aplidin<sup>®</sup> (plitidepsin) in combination with bortezomib and dexamethasone in patients with multiple myeloma. The titles of the abstracts are available on the ASCO website [www.asco.org](http://www.asco.org)

*"The principle objective of PharmaMar is to investigate new compounds of a marine origin with a novel mechanism of action that provides a progress in the treatment of certain types of oncological tumors, and an important contribution in healthcare for the patient",* explains Dr Nadia Badri, VP Medical Affairs at PharmaMar's oncology business unit.

Dr Arturo Soto, Director of Clinical Development at PharmaMar's Oncology Unit, points out that *"the results that we are going to present at ASCO 2016 are an example of how we are progressing in this field, and that we can build on an innovative and promising pipeline of compounds for different types of cancers"*.

### **Pharmamar studies highlighted at ASCO 2016**

#### **Yondelis<sup>®</sup> (trabectedin)**



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.

- **Patient-Reported Outcomes from Randomized, Phase-3 study of Trabectedin (T) vs. Dacarbazine (D) in Advanced Leiomyosarcoma (LMS) or Liposarcoma (LPS) (Abstract #11061) – sponsored by Janssen Products, L.P**

Poster session: Sarcoma. Monday, June 6<sup>th</sup> from 8:00 a.m. to 11:30 a.m

Lead author: George Demetri, MD et al. Dana-Farber Cancer Institute, Boston, MA, USA.

- **Trabectedin (T)-related liver toxicity: Results of a pharmacokinetic study with T in patients with hepatic dysfunction (OVC1004) and experience from a phase 3 clinical trial (SAR3007) (Abstract #11064) – sponsored by Janssen Products, L.P**

Poster session: Sarcoma. Monday, June 6<sup>th</sup> from 8:00 a.m. to 11:30 a.m

Lead author: Emiliano Calvo, MD et al. Centro Integral Oncológico Clara Campal (CIOCC), Madrid Norte Sanchinarro Hospital, Spain

- **Cardiac Safety Analysis of Trabectedin (T) vs. Dacarbazine (D) in Patients (Pts) with Advanced Leiomyosarcoma (LMS) or Liposarcoma (LPS) After Prior Anthracycline Chemotherapy (Abstract #11060) – sponsored by Janssen Products, L.P**

Poster session: Sarcoma. Monday, June 6<sup>th</sup> from 8:00 a.m. to 11:30 a.m

Lead author: Scott M. Schuetze, MD et al. Michigan University, Ann Arbor, USA.

- **A phase 1b trial with the combination of trabectedin and olaparib in relapsed patients (pts) with advanced and unresectable bone and soft tissue sarcomas (BSTS): an Italian Sarcoma Group (ISG) study (TOMAS study) (Abstract #11018)**

Poster session: Sarcoma. Monday, June 6<sup>th</sup> from 8:00 am to 11:30 am

Discussed at the Poster Discussion Session on Monday, June 6<sup>th</sup> from 3:00 pm to 4:15 pm at S406

Lead author: Giovani Grignani, MD, et al. Istituto per la Ricerca e la Cura del Cancro di Candiolo, Italy

### **Aplidin® (plitidepsin)**

Plitidepsin, an antitumor drug of marine origin, is being investigated in hematological tumor indications, including a Phase Ib study in relapsed and refractory multiple myeloma, in triple combination with bortezomib and dexamethasone, along with a phase II study in relapsed and refractory angioimmunoblastic T-cell Lymphoma. Recently, plitidepsin showed positive results in a pivotal study in combination with dexamethasone in patients with multiple myeloma.

- **Phase I study of plitidepsin in combination with bortezomib and dexamethasone in patients with relapsed and/or refractory multiple myeloma. (Abstract #8006)**

Oral abstract session: Hematologic Malignancies – Plasma Cell Dyscrasia. Friday, June 3<sup>rd</sup> from 3:00 pm to 6:00 pm. Presentation time/Duration: 5:00 pm a 5:12 pm. Speaker: María Victoria Mateos, MD University Hospital of Salamanca, Spain

Lead author: María Victoria Mateos, MD et al.

### **PM1183 (lurbinectedin)**

PM1183 is compound under clinical investigation, inhibitor of the RNA polymerase II enzyme. It is essential for the transcription process, which inhibits tumor growth, and resulting in tumor death. The antitumor efficacy of PM1183 is being investigated in various types of solid tumors.

- **CORAIL trial: Randomized Phase III Study of Lurbinectedin (PM01183) versus Pegylated Liposomal Doxorubicin (PLD) or Topotecan (T) in Patients with Platinum-resistant Ovarian Cancer. (Abstract #TPS5597)**

Poster session: Gynecologic Cancer. Monday, June 6<sup>th</sup> from 1:00 pm to 4:30 pm.



Lead author: S. Gaillard et al. MD, Duke Cancer Institute, Durham, USA.

**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 nearly 80 countries in North America, Europe, South America and Asia for the treatment of advanced Soft Tissue Sarcomas, or specific L-sarcoma sub-types, as a single-agent. It is approved in almost 70 countries outside of the USA 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 plitidepsin**

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. It is thought that it specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programmed death). Plitidepsin is currently in clinical development for hematological cancers, including a Phase Ib trial in relapsed or refractory multiple myeloma as a triple combination of plitidepsin, bortezomib and dexamethasone, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma. A Phase III trial in relapsed or refractory multiple myeloma has been completed. Plitidepsin has received orphan drug designation both in the EU and the US.

**About lurbinectedina (PM1183)**

Lurbinectedin (PM1183) is a compound under clinical investigation, and is thought to be an inhibitor of RNA polymerase II enzyme. It is essential for the transcription process, inhibiting tumor growth, and resulting in tumor death. The antitumor efficacy of PM1183 (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 BRCA1/2-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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