

## ZELTIA NEWS:

### **PharmaMar announces that Taiho Pharmaceutical has submitted a New Drug Application (J-NDA) for Yondelis<sup>®</sup> (trabectedin) to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for different subtypes of soft tissue sarcoma**

*The NDA has been granted priority review, as trabectedin received orphan drug designation in Japan*

**Madrid, January 5<sup>th</sup> 2015:** PharmaMar announces that Taiho Pharmaceutical, PharmaMar's partner for Yondelis<sup>®</sup> development and sales in Japan, has filed a marketing authorization application that seeks approval of Yondelis<sup>®</sup> (trabectedin; development code: ET-743) for the treatment of different subtypes of advanced soft tissue sarcoma in Japan, given the clinical benefit shown in a pivotal Phase II study.

"This is a milestone for PharmaMar and a step forward for Yondelis<sup>®</sup>, which keeps showing its efficacy as treatment for this type of cancer", said Luis Mora, Managing Director, PharmaMar. "We hope that patients suffering from soft tissue sarcoma in Japan will soon have access to this treatment".

This J-NDA is based on the results from the open-label, randomized Phase II clinical study (JapicCTI-121850) that compared the progression-free survival (PFS) of Japanese patients treated with Yondelis<sup>®</sup> (trabectedin) against best supportive care (BSC), which was the primary endpoint. The data, presented at the 2014 ASCO, showed a median PFS of 5.6 months for Yondelis<sup>®</sup> (trabectedin), which was significantly superior compared to the 0.9 months achieved by patients on BSC<sup>1</sup>.

### **About Soft Tissue Sarcoma**

Soft tissue sarcomas are a rare type of cancer originating in the soft tissues that connect, and support other body structures, such as muscle, fat, and blood vessels, among others<sup>2,3</sup>. It affects about 3,000 people in Japan, where it is estimated that there are 2 to 3 new cases for every 100,000 people<sup>4</sup>. Only 16% of patients with disease that has already spread will achieve a 5-year survival<sup>2</sup>.

### **About Yondelis® (trabectedin)**

Yondelis® (trabectedin) is a new, multimodal, synthetically produced anti-cancer agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The drug prevents tumor progression through different mechanisms of action, which include the inhibition of activated transcription and proteins involved in DNA repair, as well as the modulation the tumor microenvironment. PharmaMar has granted a license to Taiho Pharmaceutical to develop and sell Yondelis® (trabectedin) in Japan, where it has orphan drug designation.

### **Disclaimer**

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<sup>1</sup> <http://meetinglibrary.asco.org/content/132813-144>

<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>

<sup>4</sup> Taiho Pharma News Release. Available at: <http://www.taiho.co.jp/english/news/20140604.html>