PharmaMar has filed lurbinectedin for Temporary Marketing Authorisation with the Swiss Agency for Therapeutic Products

- **The Company has filed for lurbinectedin's "*Temporary Authorisation*", in monotherapy, for the treatment of relapsed Small Cell Lung Cancer (SCLC).**
- **The filing is based on the phase II multicentre *basket trial* efficacy data.**
- **The lurbinectedin monotherapy basket trial for SCLC achieved its primary endpoint of Overall Response Rate (ORR).**

Madrid, 20th July, 2020.- PharmaMar (MSE:PHM) has announced that it has submitted lurbinectedin for "*Temporary Authorisation*" for marketing to the Swiss Agency for Therapeutic Products (Swissmedic) for the treatment of patients with SCLC who have progressed after prior platinum-containing therapy.

This filing is based on data from the phase II monotherapy *basket trial* with lurbinectedin for the treatment of SCLC. The data, which appeared in *The Lancet Oncology*[1], in the May 2020 issue, showed that in relapsed SCLC, lurbinectedin demonstrated an Overall Response Rate (ORR) of 35 percent and a median Duration of Response (DoR) of 5.3 months, as measured by investigator assessment (30 percent and 5.1 months respectively, as measured by an independent review committee (IRC).

Temporary authorisation is granted by Swissmedic under certain conditions to make medicinal products for the treatment of life-threatening diseases available to patients as quickly as possible. It is a streamlined procedure with shorter overall timelines than that of a standard registration procedure. There must be no alternative medicinal product authorised or available in Switzerland. Major therapeutic benefit is expected from use of the product for which authorisation is being requested.

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 (Zepzelca™), 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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[1] Trigo J. et al, Lancet Oncology, 2020, Vol 21 (5), P645-654