

## PharmaMar initiates the phase III study CORAIL for the anticancer agent PM1183 in patients with platinum-resistant ovarian cancer

*The first patient for the pivotal study has been enrolled in the US*

**Madrid, June 29<sup>th</sup>, 2015:** PharmaMar announced today the start of a phase III study for the anticancer agent PM1183 in patients with platinum-resistant ovarian cancer (PROC). Once study objectives are met, the CORAIL trial (NCT02421588) will be used to support the regulatory filing of PM1183 as treatment for this indication.

The pivotal study is a randomized, open-label, and international multicenter trial designed to evaluate the activity and safety of PM1183 compared with investigator's choice of topotecan or pegylated liposomal doxorubicin (PLD) in patients with PROC. Enrolling a total of 420 women with unresectable disease across more than 100 medical centers in the US and Europe, the CORAIL trial will assess whether PM1183 can improve progression-free survival, as primary endpoint, compared to topotecan and PLD, which are currently approved for ovarian cancer in second-line treatment. Secondary outcome measures include assessing overall survival, overall response rate and patient-reported quality of life.

Data from the preceding phase II trial in these patients showed a progression-free survival of 5.7 months, which was significantly better compared to the 1.7 months achieved by patients treated with topotecan<sup>i</sup>.

Arturo Soto, Director of Clinical Development at PharmaMar said, "*Women with platinum-resistant ovarian cancer have poor prognosis and do not respond well to current therapies. PM1183 is a novel drug that works differently compared to other drugs used to treat this type of cancer.*"

### **About PM1183**

PM1183 is an investigational drug from the class of inhibitors of the enzyme RNA polymerase II, which is crucially involved in transcription<sup>ii</sup>. 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 (lurbinedin) 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 deaths<sup>iii</sup>. Most patients with ovarian cancer have late-stage disease, in which the cancer has spread, at the moment of diagnosis<sup>iv</sup>. 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 alternatives<sup>v</sup>.

### **About PharmaMar**

Headquartered in Madrid, PharmaMar is the world-leading biopharmaceutical company in advancing cancer care through the discovery and development of innovative marine-derived anticancer drugs. The company has a rich pipeline of drug candidates and a robust R&D oncology program. YONDELIS<sup>®</sup> is the first anticancer drug of marine origin and is commercially available in 81 countries for the treatment of advanced soft-tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL<sup>®</sup>/CAELYX<sup>®</sup>. PharmaMar develops and commercializes YONDELIS<sup>®</sup> in Europe and has three clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland and the United States. To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://www.pharmamar.com).

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<sup>i</sup> <http://meetinglibrary.asco.org/content/131577-144>

<sup>ii</sup> <http://www.pharmamar.com/en/press/pharmamar-results-antitumoral-compounds-and-their-mechanism-action-eortenciaacr-emphasize>

<sup>iii</sup> 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.

<sup>iv</sup> <http://www.cancer.org/cancer/ovariancancer/>

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