PharmaMar announces the initiation of Phase I clinical trials with PM01183, a new antitumor compound

- ***PM01183 is a new compound developed by PharmaMar's internal research program***
- ***In preclinical studies it has shown strong in vitro and in vivo antitumoural activity in a wide variety of tumour cell lines and human transplantable xenografted tumours***

Madrid, June 22nd, 2009: PharmaMar SA (Grupo Zeltia, ZEL.MC) today announces the initiation of Phase I clinical trials with PM01183, a new antitumor compound developed by PharmaMar's internal research program. The first patient enrolled in the trial has already started treatment with the compound.

PM01183 is a new synthetic alkaloid which binds to the minor groove of DNA, generates DNA double strand breaks and caused cell cycle perturbation that finally results in a specific type of cell death calles apoptosis. Results from preclinical studies indicate a pattern of activity of PM01183 different from that of conventional alkylating agents.

In preclinical studies PM01183 demonstrated strong *in vitro* and *in vivo* antitumor activity in a wide variety of tumour cell lines and human transplantable xenografted tumours. PM11883 also demonstrated a manageable and reversible preclinical toxicology profile.

As a single agent, PM01183 significantly reduced tumor proliferation in vivo, with the strongest effect observed on the xenografts of the breast cancer cell line MX1. PM01183 was also evaluated for in vivo activity using M5076 sarcoma model that spontaneously metastasizes in the liver of the C57Bl/6 female tumor bearing mice. The compound statistically reduced the number of liver metastasis compared to placebo-treated animal.

In vitro studies show cell lines with mutant p53 or lacking P53 are more sensitive with PM01183. Further studies are on going in human ovarian cancer and human sarcoma xenografts.

PharmaMar's clinical portfolio currently includes five new, first-in-class compounds: Yondelis®, Aplidin®, Zalypsis®, Irvalec® and PM01183. The PharmaMar patent portfolio is composed of over 1,800 files and it has a continuous flow of new compound into the clinic (1 new compound every 24 months).

About PM01183

PM01183 is a new synthetic alkaloid compound developed by PharmaMar's internal research program. It binds to the minor groove of DNA, generates DNA double strand brakes and caused cell cycle perturbation mainly consisting in a delayed progression of S phase and cycle arrest in G2M. Results from preclinical studies indicate a pattern of activity of PM01183 different from that of conventional alkylating agents.

PharmaMar

PharmaMar is the world leader biopharmaceutical company of the Zeltia Group, committed to advancing the treatment of cancer through the discovery and development of new marine-derived medicines. PharmaMar's first product, Yondelis®, received marketing authorisation from the European Commission for the treatment of advanced or metastatic soft tissue sarcoma in September 2007. In 2008 a registration dossier was submitted to the European Medicines Agency (EMEA) and Food and Drug Administration (FDA, USA) for Yondelis® when administered in combination with DOXIL®/Caelyx™ (pegylated liposomal doxorubicin) for the treatment of women with relapsed ovarian cancer. It is also in phase II clinical trials for prostate, breast, and lung cancers. Three other PharmaMar compounds, Aplidin®, Irvalec®, Zalypsis® and, PM01183 are in various stages of clinical development.

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