



## **Yondelis® receives positive recommendation from the UK's NICE for the treatment of advanced soft tissue sarcoma**

- *The National Institute for Health and Clinical Excellence (NICE) has recommended Yondelis® as a treatment option for people with advanced soft tissue sarcoma, a rare form of cancer.*

**London, December 21<sup>st</sup> 2009:** Today the National Institute for Health and Clinical Excellence (NICE) has recommended Yondelis® as a treatment option for people with advanced soft tissue sarcoma, a rare form of cancer. The positive recommendation follows PharmaMar's decision to offer a patient access scheme which caps the overall cost exposure of the UK's National Health System (NHS) at the average number of cycles received by patients in the STS-201 trial.

PharmaMar started commercialization of Yondelis® in UK in October 2007, after the European Commission granted the marketing authorization for advanced soft tissue sarcoma but until now the treatment was available in UK through individual funding from Primary Care Trusts. Reimbursement of the treatment by the NHS will allow many more patients in the UK to benefit from this therapy.

Commenting on NICE's decision, Luis Mora, General Manager of PharmaMar (Grupo Zeltia) said: *"We are delighted that NICE has recommended Yondelis® for use in advanced soft tissue sarcoma. This decision is great news for NHS patients, who will now be able to gain access to Yondelis® if their clinician recommends it. We are proud to play our part in making this important treatment available to all NHS patients who could benefit."*

Responding to the positive recommendation, Prof. Ian Judson, Professor of Cancer Pharmacology at the Drug Development Unit of The Royal Marsden Hospital, said: *"I warmly welcome the news that Yondelis® will now be available for all the patients who are eligible for treatment with the drug, given the prolonged benefit we have seen in some of the patients treated here at the Marsden."*



Roger Wilson, from Sarcoma UK stated: *"Sarcoma patients welcome the approval of Yondelis® by NICE. It has been a challenging journey for everyone concerned, doctors, patients, regulators and for the manufacturer. I am delighted. Despite having advanced disease many patients who have had access to Yondelis® through individual funding from Primary Care Trusts have responded well. This news encourages everyone as it opens the way for a new era in the treatment of advanced soft tissue sarcoma, for which there have been few advances in over 20 years. Few pharmaceutical companies pay much regard to rare cancers so I would pay tribute to Pharmamar for their determination to see Yondelis® into clinical use, and to thank them for the patient access scheme which makes it possible."*

### **About Yondelis**

Yondelis® is a new antitumour agent originally derived from the Caribbean tunicate *Ecteinascidia turbinata* ("ascidia"). The compound is currently produced synthetically. Yondelis® binds to the minor groove of DNA, interfering with cell division and genetic transcription processes and the DNA repair machinery. Under a licensing agreement with PharmaMar SA, Centocor Ortho Biotech Products, L.P. has the rights to market trabectedin worldwide except in Europe, where the drug is marketed by PharmaMar SA as Yondelis®, and in Japan, where PharmaMar SA and Taiho Pharmaceutical Co., Ltd. have a licensing agreement to develop and market Yondelis®.

### **About soft tissue sarcomas**

Soft tissue sarcomas 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. Sarcomas account for about 1% of all cancers diagnosed – about 3,000 cases a year in the UK. Soft tissue sarcomas affect around 4 out of every 100,000 people per year and account 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 PharmaMar**

PharmaMar, a biotechnology company in the Zeltia Group (ZEL.MC), is the world leader in the discovery, development and commercialization of anti-cancer drugs of marine origin. Yondelis® is Spain's first anti-cancer drug. In 2007, it was approved for sale in the European Union to treat soft tissue sarcoma. In 2009, the European Commission authorised the sale of Yondelis® in combination with pegylated liposomal doxorubicin for relapsed platinum-sensitive ovarian cancer. Phase II clinical trials with Yondelis® are also under way on prostate, breast and paediatric cancers. PharmaMar has four other new compounds in clinical development. Clinical trials are underway with 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 Zeltia, S.A. (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 PharmaMar or Zeltia. Moreover, no reliance should be placed upon this document for any investment decision or contract and it does not constitute a recommendation of any type with regard to the shares of PharmaMar or Zeltia.

### **For more information:**

#### **Media Relations (tel. +34 91 846 60 00)**

Fernando Mugarza

#### **Capital Markets (tel. + 34 91 444 45 00)**

Jose Luis Moreno  
Florencia Radizza

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