ZELTIA NEWS:

PharmaMar will be present at the 39th Congress of the European Society for Medical Oncology (ESMO 2014) with eight studies

Madrid, 17 September 2014: PharmaMar, the biotechnology subsidiary of Grupo Zeltia (MC:ZEL), will be represented in eight scientific papers, seven of them related to Yondelis® (trabectedin), at the 39th Congress of the European Society for Medical Oncology (ESMO 2014), to be held in Madrid from 26 to 30 September.

One of the most important studies, “Benefit of maintenance therapy with trabectedin (T) beyond the 6 first cycles: Results of a prospective randomized phase II trial comparing interruption vs. continuation of T in patients (pts) with advanced soft tissue sarcoma (ASTS): an update”, will be presented by the French Sarcoma Group as an oral presentation. In this trial 178 patients were enrolled from February 2011 to March 2013. After six initial cycles of treatment with trabectedin, patients free from progressive disease (PD) were randomly assigned either to continuous treatment with trabectedin (C arm) or therapy interruption (I arm). The rate of non-progression after 6 cycles of trabectedin was higher than previously reported. Continuation of trabectedin treatment beyond six cycles and until progression was associated with a statistically significant improvement of progression-free survival (PFS). The study will continue to evaluate whether PFS improvement is associated with a further beneficial impact on overall survival (OS).

Taiho Pharmaceuticals Co., Ltd. will present the study entitled “Intra- and inter-patient comparison of efficacy between two phase II studies of trabectedin (T) in patients (pts) with translocation-related sarcomas (TRS); a randomized comparative study (study-C) and a single arm study (study-S)”, as part of the development of trabectedin (Yondelis®) in Japan. It has been reported that trabectedin is an active drug in TRS patients unresponsive to available chemotherapies with a significant increase of PFS and OS in a randomized comparative study (study-C) which was presented at ASCO 2014. For patients with confirmed disease progression in the best supportive care (BSC) arm of study-C, study-S was conducted as a rescue therapy to evaluate safety and efficacy of...
trabectedin. Patients in study-S achieved a median PFS of 7.3 months, which is statistically significantly longer than PFS observed in the BSC arm of study-C (median PFS with BSC was 0.9 months; hazard ratio=0.08; p<0.0001). These results indicated that the treatment with trabectedin can have a positive benefit on tumor progression even when the disease is in an advanced stage.

“Trabectedin in patients with BRCA mutated and BRCAness phenotype advanced ovarian cancer (AOC); phase II prospective MITO-15 study”. This prospective phase II study performed by the Multicenter Italian Trial in Ovarian Cancer (MITO) group was designed to evaluate trabectedin (Yondelis®) activity in patients with documented BRCA mutated and BRCAness phenotype AOC. A total of 88 patients were evaluable for response after a median follow-up of 6 months. Patients were pretreated with a median of 4 chemotherapy lines and received a median of 6 cycles of trabectedin. In the whole population, objective response rate (ORR) was 41%, median PFS was 4.5 months, while median OS was not reached. In patients with BRCA mutations 57.1% of patients achieved partial response. These results suggest that trabectedin represents an efficacious treatment option in patients with platinum-sensitive AOC and documented BRCA mutation or BRCAness phenotype after multiple platinum lines.

“Choi and RECIST assessment of tumor response in a retrospective analysis of patients (pts) receiving trabectedin (T) for advanced soft tissue sarcomas (ASTS)”. In this trial, performed by the French Sarcoma Group, a cohort of 133 eligible patients treated with trabectedin (Yondelis®) in six hospitals was analyzed to identify the best tumor assessment method. Results suggested that tumor assessment based on both size and density (Choi assessment) provides more meaningful clinical information on tumor response to trabectedin compared with RECIST criteria, which is based only on tumor size assessment.

Other trabectedin (Yondelis®) abstracts that will be presented at ESMO 2014 include;

“Trabectedin combined with Hyperthermia: Characterization of enhanced drug-efficacy in human tumor cells”

“Low skeletal muscle density is predictive for febrile neutropenia in patients treated by doxorubicin/trabectedin/pegfilgrastim combination as a first-line treatment of advanced or metastatic leiomyosarcoma (LMS) (LMS-02 study)”
"Trabectedin and pegylated liposomal doxorubicin (PLD) versus carboplatin and PLD in partially platinum-sensitive ovarian cancer patients: INOVATYON study". (Trial in progress session)

PM01183 (Lurbinectedin), a promising compound

PharmaMar will also present a paper it has performed with its marine-based compound PM01183, one of the company's most promising drugs, entitled "Lurbinectedin (PM01183) on Days (D) 1 & 8 in combination with capecitabine (XEL) in patients (pts) with metastatic breast (MBC), colorectal (CRC) or pancreatic (Pa) cancer".

ESMO's mission

The European Society for Medical Oncology (ESMO) is the leading European professional organization, committed to advancing the specialty of medical oncology and promoting a multidisciplinary approach to cancer treatment and care. ESMO’s mission is to advance cancer care through fostering and disseminating best scientific practices which lead to better clinical practice and medicine by evaluating the most relevant innovations arising each year in the field of oncology.

About PharmaMar

PharmaMar is a biopharmaceutical subsidiary of Grupo Zeltia; it is a world leader in discovering, developing and marketing marine-based drugs to treat cancer. Yondelis® is the first marine-based antitumour drug. PharmaMar has four other compounds in clinical development: Aplidin®, 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. 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; Genómica, Spain's leading company in molecular diagnostics based on DNA analysis; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi).

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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