

Pharmaceutical Council Recommends Approval of YONDELIS[®] (trabectedin) in Japan

Madrid, September 1st, 2015 – PharmaMar announces that the Japanese Pharmaceutical Affairs and Food Sanitation Council (PAFSC) has recommended approval of YONDELIS[®] (trabectedin) for the treatment of patients with soft tissue sarcoma in Japan. Based on the review report prepared by the Japanese regulatory agency (PMDA) for YONDELIS[®], the PAFCS has provided a positive opinion to the Japanese Ministry of Health, Labour and Welfare (MHLW), which will then issue the marketing authorization.

YONDELIS[®] has been licensed to Taiho Pharmaceutical Co. Ltd for development and commercialization in Japan.

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^{i,ii}. It affects about 5,000 people in Japan, where it is estimated that there are 2 to 3 new cases for every 100,000 peopleⁱⁱⁱ. Only 16% of patients with disease that has already spread will achieve a 5-year survivalⁱⁱ.

About YONDELIS[®] (trabectedin)

YONDELIS[®] (trabectedin) is a novel, multimodal, 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 78 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 Pharmaceutical.

About PharmaMar

Headquartered in Madrid, PharmaMar is a 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 78 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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ⁱ 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>

ⁱⁱ General information about adult soft tissue sarcoma. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/adult-soft-tissue-sarcoma/HealthProfessional>

ⁱⁱⁱ Calculated by subtracting 1,000 “mesothelioma” patients from the 6,000 “malignance of mesothelioma and soft tissue” patients, referencing the MHLW Patient Survey (2011).