

## ZELTIA PRESS RELEASE

# U.S. FDA grants priority review to YONDELIS<sup>®</sup> NDA for advanced soft-tissue sarcoma

**Madrid, February 3, 2015** – PharmaMar announces that the U.S. Food and Drug Administration (FDA) has granted priority review to YONDELIS<sup>®</sup> (trabectedin) New Drug Application (NDA) for the treatment of patients with advanced soft tissue sarcoma (STS), including liposarcoma and leiomyosarcoma subtypes, who have received prior chemotherapy including an anthracycline. Janssen Research & Development, PharmaMar's strategic partner for the development of YONDELIS<sup>®</sup> in the U.S., submitted the NDA on November 24, 2014<sup>1</sup>.

YONDELIS<sup>®</sup> obtained Orphan Drug designation for STS by the European Commission in 2001 and by the U.S. FDA in 2004, which is assigned to a drug for treating a rare disease or condition. The FDA grants priority review status to drug candidates that may offer major advances in treatment compared to existing options. A priority review designation means FDA's goal is to take action, following the validation and acceptance of the NDA, within six months as compared to 10 months under standard review.

YONDELIS<sup>®</sup> is now commercialized in 77 countries for the treatment of advanced soft-tissue sarcoma as single-agent, and in 70 countries for relapsed platinum-sensitive ovarian cancer in combination with pegylated liposomal doxorubicin.

### **About Soft Tissue Sarcoma**

Soft tissue sarcomas are a type of cancer originating in the soft tissues such as muscle, fat, blood vessels, nerves, tendons and the lining of joints<sup>2</sup>. In the U.S., nearly 12,000 people will be diagnosed with STS and approximately 4,870 are expected to die of this cancer in 2015<sup>3</sup>. 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 vessels. 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<sup>2</sup>.

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

PharmaMar is a world leader in the discovery and development of marine-based anticancer drugs with a rich pipeline of drug candidates and a strong R&D program. PharmaMar, which is headquartered in Madrid, is a subsidiary of Zeltia, S.A., which has been listed on the Spanish Stock Exchange since 1963 (MSE: ZEL) and on Spain's Electronic Market since 1998. YONDELIS® (trabectedin) is a new, multimodal, synthetically produced anti-cancer agent, and originally derived from the sea squirt. The drug prevents tumor progression through different mechanisms of action, including DNA binding to block its replication, inhibition of activated transcription and proteins involved in DNA repair, and the modulation of the tumor microenvironment. PharmaMar has granted a license to Janssen to develop and sell YONDELIS® (trabectedin) globally except in Europe and Japan.

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<sup>1</sup> <http://www.jnj.com/news/all/Janssen-Submits-New-Drug-Application-for-YONDELIS-trabectedin-to-US-FDA-for-the-Treatment-of-Patients-with-Advanced-Soft-Tissue-Sarcoma>

<sup>2</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>

<sup>3</sup> General information about adult soft tissue sarcoma. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/adult-soft-tissue-sarcoma/HealthProfessional> Accessed: January 19, 2015