ZELTIA NEWS:

PharmaMar Announces Top line Results for PM01183 Phase II trial in Patients with Platinum Resistant/Refractory Ovarian Cancer

- ***30.3% of patients with platinum resistant disease responded to treatment with PM01183,* while no patients in the topotecan arm responded**
- ***82% of patients with platinum resistant disease treated with PM01183 compared to 50% of patients treated with topotecan exhibited a clinical benefit***
- ***The median progression-free survival (PFS) in resistant disease was 4.8 months for PM01183 and 1.7 months for topotecan (p=0.0004)***
- ***Although survival data is not yet mature, a significant increase in overall survival was observed in patients treated with PM01183 compared to topotecan***

Madrid, 12 September 2013: Zeltia today announced that its oncology subsidiary, PharmaMar, reported results of a multicenter, open-label Phase II trial of PM01183 in patients with platinum resistant/refractory ovarian cancer. The study was a two-stage trial, enrolling 22 patients in the first stage and 58 in the second part of the study. Patients in the first stage were treated with a one hour infusion of 7mg of PM01183 every three weeks. Results for the first stage of the trial were presented at the European Society for Medical Oncology (ECCO-ESMO-ESTRO) Congress in 2012 and are publicly available in Zeltia's website.

In the second stage of the trial, patients were treated with either PM01183 or topotecan. The primary endpoint was overall response rate (sum of complete responses plus partial responses). Progression free survival and overall survival were secondary endpoints in this study.

Thirty percent (30.3%) of platinum resistant patients had an objective response to treatment with PM01183, while no patients in the topotecan arm responded. Clinical benefit (sum of objective responses plus stable diseases) was observed in 82% of patients treated with PM01183 and in 50% of patients in the topotecan arm. Median progression-free survival in resistant patients was 4.8 months for PM01183 and 1.7 months with topotecan (p=0.0004). Survival data is not yet mature, but a significant increase in overall survival can be observed in patients treated with PM01183 compared to topotecan. Neutropenia was the most common adverse event in both treatment arms and unexpected toxicity was not observed with PM01183. Detailed results will be presented at the upcoming European Cancer Congress (ECCO-ESMO-ESTRO) that will take place in Amsterdam from September 27th to October 1st this year.

PharmaMar is now designing a pivotal phase III study for PM01183 in platinum resistant ovarian cancer patients, which will be submitted to the appropriate regulatory authorities.

About ovarian cancer

In the West, epithelial ovarian cancer represents 4% of all cancers among women and ranks fifth as a cause of female deaths from cancer (American Cancer Society [ACS], Cancer Reference Information, 2005). According to 2009 clinical data from the European Society for Medical Oncology (ESMO), ovarian cancer in the European Union affects 18 out of every 100,000 women per year, and the mortality rate is 12 per 100,000 women per year. The average age of diagnosis is 63, and the incidence increases with age; however, it may also occur in younger women, especially in those with a family history of the disease. Seventy per cent of women with ovarian cancer are diagnosed late, when the disease is already advanced (Stages III and IV). The 5-year survival rate for these women is only 15%-20%, compared with nearly 90% for patients in Stage I of the disease (i.e. the earliest stage) and 70% for Stage II (intermediate).

About PharmaMar

PharmaMar is a biopharmaceutical 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. 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 specialized 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 molecular diagnostics company and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi).

Disclaimer

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This note is also available on the PharmaMar and Zeltia websites: www.pharmamar.com and www.zeltia.com.