

## **U.S. FDA Approves YONDELIS<sup>®</sup> (trabectedin) for Soft Tissue Sarcoma (Liposarcoma or Leiomyosarcoma)**

**Madrid, October 23, 2015:** PharmaMar announced today that its licensing partner, Janssen Biotech, Inc. received marketing approval for YONDELIS<sup>®</sup> (trabectedin) by the U.S. Food and Drug Administration (FDA) for the treatment of patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS) who have received a prior anthracycline-containing regimen. LPS and LMS are among the most common types of soft tissue sarcoma and this is the first treatment to be specifically approved for LPS in the U.S.

The approval was based on the clinical efficacy and safety data from a recently published Phase 3, randomized, open-label, controlled study, ET743-SAR-3007, which evaluated YONDELIS<sup>®</sup> versus dacarbazine in this patient population<sup>i</sup>. This pivotal trial confirmed the results of previous clinical studies and provides strong evidence of the clinical benefit of trabectedin.

"Since YONDELIS<sup>®</sup> was first approved in Europe in 2007 approximately 50,000 patients in 80 countries have benefited from this therapy across all indications," says Luis Mora, Managing Director, PharmaMar, who added that "the approval in the U.S. will allow more patients with this disease to have access to a drug that will address an unmet medical need."

For the approval of YONDELIS<sup>®</sup> in the U.S., PharmaMar will receive the appropriate milestone from Janssen Products, LP.

### **About Liposarcoma (LPS) or Leiomyosarcoma (LMS)**

LPS and LMS represent approximately 35% of all STS cases, of which there are 50 subtypes.<sup>ii,iii,iv</sup> LMS is an aggressive type of STS that occurs in smooth muscles, such as those in the uterus, abdominal cavity, or blood vessels.<sup>v</sup> LPS 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.<sup>vi,vii</sup>

### **About YONDELIS<sup>®</sup> (trabectedin)**

YONDELIS<sup>®</sup> (trabectedin) is a synthetically produced anti-tumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. It works by targeting the transcription machinery<sup>viii</sup> and impairing DNA

repair<sup>x</sup> in cancer cells, thus inducing tumor cell death. It is approved in 80 countries in North America, Europe, South America and Asia. Indications vary by country and include the treatment of advanced soft tissue sarcomas and relapsed ovarian cancer in combination with DOXIL<sup>®</sup>/CAELYX<sup>®</sup> (doxorubicin HCl liposome injection). Under a licensing agreement with PharmaMar, Janssen Products, L.P. has the rights to develop and sell YONDELIS<sup>®</sup> globally except in Europe, where PharmaMar holds the rights, and in Japan, where PharmaMar has granted a license to Taiho Pharmaceutical Co., Ltd.

#### **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 strong pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS<sup>®</sup> 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, UK and the United States. To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://www.pharmamar.com).

#### **Disclaimer**

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

<sup>ii</sup> American Cancer Society. What are the key statistics about soft tissue sarcomas?

Available at: <http://www.cancer.org/cancer/sarcoma-adultsofttissuecancer/detailedguide/sarcoma-adult-soft-tissue-cancer-key-statistics>. Accessed: October 2015.

<sup>iii</sup> Toro JR, et al. *Int J Cancer*. 2006;119:2922-2930.

<sup>iv</sup> SARC. Soft Tissue Sarcoma Subtypes. Available at: <http://www.sarctrials.org/soft-tissue-sarcoma>. Last accessed October 2015.

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

vii University of Rochester Medical Center. Liposarcoma.

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<http://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=134&ContentID=221>

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