YONDELIS® HAS BEEN AUTHORIZED FOR COMMERCIALIZATION IN SWITZERLAND

- Yondelis® is now available for commercialization in Switzerland
- The regulatory process in Switzerland is independent from the EMEA regulatory process
- Switzerland joins the list of the EEA (European Economic Area) countries where PharmaMar is currently commercializing Yondelis®

Madrid, 6 Feb. 2009: Swissmedic, the Swiss Agency for Therapeutic Products, has authorized the commercialization of Yondelis® for the treatment of soft tissue sarcoma. The regulatory process required the presentation of a registration dossier adapted to Swissmedic requirements.

PharmaMar has the distribution license of the product in Switzerland, which guarantees the product launch. Switzerland joins now the list of 30 countries of the EEA (European Economic Area) where Yondelis® is already authorized for commercialization.

PharmaMar is also conducting clinical trials to expand the use of Yondelis® in sarcoma, such as a phase III multicenter study of Yondelis® as first-line therapy in patients with tumor traslocation, and a Phase II study in Children diagnosed with Ewing Sarcoma, Rhabdomyosarcoma, and other types of STS. Yondelis® is being studied in solid tumors with high incidence and prevalence in the population, such as prostate, breast and lung cancer.

Yondelis® has been designated orphan drug for the treatment of soft tissue sarcomas and ovarian cancer in the European Union, United States and Switzerland, and for soft tissue sarcomas in Korea.

According to the agreement between PharmaMar – a subsidiary of Zeltia, S.A- and Ortho Biotech Products, L.P. –a subsidiary of Johnson & Johnson- , under which Yondelis® is developed, PharmaMar will market Yondelis® in Europe (including Eastern Europe) and Japan, and Ortho Biotech Products, L.P. will market Yondelis® in the rest of the world. Both companies filed a registration dossier to the EMEA and the FDA for Yondelis for the
treatment of refractory ovarian cancer at the end of 2008. At the end of 2008 both companies submitted a Registration Dossier of Yondelis® in relapsed ovarian cancer (ROC) to the EMEA and the FDA. A decision on the approval for this indication is expected to take place during 2009.

Soft tissue sarcomas
STS are a diverse group of more than 50 types of tumours that appear in fatty tissue, muscle, nerve tissue, tendons and blood and lymph vessels. Nearly half of them affect the extremities. According to data from GEIS (Spanish research group in sarcomas) soft tissue sarcomas (STS) have an incidence of around 3/100,000 new cases per year, which represents 2% of the overall mortality from cancer. The highest incidence is situated in patients around 50 years of age. The five-year survival rate of patients with STS is around 90% when detected early (stage I), that is, when the tumour is small and with no metastasis. However, the five-year survival rate in patients with metastatic disease is 10-20%. The estimated life expectancy in metastatic patients is 8-12 months after receiving the first line of cytotoxic therapy.

PharmaMar
PharmaMar is the world-leading biopharmaceutical company of the Zeltia Group, committed to advancing the treatment of cancer through the discovery and development of new marine-derived medicines. Yondelis® is the first Spanish antitumoral compound, currently marketed in several countries of the European Union for the treatment of soft tissue sarcomas in adults after the failure of standard therapy. Last December 4th, 2008. PharmaMar submitted a Registration Dossier of Yondelis® in relapsed ovarian cancer (ROC) to the EMEA. A decision on the approval for this indication is expected to take place by mid-2009. PharmaMar has four novel compounds in clinical development: Yondelis® is also in Phase II studies in prostate, breast and pediatric cancers. Aplidin ®, Zalypsis ®, and Irvalec ® are new marine-derived agents in clinical development. PharmaMar also has an extensive portfolio of products in preclinical research and a sound R&D program.

Important note
PharmaMar, based in Madrid, Spain, is a company of the Zeltia Group (Spanish Stock Exchange, ZEL) that has been listed on the Spanish Stock Exchange since 1963. This document is a press release, not a brochure. This document does not constitute nor is it part of any offer or invitation to sell or issue any application of purchase, offer, or shares subscription of the Group. Likewise, this document nor its distribution is part or can be of base for any contract or investment decision and does not constitute any kind of recommendation in relation with the shares of the Company.
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