The U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation to PharmaMar's lurbinectedin

- **The U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation to lurbinectedin for the treatment of small cell lung cancer (SCLC)**
- **SCLC is a very aggressive cancer, about 18% of all the lung cancer cases diagnosed are SCLC, and in the US alone more than new 34,000 new cases are diagnosed every year**

Madrid, August 3rd, 2018. PharmaMar (PHM:MSE) announces that lurbinectedin has been granted orphan drug status by the FDA for the treatment of small cell lung cancer.

The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan Drug designation may provide certain benefits, including a 7-year period of market exclusivity if the drug is approved, tax credits for qualified clinical trials, and an exemption from FDA application fees.

"We are delighted to receive this orphan drug designation as it underscores the great need for innovative, effective treatments for this cancer, and recognizes the potential benefits that lurbinectedin may provide for patients with small cell lung cancer," said **Luis Mora**, Managing Director of the Oncology Business Unit of PharmaMar. *"Receiving orphan drug designation for the treatment of small cell lung cancer (SCLC) is a significant regulatory milestone in the development of lurbinectedin",* has added.

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 a pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has other clinical-stage programs under development for several types of solid and hematological cancers, Zepsyre® (lurbinectedin, PM1183), plitidepsin, PM184 and PM14. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom, Belgium, Austria and the United States. PharmaMar fully owns other companies: GENOMICA, a

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.

About lurbinectedin

Lurbinectedin (PM1183) is a compound 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.

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 problem[ii]. 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.

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[i] http://www.cancer.gov/types/lung/hp/small-cell-lung-treatment-pdq
[ii] http://www.jnccn.org/content/11/1/78.full.pdf