

**PharmaMar announces that Janssen´s study shows that
trabectedin improves disease control in patients with
advanced soft tissue sarcoma**

*Oral presentation (abstract 10503) featured at the annual meeting of the
American Society of Clinical Oncology*

Chicago and Madrid, June 2, 2015: PharmaMar communicates that Janssen Research & Development, LLC (Janssen) announced data from the Phase 3 multicenter study SAR3007, which demonstrated a significant improvement in progression-free survival (PFS) with trabectedin (YONDELIS®) compared to dacarbazine in patients with advanced liposarcoma (LPS) or leiomyosarcoma (LMS) previously treated with an anthracycline and at least one additional chemotherapy regimen. SAR3007 is the largest randomized Phase 3 study ever conducted in this patient population. These data were presented yesterday in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

Soft tissue sarcoma (STS) 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}. LPS and LMS are among the most common types of STS in adults and represent approximately 40-50% of all STS cases^{3,4}.

“Advanced soft tissue sarcoma represents a complex set of rare diseases which, when advanced, are life-threatening. Our patients need new treatment options that are well-tolerated, as the treatment landscape has been stagnant for decades” said George Demetri, M.D., Director, Center for Sarcoma and Bone Oncology at the Dana-Farber Cancer Institute and Professor at Harvard Medical School. “In soft tissue sarcomas, disease stabilization is a valuable metric for evaluating treatment success in patients with advanced disease. The safety data from this trial were consistent with adverse events observed in previous clinical trials of trabectedin and in clinical use outside the United States where trabectedin has been approved to treat these aggressive diseases.”

Trabectedin is approved in 77 countries in North America, Europe, South America

and Asia under the tradename YONDELIS[®] for the treatment of advanced STS as a single-agent. Janssen submitted a New Drug Application for YONDELIS[®] to the U.S. Food and Drug Administration on November 24, 2014, which was granted a Priority Review on February 3, 2015.

In this randomized, active-controlled Phase 3 study in patients with advanced LPS or LMS, trabectedin significantly reduced the risk of disease progression or death by 45 percent compared with those who received dacarbazine (hazard ratio [HR] = 0.550; $P < 0.0001$; median [M] 4.2 vs 1.5 months, respectively), with results validated through an audit by independent radiologists. The improved PFS benefit with trabectedin treatment was consistently observed across all clinically relevant subgroups and was further supported by an increased objective response rate, a longer duration of response, and a higher clinical benefit response rate as compared to dacarbazine. At the interim analysis for overall survival (OS), the trial had not met the primary endpoint of OS and the study is ongoing to determine the final OS results, which will be presented at a future meeting. The results for the secondary efficacy endpoints are mature.

Safety findings were consistent with the well-characterized safety profiles of both agents, with the most common Grade 3-4 toxicities in the trabectedin versus the dacarbazine groups being decreased absolute neutrophil count (40% vs. 25%), decreased platelets (19% vs. 20%), and transient increases in liver transaminases, including alanine transaminase (ALT) (29% vs. 1%). Drug-related deaths occurred in 2.1% of patients in the trabectedin group versus 0% of patients in the dacarbazine group.

About SAR3007

The Phase 3 multicenter study SAR3007 compared trabectedin (YONDELIS[®]) with dacarbazine in patients with advanced liposarcoma (LPS) or leiomyosarcoma (LMS) previously treated with an anthracycline and at least one additional chemotherapy regimen. The primary endpoint is overall survival (OS) and secondary endpoints included progression-free survival (PFS), time to progression (TTP), objective response rate (ORR), duration of response (DOR), symptom severity and safety. Both treatments were administered via an IV infusion every three weeks with the trabectedin dose of 1.5 mg/m² given over 24 hours versus dacarbazine dose of 1 g/m² given over 20-120 min. Ninety-four percent of study participants were in the U.S.

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}. In

the United States, nearly 12,000 people will be diagnosed and approximately 4,870 are expected to die of soft tissue sarcomas in 2015⁵. 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 vessels⁶. 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^{7,8}.

About YONDELIS® (trabectedin)

YONDELIS® (trabectedin) is a novel, synthetically produced antitumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The drug exerts its activity by targeting the transcriptional machinery. It is approved in 81 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 PharmaMar

Headquartered in Madrid, PharmaMar is the 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 81 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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