

PharmaMar showcases new data for YONDELIS[®] and PM1183 in soft tissue sarcoma and solid tumors at ECCO 2015

- *Final OS and subgroup analysis of the pivotal study SAR-3007*
- *First interim results of the Y-IMAGE prospective study showing real-world data for trabectedin in advanced soft tissue sarcoma (STS)*
- *Clinical data of trabectedin in translocated-related sarcomas, and in advanced leiomyosarcomas and liposarcomas*
- *Early clinical studies of PM1183 in combination with paclitaxel or cisplatin show a synergistic activity*

Madrid, September 14, 2015: PharmaMar announces that it will show new data from clinical pivotal studies as well as real-life data from prospective non-interventional studies to highlight the role of YONDELIS[®] (trabectedin) in STS, during the 18th ECCO – 40th ESMO European Cancer Congress, Vienna, 25 – 29 September 2015 (ECC 2015). This congress is the leading European forum for oncologists to keep abreast of practice-changing scientific studies and learning the most innovative approaches for cancer patient management. The abstracts have been selected for oral presentation and general poster presentation, and will feature data from the first-in-class drug YONDELIS[®] (trabectedin), and the transcription inhibitor PM1183 (lurbinectedin).

“Being part of this important oncology platform, as it is the European Cancer Congress, allows us to add to the clinical cancer community. We are glad we can present both clinical and real-life data for our compounds that will help clinicians and researchers, as they continue to seek new therapeutic avenues and improved treatments”, says Nadia Badri, MD, VP Medical Affairs, PharmaMar. “PharmaMar is not only witnessing a major change in treatment approaches, but also contributing to this ongoing transformation.”

Meeting abstracts are available at <https://www.europeancancercongress.org/en>

Studies highlighted at ECC 2015

YONDELIS® (trabectedin)

Final results for trabectedin in STS, as well as real-world data from a large prospective phase IV study in this same tumor type will be showcased in 4 studies in oral and poster presentations. In addition, the role of trabectedin in the tumor microenvironment and its effect on tumor-associated macrophages will be highlighted during a special session.

- ***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). (Abstract #3403) - sponsored by Janssen Products***

Oral presentation: Sarcoma - Soft Tissue. Saturday, Sep 26 from 11:25 – 11:35 at LEHAR 3

Lead Author: Shreyaskumar Patel, MD, Department of Sarcoma Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA.

- ***Trabectedin and M2 macrophages.***

Special Session oral presentation: Targeted Therapies of Sarcomas. Saturday, Sep 26 from 15:15 – 11:25 at LEHAR 3

Speaker: Maurizio D'Incalci, MD PhD, Department of Oncology, IRCCS Institute for Pharmacological Research 'Mario Negri', Florence, Italy.

- ***A non-interventional, multicenter, prospective phase IV study of trabectedin in patients with advanced soft tissue sarcoma (STS): the first interim analysis of Y-IMAGE study. (Abstract #3435)***

Poster Session: Sarcoma - Soft Tissue and Bone. Saturday, Sep 26 from 16:15 - 18:45 at Hall C Poster Board P300

Lead Author: Nicolas Penel, MD PhD, Department of Medical Oncology, Centre Oscar Lambret, France.

- ***Final results of a randomized phase II study comparing trabectedin and best supportive care (BSC) in patients with translocation-related sarcomas (TRS). (Abstract #3445A) - sponsored by Taiho Pharmaceutical***

Poster Session: Sarcoma - Soft Tissue and Bone. Saturday, Sep 26 from 16:15 - 18:45 at Hall C Poster Board P310A

Lead Author: Toshiyuki Kunisada, MD, Okayama University Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences, Okayama, Japan

- ***Efficacy and safety of trabectedin (T) or dacarbazine (D) for treatment of patients (pts) with advanced leiomyosarcoma (LMS) or liposarcoma (LPS) after prior chemotherapy. (Abstract #3436) - sponsored by Janssen Products***

Poster Session: Sarcoma - Soft Tissue and Bone. Saturday, Sep 26 from 16:15 - 18:45 at Hall C Poster Board P301

Lead Author: George Demetri, MD, Dana-Farber Cancer Institute, Boston, MA, USA.

- ***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 (Abstract #1321) - sponsored by Janssen Products***

Poster Session: Cancer in the Elderly. Sunday, Sep 27 from 16:15 - 18:45 at Hall C Poster Board P108

Lead Author: Margaret Von Mehren, MD, Sarcoma Oncology Physician Director, Fox Chase Cancer Center and Temple University, Philadelphia, PA, USA.

- **Drugs acting on ovarian cancer cells and tumor microenvironment**

Scientific symposium: Biology-based Selected Drugs in Ovarian Cancer Treatment. Monday, Sep 28 from 17:40 – 18:00 at Hall A2

Speaker: Maurizio D'Incalci, MD PhD, Department of Oncology, IRCCS Institute for Pharmacological Research 'Mario Negri', Florence, Italy.

PM1183 (lurbinectedin)

At ECC 2015, there will be two PharmaMar-sponsored studies presented in poster sessions for the role of PM1183 in advanced solid tumors.

- ***Phase I study of lurbinectedin (PM01183) in combination with cisplatin (C) with or without aprepitant (Ap) in patients (pts) with advanced solid tumors. (Abstract #316)***

Poster Session: Early Drug Development. Sunday, Sep 27 from 16:45 to 18:45 at Hall C Poster Board P127

Lead Author: Martin Forster, MD University College Hospital, London, UK.

- ***Lurbinectedin (PM01183) in combination with paclitaxel (P) in patients (pts) with advanced solid. (Abstract #335)***

Poster Session: Early Drug Development. Sunday, Sep 27 from 16:45 to 18:45 at Hall C Poster Board P146

Lead Author: Elena Garralda, MD Spanish National Cancer Research Center (CNIO), Madrid, Spain.

PM60184

- ***Phase I, Open-label, Dose-escalating Clinical and Pharmacokinetic Study of the Novel Antimicrotubulin Agent PM060184 administered over 10 Minutes on Days 1-3 and 15-17 every 28 days to Patients with Advanced Malignant Solid Tumors. (Abstract***

Poster Session: Early Drug Development (TUBULIN-INTERACTING AGENTS). Sunday, Sep 27 from 16:45 - 18:45 at Hall C Poster Board P172

Lead Author: Manuel Hidalgo, MD, PhD, Spanish National Cancer Research Center (CNIO), Madrid, Spain.

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 78 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 PM1183 (lurbinectedin)

PM1183 is an investigational drug from the class of inhibitors of the enzyme RNA polymerase II, which is crucially involved in transcription. By targeting transcription, the drug inhibits the expression of factors important for tumor progression, and impairs the DNA repair system called NER, thereby enhancing tumor cell killing. PM1183 (lurbinectedin) is currently being investigated in different tumor types, including a Phase 3 study for platinum-resistant ovarian cancer, a Phase 2 study for BRCA1/2-associated metastatic breast cancer and a Phase 1b study for small cell lung cancer.

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^{1,2}. Only 16% of patients with disease that has already spread will achieve a 5-year survival². Leiomyosarcoma is an aggressive type of soft tissue sarcoma that occurs in smooth muscles, such as those in the uterus,

gastrointestinal tract or lining of blood vesselsⁱ. Liposarcoma originates in fat cells and most commonly occurs in the thigh and abdominal cavity, though it can occur in fat cells in any part of the body^{ii,iii}.

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in advancing cancer care through the discovery and development of innovative marine-derived anticancer drugs. The company has a rich pipeline of drug candidates and a robust R&D oncology program. YONDELIS® is the first anticancer drug of marine origin and is commercially available in 78 countries for the treatment of advanced soft tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL®/CAELYX®. PharmaMar develops and commercializes YONDELIS® in Europe and has 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 and the United States. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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ⁱ The Liddy Shriver Sarcoma Initiative. An Introduction to Leiomyosarcoma of the Bone and Soft Tissue. Available at: <http://sarcomahelp.org/leiomyosarcoma.html>. Accessed: May 2015.

ⁱⁱ The Liddy Shriver Sarcoma Initiative. What is Liposarcoma? Available at: <http://sarcomahelp.org/liposarcoma.html>. Accessed: May 2015.

ⁱⁱⁱ University of Rochester Medical Center. Liposarcoma. Available at: <http://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=134&ContentID=221>. Accessed: May 2015.