

Yondelis[®] approved for sale in 6 additional countries

- *The regulatory authorities in 6 countries have granted 10 sales authorisations for Yondelis[®]*
- *Five of those authorisations are for Yondelis[®] in combination with Caelyx[®] (pegylated liposomal doxorubicin) for treating relapsed platinum-sensitive ovarian cancer: Bangladesh, Costa Rica, Kuwait, Moldavia and Saudi Arabia*
- *The other five authorisations are for Yondelis[®] for soft tissue sarcoma in Bangladesh, Brunei, Kuwait, Moldavia and Saudi Arabia*

Madrid, 3rd of March, 2016: Janssen Products, LP has informed PharmaMar (MSE:PHM) that regulatory authorities in 6 countries have granted 10 new authorisations to sell Yondelis[®]: five for treating relapsed platinum-sensitive ovarian cancer (ROC), in combination with Caelyx[®] (pegylated liposomal doxorubicin), and 6 as monotherapy for treating soft tissue sarcoma (STS).

The six countries that have authorised Yondelis[®] for ROC and/or STS are Saudi Arabia, Moldavia, Bangladesh, Brunei, Costa Rica and Kuwait.

As a result, Yondelis[®] is now approved in nearly 80 countries, 31 of which are in the European Economic Area (EEA). The European Commission approved Yondelis[®] for soft tissue sarcoma in 2007, and at the end of 2009 they approved the sale of this drug in combination with pegylated liposomal doxorubicin for relapsed platinum-sensitive ovarian cancer.

In 2015, the U.S. Food and Drug Administration (FDA) gave Janssen Products, LP, the marketing approval for YONDELIS[®] for the treatment of patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS); and the drug was also approved by the Japanese Minister of Health, Labour and Welfare to Taiho Pharmaceutical Co., Ltd. for the treatment of patients with soft tissue sarcoma.

Yondelis[®] has orphan drug status for soft tissue sarcoma and ovarian cancer in the European Union, the United States, and Switzerland, and for soft tissue sarcoma in Japan and South Korea.



According to the licensing agreement between PharmaMar and Janssen Products, LP, PharmaMar has the rights to sell Yondelis® in Europe (including Eastern Europe), while Janssen Products, LP has the rights to sell the drug everywhere else except Japan, where PharmaMar has granted a license to Taiho Pharmaceutical Co., Ltd. for the development and sale of Yondelis®.

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 nearly 80 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 a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has other three clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom, Belgium and the United States. PharmaMar fully owns other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and two other chemical enterprises, Zelnova Zeltia and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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