

Yondelis[®] receives 5 new approvals outside the European Economic Area

- ***Yondelis[®] has been approved for soft tissue sarcoma (STS) in Israel, Panama and Ukraine, and the authorities in Paraguay and Azerbaijan have approved the drug for platinum-sensitive recurrent ovarian cancer (ROC)***
- ***Yondelis[®] is currently approved in 56 countries***

Madrid, 15 March 2010: Centocor Ortho Biotech Products has informed PharmaMar SA (Grupo Zeltia, ZEL.MC) that the regulatory authorities in Israel, Panama and Ukraine have approved Yondelis[®] for advanced soft tissue sarcoma (STS) in adults, and the authorities in Paraguay and Azerbaijan have approved the drug for platinum-sensitive recurrent ovarian cancer (ROC). Yondelis is already approved for STS in Paraguay and Azerbaijan.

The European Commission approved Yondelis[®] for platinum-sensitive ROC in September 2009. Outside the European Economic Area (EEA), Yondelis[®] has now been approved for platinum-sensitive ROC in Azerbaijan and Paraguay; it had already been approved in Kazakhstan and the Philippines.

In view of the 3 new approvals for STS, Yondelis[®] now has authorization for this indication in 25 countries outside the EEA: Argentina, Azerbaijan, Bolivia, Chile, Colombia, Curaçao, Hong Kong, India, Israel, Kazakhstan, Macao, Malaysia, Mexico, Panama, Paraguay, The Philippines, Russia, Singapore, South Korea, Switzerland, Thailand, Ukraine, Uruguay, Venezuela and Vietnam. PharmaMar has already begun collecting royalties from sales in the above-mentioned countries.

Clinical trials are under way to expand the use of Yondelis[®] in sarcoma, including a trial as first-line treatment in patients with translocation-associated tumours and in children with Ewing sarcoma, rhabdomyosarcoma and other forms of STS. Yondelis[®] is also undergoing trials in solid tumours, such as prostate, breast and lung cancer.

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 South Korea.



According to the licensing agreement between PharmaMar (Zeltia, S.A. subsidiary) and Centocor Ortho Biotech Products, L.P., PharmaMar has the rights to sell Yondelis® in Europe (including Eastern Europe), while Centocor Ortho Biotech Products, L.P. has the rights to sell the drug everywhere else, except in Japan, where Taiho Pharmaceutical Co., Ltd. has a licensing agreement for the development and sale of Yondelis®.

About soft tissue sarcoma (STS)

STS are a heterogeneous group of more than 50 types of tumours that arise in adipose, muscle or nerve tissue, tendons, blood and the lymph vessels. Almost half of these tumours affect the limbs. Every year 4 new cases of STS are detected per 100,000 people, and the disease accounts for 2% of the overall cancer mortality rate. STS is most common among people in their 50s. The 5-year survival rate of patients with STS is around 90% when it is detected early (Phase I), i.e. when the tumour is small and has not metastasised, but only 10-20% if the disease has metastasised. The life expectancy in patients with metastasis is 8-12 months after having received first-line therapy.

About ovarian cancer

In the West, epithelial ovarian cancer represents 4% of all cancers among women and ranks fifth as a cause of female deaths from cancer (American Cancer Society [ACS], Cancer Reference Information, 2005). According to 2009 clinical data from the European Society for Medical Oncology (ESMO), 18 new cases of ovarian cancer are detected each year in the European Union per 100,000 women, and the mortality rate is 12 per 100,000 women per year. The average age of diagnosis is 63, and the incidence increases with age, particularly above the age of 70; however, it may also occur in younger women, especially in those with a family history of the disease. 70% of women with ovarian cancer are diagnosed late, when the disease is already advanced (Stages III and IV). The 5-year survival rate for these women is only 15%-20%, compared with nearly 90% for patients in Stage I of the disease (i.e. the earliest stage) and 70% for Stage II (intermediate).

About PharmaMar

PharmaMar is Grupo Zeltia's biotechnology subsidiary; it is a world leader in discovering, developing and selling marine-based drugs to treat cancer. Yondelis® is Spain's first anti-cancer drug. It is currently approved for STS in 25 countries outside the EEA, and in 5 of those countries for platinum-sensitive ROC as well. Yondelis® is approved for STS and platinum-sensitive ROC in all 30 countries of the EEA; in Switzerland it is approved for STS. Phase II clinical trials with Yondelis® are also under way on prostate, breast, lung and paediatric cancers. PharmaMar has four other compounds in clinical development: Aplidin®, Irvalec®, Zalypsis® and PM01183. PharmaMar also has a rich pipeline of pre-clinical candidates and a major R&D programme.

Important note

PharmaMar, which is headquartered in Madrid (Spain), is a subsidiary of Grupo Zeltia (Spanish stock exchange: ZEL), which has been listed on the Spanish Stock Exchange since 1963 and on Spain's Electronic Market since 1998. This document is a press release, not a prospectus. This document does not constitute or form part of an offering or invitation to sell or a solicitation to purchase, offer or subscribe shares of the company. Moreover, no



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This note is also available in the "News" section of the PharmaMar web site: www.pharmamar.com