# PharmaMar will submit NDA for lurbinectedin under accelerated approval in SCLC in the USA

- **New Drug Application (NDA) for lurbinectedin for second-line treatment of small cell lung cancer (SCLC) will be submitted under accelerated approval regulations pursuant to discussion with FDA.**
- **The filing, anticipated in the fourth quarter of 2019, will be based on data from the Phase II basket trial.**
- **The lurbinectedin monotherapy trial in SCLC achieved its primary endpoint of Overall Response Rate (ORR), both by investigator review and by the Independent Review Committee (IRC) assessment.**

**Madrid, August 19th, 2019.-** PharmaMar (MSE:PHM) today announced that the FDA (Food and Drug Administration) agreed with PharmaMar's proposal to file for accelerated approval its New Drug Application (NDA) for lurbinectedin monotherapy for the treatment of second-line SCLC.

The FDA's accelerated approval program allows the submission of the registration dossier for evaluation based on investigational drug results of a Phase II study for serious conditions that satisfy an unmet medical need.

The application will be based on data from the SCLC cohort of the lurbinectedin Phase II monotherapy basket trial that enrolled a total of 105 patients at 39 centers in more than 9 countries in Western Europe and the United States. The primary endpoint of Overall Response Rate (ORR), was achieved by both the investigator and the Independent Review Committee (IRC) assessment. Secondary endpoints included Duration of Response (DOR), Progression-Free Survival (PFS), Overall Survival (OS), and safety.

PharmaMar anticipates that the NDA filing will take place in the fourth quarter of 2019.

**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.

**Media Contact:**

Alfonso Ortín – Communications Director aortin@pharmamar.com Mobile: +34 609493127
Miguel Martínez-Cava – Communication Manager mmartinez-cava@pharmamar.com Mobile: +34 606597464
Phone: +34 918466000

**Investor Relations:**

José Luis Moreno Martínez-Losa – Capital Markets & Investor Relations Director
investorrelations@pharmamar.com
Phone: +34 914444500

Or please visit our website at www.pharmamar.com