



PharmaMar initiates a pivotal Phase III ATLANTIS study with PM1183 in combination with doxorubicin in patients with small cell lung cancer

Madrid, August 2nd, 2016 – PharmaMar (MSE:PHM) today announced the start of a pivotal Phase III ATLANTIS study evaluating efficacy and safety of PM1183 (lurbinectedin) in combination with doxorubicin versus topotecan or the combination VCR (cyclophosphamide, adriamycin (doxorubicin) and vincristine) in patients with small cell lung cancer (SCLC) after the failure of one prior platinum-containing line. Topotecan is the only drug approved both in USA and Europe for this indication.

ATLANTIS is a multicenter, open-label, randomized, and controlled Phase III clinical trial that is to include 600 patients at clinical sites across 21 countries. The primary endpoint of this study is to improve the progression free-survival (PFS) of those patients that will be evaluated by an Independent Review Committee following Response Evaluation Criteria in Solid Tumors (RECIST 1.1). Secondary objectives include overall survival (OS); duration of the response (DR); along with quality of life indicators; response rate (RR) according to the RECIST 1.1 criteria; and also the correlation between pharmacokinetics and pharmacodynamics.

"We are pleased to start this pivotal Phase III clinical trial after PM1183 demonstrated encouraging results of the Phase IB study, where 67% of the patients responded to the treatment of lurbinectedin in combination with doxorubicin. In the Phase IB study we have seen a complete response, with total remission of the symptoms of the illness in 10% of the patients", explains Dr Arturo Soto, director of Clinical Development of PharmaMar's Oncology Business Unit, who also adds *"that the novel mechanism of action of PM1183, along with the synergy observed in the combination with doxorubicin, could provide a new treatment option for patients with small cell lung cancer, an indication that has such a poor prognosis".*

About PM1183 (lurbinectedin)

PM1183 is a compound of marine origin 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 a 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 small cell lung cancer

SCLC is a very aggressive cancer that usually presents with distant metastases and has already spread at the time of diagnosis, thus limiting the role of traditional approaches and posing a worse prognosis compared to other lung cancer types. The 5-year survival rate is about 5%ⁱ. About 18% of all the lung cancer cases diagnosed are SCLC, and only in the US more than 34,000 new cases are recorded every year. This tumor is strongly associated with tobacco smoking, posing an important public health problemⁱⁱ. After failure to treatment with a platinum-based therapy in first line, the therapeutic alternatives are very limited, and the approval of the last drug for this disease took place 20 years ago.

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.

Disclaimer

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.

Media Inquiries:

Paula Fdez. Alarcón – Media Relations

pfalarcon@pharmamar.com

Phone: +34 91 846 6000

Mobile: +34 638796215



Investor Relations:

Phone: +34 914444500

Or please visit our website at www.pharmamar.com

ⁱ <http://www.cancer.gov/types/lung/hp/small-cell-lung-treatment-pdq>

ⁱⁱ <http://www.jnccn.org/content/11/1/78.full.pdf>