

ZELTIA NEWS

PharmaMar announces that its partner Janssen has submitted a New Drug Application for YONDELIS[®] to the U.S. FDA for the treatment of advanced soft tissue sarcoma

- *The results from a Phase III randomized, open label study are the basis for the submission of a registration dossier for YONDELIS[®] by Janssen Research & Development, LLC for the treatment of advanced soft tissue sarcoma in the US*
- *In the U.S., more than 12,000 people will be diagnosed with soft tissue sarcoma and 4,700 deaths due to this disease are expected to occur in 2014*
- *The U.S. expanded access program will now be open to eligible patients with previously treated advanced soft tissue sarcoma, including those with liposarcoma and leiomyosarcoma to be treated with YONDELIS[®]*

Madrid, November 25th, 2014 – PharmaMar announces that Janssen Research & Development, LLC (Janssen) has submitted a New Drug Application (NDA) for YONDELIS[®] (trabectedin) to the U.S. Food and Drug Administration (FDA) for the treatment of patients with advanced soft tissue sarcoma (STS), including liposarcoma and leiomyosarcoma subtypes, who have received prior chemotherapy including an anthracycline.

In its press release, Janssen also announced plans to amend the protocol for the Phase III randomized, open-label study ET743-SAR-3007, on which the NDA submission is based. The protocol will be revised to offer patients who were randomized to the dacarbazine comparator arm the option of receiving trabectedin treatment at their physician's discretion. This trial is evaluating the safety and efficacy of trabectedin versus dacarbazine for the treatment of advanced liposarcoma and leiomyosarcoma, the most common types of STS in

adults, in more than 500 patients previously treated with an anthracycline and ifosfamide, or an anthracycline followed by one additional line of chemotherapy. Results of the study will be presented at a future date.

At the same time, Janssen will be revising the current U.S. trabectedin expanded access program (EAP), ET743-SAR-3002, to allow entry of eligible patients with liposarcoma and leiomyosarcoma. The program was developed to provide trabectedin to eligible patients with previously treated STS who cannot be expected to benefit from limited currently available therapeutic options. Patient enrolment will be extended to those with liposarcoma or leiomyosarcoma once the protocol amendment is implemented at participating sites.

Information about the Study ET743-SAR-3007 (NCT01343277) and the EAP treatment protocol (NCT00210665) may be found on <http://www.clinicaltrials.gov/>

About Soft Tissue Sarcoma

Soft tissue sarcomas are a type of cancer originating in the soft tissues that connect, support and surround other body structures,ⁱ such as muscle, fat, blood vessels, nerves, tendons and the lining of joints. In the U.S., more than 12,000 people will be diagnosed with and approximately 4,700 are expected to die of soft tissue sarcomas in 2014.ⁱⁱ Leiomyosarcoma is an aggressive type of soft tissue sarcomaⁱⁱⁱ that occurs in smooth muscles, such as those in the uterus, gastrointestinal tract or lining of blood vessels.¹ 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.^{iv,v}

About YONDELIS® (trabectedin)

YONDELIS® (trabectedin) is a novel, multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The anti-cancer medicine works by preventing tumor cells from multiplying through different mechanisms of action. It is approved in 76 countries in North America, Europe, South America and Asia for the treatment of advanced soft-tissue sarcomas as a single-agent, and in 69 countries for relapsed ovarian cancer in combination with DOXIL®/CAELYX® (doxorubicin HCl liposome injection). PharmaMar develops and commercializes YONDELIS® in Europe, where it is approved for the treatment of advanced soft-tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL®/CAELYX® (doxorubicin HCl liposome injection). Under a licensing agreement with PharmaMar, a wholly owned member of the Zeltia Group, Janssen Products, LP has the rights to develop and sell YONDELIS globally except in Europe, where PharmaMar SA holds the rights, and in Japan, where PharmaMar has granted a license to Taiho Pharmaceuticals Co., Ltd.

About PharmaMar

PharmaMar is a biopharmaceutical subsidiary of Grupo Zeltia; it is a world leader in discovering, developing and marketing marine-based drugs to treat cancer. Yondelis® is the first marine-based antitumour drug. PharmaMar has four other compounds in clinical development: Aplidin®, Zalypsis®, PM01183 and PM060184. PharmaMar also has a rich pipeline of pre-clinical candidates and a strong R&D program.

About Zeltia

Zeltia S.A. is a world-leading biopharmaceutical company specialized in the development of marine-based drugs for use in oncology. Grupo Zeltia consists mainly of the following companies: PharmaMar, the world-leading biotechnology company in advancing cancer care through the discovery and development of innovative marine-derived medicines; Genómica, Spain's leading company in molecular diagnostics based on DNA analysis; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi).

Disclaimer

PharmaMar, which is headquartered in Madrid (Spain), is a subsidiary of Zeltia, S.A. (Spanish stock exchange: ZEL), which has been listed on the Spanish Stock Exchange since 1963 and on Spain's Electronic Market since 1998. This document is a press release, not a prospectus. This document does not constitute or form part of an offering or invitation to sell or a solicitation to purchase, offer or subscribe shares of the company. Moreover, no reliance should be placed upon this document for any investment decision or contract and it does not constitute a recommendation of any type with regard to the shares of the company.

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ⁱ Mayo Clinic. Disease Conditions: Soft tissue sarcoma.

Available from: <http://www.mayoclinic.org/diseases-conditions/soft-tissue-sarcoma/basics/definition/con-20033386>.

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ⁱⁱ 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 22, 2014.

ⁱⁱⁱ The Liddy Shriver Sarcoma Initiative. An Introduction to Leiomyosarcoma of the Bone and Soft Tissue.

Available at: <http://sarcomahelp.org/leiomyosarcoma.html>.

Accessed: October 22, 2014.

^{iv} The Liddy Shriver Sarcoma Initiative. What is Liposarcoma? Available at:
<http://sarcomahelp.org/liposarcoma.html>.

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^v University of Rochester Medical Center. Liposarcoma.

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

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