PharmaMar presents new trials with four marine-based drugs at the Annual Meeting of the American Association for Cancer Research (AACR)

Chicago (USA), 4 April 2012: PharmaMar, a biopharmaceutical company owned by Grupo Zeltia (ZEL.MC), presented six new trials with marine-based anti-tumour drugs Aplidin®, PM01183, Zalypsis® and Irvalec® at the 103rd Annual Meeting of the American Association for Cancer Research (AACR), held in Chicago, from 31 March to 4 April.

The AACR meeting is the leading convention on cancer research, bringing together more than 17,000 attendees each year and covering breakthroughs in oncology and basic, clinical and epidemiological research.

The company presented three new trials with its compound PM01183. The first study, “Antitumor effect of PM01183 in a patient-derived cisplatin-sensitive and resistant serous epithelial ovarian orthotopic tumour model”, describes PM01183's antitumour activity in significant animal models of ovarian cancer. Essentially, tumours which are initially sensitive become resistant after treatment with cisplatin. PM01183 exhibited very significant antitumour activity in cisplatin-sensitive and -resistant tumours. The study also evidences strong in vivo synergies when the animals were treated with PM01183 in combination with cisplatin. The second study, “Antitumor effect of PM01183 in a human pancreatic adenocarcinoma orthotopic model”, reports very significant antitumour activity of PM01183 in an orthotopic model of pancreatic cancer. The antitumour activity induced by PM00183, evaluated using bioluminescence and in terms of overall survival, was greater than that observed with gemcitabine. In vivo synergies were also observed after administration of PM01183 in combination with gemcitabine in animal models of pancreatic cancer. The third trial, “Antitumor effect and tumor distribution of PM01183 in human pancreatic y breast xenograft mouse models”, describes how PM01183 distribution in various organs (pancreas, breast) and tumours is
compatible with the activity observed following administration of PM01183 in animals carrying those tumour types.

These results, together with the antitumour activity observed in the Phase I clinical trials, made it possible to undertake a Phase II trial in patients with platin-resistant ovarian cancer. Recruitment for that trial was completed in a month and a half and the results, which are very promising, will be presented at an upcoming oncology conference. Additionally, a Phase II trial in patients with pancreatic cancer has commenced in view of the activity observed in this indication in preclinical and Phase I trials.

The fourth study is entitled “Aplidin induces a non-canonical Endoplasmic Reticulum Stress in HeLa cells”. Aplidin® is PharmaMar’s second most-advanced compound, and its mechanism of action includes rapid oxidative imbalance in tumour cells by activating intracellular signalling pathways leading to cell death by apoptosis. It is currently in Phase III trials for multiple myeloma. Among other findings, the study shows that Aplidin® induces the expression of specific molecular markers consistent with a non-canonical endoplasmic reticulum stress leading to cell death by apoptosis. The trial shows that this particular response is observed only in tumour cells that are sensitive to the drug, and not in resistant cells.

A fifth study, with Zalypsis®, is entitled “Phase I Study of PM00104 (Zalypsis®) in combination with Carboplatin in Patients with Advanced Solid Tumors”. This trial was implemented in view of data from a trial using in vivo models which suggested synergic activity between PM00104 and a platin compound in the treatment of human gastric and bladder tumour xenografts. The primary endpoint of the trial is to determine the maximum tolerated dose (MTD) and the recommended dose (RD) for PM00104 (Zalypsis®) in combination with carboplatin in patients with advanced solid tumours.

A study was also presented with Irvalec®, which has demonstrated a novel mechanism of action.

About PharmaMar

PharmaMar is a biotechnology subsidiary of Grupo Zeltia; it is a world leader in discovering, developing and selling marine-based drugs to treat cancer. Yondelis® is Spain’s first antitumour drug. It is currently
approved for soft tissue sarcoma (STS) in 39 countries outside the EEA, and for platinum-sensitive relapsed ovarian cancer (ROC) in 25 of those countries plus Brazil. Yondelis® is approved for STS and platinum-sensitive ROC in all 30 countries of the EEA. Yondelis® is also undergoing Phase II trials on breast and paediatric cancers. PharmaMar has five other compounds in clinical development: Aplidin®, Irvalec®, Zalypsis®, PM01183 and PM060184. PharmaMar also has a rich pipeline of pre-clinical candidates and a major R&D programme.

About Zeltia

Zeltia S.A. is a world-leading biopharmaceutical company specialised in the development of marine-based drugs for use in oncology and central nervous system illnesses. Grupo Zeltia consists mainly of the following companies: PharmaMar, the world-leading biotechnology company in advancing cancer care through the discovery and development of innovative marine-derived medicines; Noscira, a biotech firm focused on discovering and developing new drugs against Alzheimer’s disease and other neurodegenerative diseases of the central nervous system; Genomica, Spain’s leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and a chemical division comprising Zelnova and Xylazel, two highly profitable companies that are leaders in their respective market segments.

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 the company. 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 the company.

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