



PharmaMar announces the IDMC´s response on the CORAIL trial using PM1183

Madrid, August 11th, 2016 – PharmaMar (MSE:PHM) announces that it has received the approval from the Independent Data Monitoring Committee (IDMC) to continue with the pivotal CORAIL study of PM1183 (lurbinectedin) in patients with platinum-resistant ovarian cancer up to the recruitment of the 420 patients established in the protocol.

This decision is based on the futility analysis of the first 210 patients (50% of the total 420), in which the safety and efficacy of PM1183 in this indication were evaluated.

CORAIL is a randomized Phase III Trial to evaluate the efficacy of PM1183 in comparison with topotecan or pegylated liposomal doxorubicin, standard treatment of care for this pathology, in 420 patients. The primary endpoint of this study is to evaluate the Progression Free Survival (PFS), the secondary objectives being to analyze overall survival (OS), objective response rate along with the patients´ quality of life parameters.

About PM1183 (lurbinectedin)

PM1183 is a compound under clinical investigation. It is an inhibitor of RNA polymerase II. This enzyme is essential for the transcription process that is over-activated in tumors with transcription addiction. The antitumor efficacy of lurbinectedin is being investigated in various types of solid tumors, including this Phase III study for platinum-resistant ovarian cancer, a Phase II study for BRCA 1 and BRCA 2-associated metastatic breast cancer and a Phase III 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 three other 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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ⁱⁱⁱ 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.

^{iv} <http://www.cancer.org/cancer/ovariancancer/>

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