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The Japanese Pharmaceutical Affairs and Food Sanitation Council (PAFSC) has recommended an approval for Madrid-based PharmaMar's Yondelis (trabectedin) that is indicated 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.

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

Yondelis (trabectedin) is a 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 DOXILÃ?Â® CAELYXÃ?Â® (doxorubicin HCl liposome injection).