PharmaMar presents new data on lurbinectedin for Small Cell Lung Cancer at ESMO 2023

- The Company will also present other research results on trabectedin for leiomyosarcoma.

Madrid, October 18th, 2023. – PharmaMar (MSE:PHM) has announced today that it will present new data on lurbinectedin in Small Cell Lung Cancer (SCLC) at the European Society for Medical Oncology (ESMO) congress, being held in Madrid from October 20-24th.

Among the most outstanding studies will be an oral presentation by Dr. Antonio Calles, where final data from the LUPER trial of lurbinectedin in combination with pembrolizumab (immunotherapy) in second-line SCLC will be presented. The presentation called “Lurbinectedin (LUR) in combination with pembrolizumab (PBL) in relapsed small cell lung cancer (SCLC): the phase 1/2 LUPER study” concludes that the combination of lurbinectedin and pembrolizumab is an effective second-line treatment for SCLC in patients who did not receive prior immunotherapy, achieving in some cases deep and durable responses, with a manageable safety profile and no new emerging signs of toxicity when combining the two drugs.

Dr. Antonio Calles, Specialist in Medical Oncology at the Hospital General Universitario Gregorio Marañón, Madrid, Spain, who has led the study, comments "the combination represents an opportunity for those patients with metastatic SCLC, who could not be treated with first-line immunotherapy. The treatment achieved a confirmed response rate of 46.4%, including deep and durable responses that exceeded one year in some patients. Median Progression-Free Survival (PFS) was significantly longer for platinum-sensitive patients compared to platinum-resistant patients, with a PFS of 10 versus 3 months, respectively. Currently, the only treatment other than lurbinectedin approved for this indication in the last 2 decades, has a response rate of only ~20% and a PFS of 4 months, in addition to very significant
toxicity. However, here we saw no unexpected side effects both drugs could be safely combined at full doses”.

Dr. Ali Zeaiter, Vice President and Head of Clinical Development at PharmaMar said: "We are pleased to present new data on the combination of lurbinectedin with immunotherapy. We believe that these data, with the suggested improvements in patients’ outcomes, confirm once again that lurbinectedin is an important treatment option for relapsed SCLC and support the ongoing investigation of lurbinectedin combination with immunotherapy”.

In addition to the above presentation, the study entitled “A randomised, multicenter phase-III study comparing doxorubicin (dox) alone versus dox with trabectedin (trab) followed by trab in non-progressive patients (pts) as first-line therapy, in pts with metastatic or unresectable leiomyosarcoma (LMS): Final results of the LMS-04 study” will show the final Overall Survival (OS) data for the combination of doxorubicin and trabectedin of 33.1 months versus 23.8 months for doxorubicin alone. These data confirm that this is the first drug combination that is able to demonstrate benefit in both PFS and OS in a phase III trial in first-line treatment of metastatic leiomyosarcoma. These data have supported further the rationale of also studying lurbinectedin in sarcoma.

Lead investigator, Dr. Patricia Pautier, from the Institut Gustave Roussy in Villejuif, Paris, France, comments "the final results were positive with a median progression-free survival (PFS) statistically improved from 6.2 months with doxorubicin alone to 12.2 months with the combination."
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<td>Zepzelca® (lurbinectedin)</td>
<td>Lurbinectedin (LUR) in combination with pembrolizumab (PBL) in relapsed small cell lung cancer (SCLC): the phase 1/2 LUPER study</td>
<td>Dr. Antonio Calles</td>
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<td>Lurbinectedin (LRB) pharmacokinetics (PK) and safety when co-administered with itraconazole (ITZ) in patients with advanced solid tumor</td>
<td>Dra. Irene Moreno</td>
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<td>Supportive measures to control myelosuppression and costs for patients with SCLC with lurbinectedin, CAV or topotecan with or without trilaciclib: a review on the basis of clinical trials</td>
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<td>Yondelis® (trabectedin)</td>
<td>A randomised, multicenter phase-III study comparing doxorubicin (dox) alone versus dox with trabectedin (trab) followed by trab in non-progressive patients (pts) as first-line therapy, in pts with metastatic or unresectable leiomyosarcoma (LMS): Final results of the LMS-04 study</td>
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<td>TOMAS2: a randomized phase 2 study from the Italian Sarcoma Group (ISG) of trabectedin plus olaparib (T+O) or trabectedin (T) in advanced, metastatic, or unresectable soft tissue sarcomas (STS) after failure of standard treatments.</td>
<td>Lorenzo D’Ambrosio</td>
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<td>Tolerability and efficacy of trabectedin plus pegylated liposomal doxorubicin (PLD) in elderly patients with ovarian cancer (OC) - GEICO 105-0 Study</td>
<td>Maria Jesús Rubio</td>
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<td>Javier Martin Broto</td>
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About PharmaMar
PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation. PharmaMar has developed and now commercializes Yondelis® in Europe by itself, as well as Zepzelca® (lurbinectedin), in the US; and Aplidin® (PLITIDEPSIN), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectin, ecubectedin, PM534 and PM54. It also has a preclinical and clinical program in virology. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland and The United States. PharmaMar also wholly owns Sylentis, a company dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

About Yondelis®
Yondelis® (trabectedin) is a novel, synthetically produced antitumor agent originally isolated from Ecteinascidia turbinata, a type of sea squirt. Yondelis® exerts its anticancer effects primarily by inhibiting active transcription, a type of gene expression on which proliferating cancer cells are particularly dependent.

About Zepzelca®
Zepzelca® (lurbinectedin), also known as PM1183, is an analog of the marine compound ET-736 isolated from the sea squirt Ecteinacidia turbinata in which a hydrogen atom has been replaced by a methoxy group. It is a selective inhibitor of the oncogenic transcription programs on which many tumors are particularly dependent. Together with its effect on cancer cells, lurbinectedin inhibits oncogenic transcription in tumor-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumor. Transcriptional addiction is an acknowledged target in those diseases, many of them lacking other actionable targets.

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