



Phase III trial with PM1183 in ovarian cancer (CORAIL) continues on the basis of positive recommendation by IDMC

Madrid, 8 February 2016 – PharmaMar (MSE:PHM) announced today that the Independent Data Monitoring Committee (IDMC) has notified the Company of its recommendation that the Phase III (CORAIL) trial currently under way with PM1183 in platinum-resistant ovarian cancer patients should continue without any changes.

The IDMC's recommendation came after an analysis of the safety data obtained with the first 80 patients treated in the trial. This pivotal randomised Phase III trial assesses the efficacy of PM1183 compared with the standard treatment for this indication—topotecan or pegylated liposomal doxorubicin—in a total of 420 patients.

About PM1183 (lurbinectedin)

PM1183 is an investigational drug from the class of inhibitors of the enzyme RNA polymerase II, which is crucially involved in transcription. By targeting transcription, the drug inhibits the expression of factors important for tumor progression, and impairs the DNA repair system called NER, thereby enhancing tumor cell killing. PM1183 (lurbinectedin) is currently being investigated in different tumor types, including a Phase 3 study for platinum-resistant ovarian cancer, a Phase 2 study for BRCA1/2-associated metastatic breast cancer and a Phase 1b study for small cell lung cancer.

About ovarian cancer

It is estimated that about 240,000 cases will be diagnosed worldwide and about 150,000 women will die of ovarian cancer. Among gynaecological malignancies, it is the second most common cancer and the one causing more deathsⁱ. Most patients with ovarian cancer have late-stage disease, in which the cancer has spread, at the moment of diagnosisⁱⁱ. Debulking surgery to remove most of the tumor is usually followed by chemotherapy; however, about 80% of women will relapse after treatment with platinum or a taxane and they may benefit from other therapeutic alternativesⁱⁱⁱ.

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS[®] in Europe and has other three clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom, Belgium and the United States. PharmaMar fully owns other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and two other chemical enterprises, Zelnova Zeltia and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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ⁱ Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <http://globocan.iarc.fr>, accessed on 15 April 2015.

ⁱⁱ <http://www.cancer.org/cancer/ovariancancer/>

ⁱⁱⁱ Ann Oncol (2013) 24 (suppl 10):x69-x76.doi: 10.1093/annonc/mdt475