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In accordance with Article 17 of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation) and Article 226 of the recast Spanish Securities Market Act (*Ley del Mercado de Valores*), the following **RELEVANT EVENT** is hereby reported:

Further to relevant event published on August 19, 2019 (registered number 281246), Pharma Mar has submitted to the FDA (Food and Drug Administration) in the United States the New Drug Application (NDA) for lurbinectedin, in monotherapy, for the treatment of relapsed Small Cell Lung Cancer (SCLC), under the "accelerated approval" regulations.

Please find attached press release that will be distribute to the media today.

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# PharmaMar has filed New Drug Application for lurbinectedin with the FDA for the treatment of relapsed small cell lung cancer

- **The Company has filed the New Drug Application (NDA) for lurbinectedin, in monotherapy, for the treatment of relapsed Small Cell Lung Cancer (SCLC), under the "accelerated approval" regulations.**
- **The NDA is based on the phase II multicenter basket trial data.**
- **The lurbinectedin monotherapy basket trial for SCLC achieved its primary endpoint of Overall Response Rate (ORR).**

**Madrid, December 17th, 2019.-** PharmaMar (MSE:PHM) has announced that it has submitted to the FDA (Food and Drug Administration) in the United States the New Drug Application (NDA) for lurbinectedin for the treatment of patients with SCLC who have progressed after prior platinum-containing therapy, under the accelerated approval regulations.

This NDA is based on data from the phase II monotherapy basket trial with lurbinectedin for the treatment of SCLC, the results of which were presented at the American Society of Clinical Oncology (ASCO) meeting in June this year. A total of 105 patients from 39 centers in more than 8 Western European countries in addition to the United States were recruited. The trial met its primary endpoint of the Overall Response Rate (ORR) by both investigator and IRC (Independent Review Committee) assessment.

The FDA's accelerated approval procedure allows for the submission of an NDA for evaluation based on the results of phase II drug investigations for the treatment of serious diseases that cover an unmet medical need. Relapsed SCLC treatment has not changed substantially in more than two decades with the last new chemical entity approved by the FDA in this setting being topotecan, in 1996.

*"The application for registration under accelerated approval regulations gives us the possibility that the FDA could approve lurbinectedin in the US for treatment of small cell lung cancer in 2020 and that, if approval is obtained, could begin to be marketed*

*in the second half of 2020 in the United States",* explains **Luis Mora**, General Manager of PharmaMar's Oncology Business Unit.

**Dr. Charles Rudin**, Chief of the Thoracic Oncology Service at Memorial Sloan Kettering Cancer Center and principal investigator of the NCI Small Cell Lung Cancer Consortium, said *"It is great to finally see some new therapeutic options arriving for small cell lung cancer patients, who represent a major unmet medical need. I have been following the emerging clinical trial data on lurbinectedin, which suggest appealing efficacy and a tolerable safety profile. I believe many treating physicians may welcome lurbinectedin, if approved, as a new standard of care option for their patients with recurrent small cell lung cancer."*

We would like to extend our sincerest gratitude to the patients, their families and caregivers, as well as the dedicated medical teams who participated in our clinical trials studies and helped bring lurbinectedin to this point.



**About PharmaMar**

Headquartered in Madrid, PharmaMar is a biopharmaceutical company, focused on oncology and committed to research and development which takes its inspiration from the sea to discover molecules with antitumor activity. It is a company that seeks innovative products to provide healthcare professionals with new tools to treat cancer. Its commitment to patients and to research has made it one of the world leaders in the discovery of antitumor drugs of marine origin.

PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes Yondelis® in Europe and has other clinical-stage programs under development for several types of solid cancers: lurbinectedin (PM1183), PM184 and PM14. With subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar wholly owns other companies: GENOMICA, a molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

**About lurbinectedin**

Lurbinectedin (PM1183) is a synthetic compound currently under clinical investigation. 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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