# PharmaMar reports Phase I results for Yondelis™ in combination with cisplatin

**New York, 14 November 2003**: PharmaMar announces the presentation of data at the XXI Chemotherapy Foundation Symposium at Mount Sinai School of Medicine in New York from 12 to 15 November 2003. The annual Chemotherapy Foundation Symposium is an international meeting of oncologists, haematologists and other specialists involved in the treatment of cancer patients, attracting 2,000 participants.

PharmaMar reports a Phase I study to determine the optimal dose, feasibility and pharmacokinetic activity of Yondelis™ when used in combination with cisplatin in patients with advanced solid tumours. The company also reports data examining the activity of Aplidin® in neuroendocrine tumours.

The Phase I study of Yondelis in combination with cisplatin involved 36 patients with a variety of solid tumours including ovarian cancer, soft tissue sarcoma, uterine cancer and melanoma. With the exception of one patient, all had received previous chemotherapy, 61% (22 patients) with a platinum treatment.

Yondelis and cisplatin (40 mg/m$^2$) were given in combination on days 1 and 8 over a 3 week period. The Yondelis dose was increased from 0.3 to 0.7 mg/m²/day by 0.1 mg/m² increments according to tolerability.

The results demonstrate that pharmacologically active doses of Yondelis and cisplatin can be administered concurrently. Plasma disposition of Yondelis and cisplatin was similar to that of each drug administered as a single agent. Three partial responses (21%) were observed from 14 evaluable ovarian cancer patients. These three patients had not responded to previous platinum treatments.

The safety data are consistent with the expected lack of overlapping toxicities. Reversible neutropenia was the most common side effect. The main non-haematological side effects are dose-dependant nausea and vomiting, asthenia and liver toxicity, all reversible and mild up to 0.6 mg/m²/day.

Dr. Nicoletta Colombo, head of the gynaecology oncology unit from the European Institute of Oncology and SENDO, Milan, Italy, presenting the results said: “These results demonstrate the potential of Yondelis in combination with other chemotherapies. We are particularly encouraged by the evidence of activity in ovarian cancer patients with platinum resistant tumours.”

The pre-clinical and clinical data being presented on Aplidin® supports the development in neuroendocrine tumours, mainly in medullary thyroid carcinoma.

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**PharmaMar**
PharmaMar is a biopharmaceutical leader in oncology, advancing cancer care through the discovery and development of innovative marine-derived medicines. PharmaMar's product portfolio currently includes Yondelis™ (co-developed with OrthoBiotech Products L.P.), designated Orphan Drug for STS by the EMEA in 2001 and Orphan Drug for ovarian cancer in 2003; Aplidin®, designated Orphan Drug for acute lymphoblastic leukaemia in 2003; Kahalalide F and ES-285 in clinical trials. PharmaMar's extensive preclinical pipeline comprises 14 candidate drugs.

PharmaMar, based in Madrid, Spain, is a subsidiary of the Zeltia Group (Spanish stock exchange: ZEL.MC; Bloomberg: ZEL@SM; Reuters: ZEL.MC). PharmaMar can be found on the Web at http://www.pharmamar.com.

* Yondelis™ is the trademark of ET-743

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