

YONDELIS® receives marketing approval in Japan for the treatment of soft tissue sarcomas

Madrid, September 28 2015: PharmaMar announced that its partner in Japan, Taiho Pharmaceutical, received marketing approval for YONDELIS® (trabectedin) by the Japanese Minister of Health, Labour and Welfare for the treatment of patients with soft tissue sarcoma. The indication includes all types of soft tissue sarcoma.

This approval is based on the positive results from a multicenter, randomized, open-label Phase 2 trial in soft tissue sarcoma patients that had chromosomal translocations to compare trabectedin treatment against best supportive care (BSC). Progression-free survival (PFS) was the primary endpoint, which was measured by central radiology review that allows a uniform process of evaluation across centers and patients. Trabectedin treatment reduced the risk of disease progression compared to BSC, achieving a median PFS of 5.6 months for patients treated with trabectedin compared to 0.9 months for the BSC group.

"We are very excited to witness the approval of YONDELIS® in Japan, so this drug can be available to patients with a disease that remains an unmet medical need in this country," said Luis Mora, Managing Director, PharmaMar. "Collaborating with Taiho was crucial to bring this product to the oncology community in Japan."

For the approval of YONDELIS® in Japan, PharmaMar will receive two payments, 600 million Japanese yen from Taiho Pharmaceutical and \$5 million from Janssen Products.

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^{1,2}. It affects about 5,000 people in Japan, where it is estimated that there are 2 to 3 new cases for every 100,000 people³. Only 16% of patients with disease that has already spread will achieve a 5-year survival⁴.

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 and impairing DNA repair. It is approved in 77 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 Pharmaceuticals.

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 rich pipeline of drug candidates and a robust R&D oncology program. YONDELIS® is commercially available in 77 countries for the treatment of advanced soft tissue sarcomas and for relapsed platinum-sensitive ovarian cancer. 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, UK and the United States. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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¹ 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>

² General information about adult soft tissue sarcoma. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/adult-soft-tissue-sarcoma/HealthProfessional>

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