



YONDELIS® RECEIVES POSITIVE OPINION IN EUROPE FOR THE TREATMENT OF SOFT TISSUE SARCOMA

It is the first anticancer drug developed and produced by a Spanish biopharmaceutical company

Madrid, July 20th, 2007: PharmaMar, a biopharmaceutical company subsidiary of the Zeltia Group announces today that **Yondelis®** (trabectedin) has received a positive opinion from the European Medicines Agency (EMA) for the treatment of metastatic or advanced soft tissue sarcoma.

José María Fernández Sousa, president of Zeltia said: "This is excellent news. Firstly for the patients and their families, since a new therapeutic option is now available. Also for the PharmaMar and Zeltia employees who have devoted long years of effort and dedication in pursuit of this challenge. It is also excellent news for Spanish science as well as for the investigators from all over the world who have participated in the clinical trials and believed in the therapeutic potential of compounds of marine origin".

Yondelis® is a compound of marine origin currently obtained semi-synthetically and the first antitumoural drug developed and produced by a Spanish biopharmaceutical company. Yondelis will also be the first new therapy to be commercialised in this indication in the last three decades. The approval of Yondelis® confirms the potential of the seas as a source of new medicines and validates PharmaMar as a world leader in the field.

The positive opinion by the EMA is based mainly on the positive results of a randomised, comparative trial of two Yondelis® regimes (24-h every 3 weeks or 3-h weekly) in 270 patients with sarcomas progressing in spite of all available standard agents. The study demonstrated a statistically significant 27% reduction in the risk of disease progression (primary endpoint) for patients allocated to the 24-h study arm, as well as longer progression-free survival (secondary endpoint). A 61% of these patients remained alive at 12 months. This is the largest clinical trial conducted to date worldwide in this setting.

The European Commission will now consider granting marketing authorization of Yondelis® in the European Union in line with the positive opinion of the EMA. Many European patients may have access to Yondelis® by the end of this year.

PharmaMar continues with the development of its oncology pipeline. This first approval converts PharmaMar into a key player within the European Pharmaceutical Industry.

About Yondelis®

Yondelis® (trabectedin, ET-743) was originally isolated from the marine tunicate *Ecteinascidia turbinata*. Yondelis has a novel mechanism of action. It is a unique anti cancer agent that binds into the minor groove of the DNA and interacts with DNA repair enzymes and transcription factors, interfering with different cell cycle processes.

In addition to STS, Yondelis® is being developed in a pivotal Phase III trial in ovarian cancer and in Phase II in prostate and breast cancers. Yondelis® was designated Orphan Drug for STS by the European Commission



(E.C.) in 2001 and by the U.S. FDA in 2004 and for ovarian cancer by the E.C. in 2003 and by the U.S. FDA in 2005.

Trabectedin is currently being developed by PharmaMar in partnership with Johnson & Johnson Pharmaceutical Research & Development (J&JPRD). According to the licensing agreement, PharmaMar will market Yondelis® in Europe (including Eastern Europe) while Ortho Biotech Products, L.P., will market it in the U.S., and Janssen-Cilag will market it in the rest of the world.

Important note

PharmaMar, based in Madrid, Spain, is a subsidiary of Grupo Zeltia (Spanish Stock Exchange, ZEL) that is quoted in the Spanish Stock Exchange since 1963 and the Spanish continuous market since 1998. Grupo Zeltia is currently part of the Ibex Nuevo Mercado (New Market).

This document is a press release, not a brochure. This document does not constitute nor is part of any offer or invitation to sell or issue any application of purchase, offer or shares subscription of the Society. 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.

.....

For more information:

Pedro Luis González
Dpto. de Comunicación,
PharmaMar
Tel: +34 91 846 6000

Catherine Moukheibir
Directora Mercados de Capitales
Zeltia
Tel: +34 91 444 4500

<http://www.pharmamar.com/en/press>