

## **PharmaMar announces that Zepsyre® (lurbinectedin) shows noteworthy clinical activity in metastatic breast cancer with mutations in BRCA 1/2**

- **A multicenter phase II trial has evaluated lurbinectedin, a selective inhibitor of active transcription of certain genes, in patients with metastatic breast cancer derived from mutations in BRCA 1/2.**
- **The response and survival rates with lurbinectedin have been more pronounced in patients with BRCA2 mutations, highlighting the anti-tumor activity of this molecule.**
- **In the prior, untreated PARP population, the confirmed ORR was 72%, this being the highest reported figure in this tumor setting so far.**

**Madrid, 8<sup>th</sup> of November, 2018** – Zepsyre® (lurbinectedin), from PharmaMar (MSE:PHM), showed noteworthy clinical activity in patients with metastatic breast cancer that have mutations in the BRCA 1 and/or BRCA 2 genes. This is the conclusion contained in the "[The Lancet Oncology](#)" and the "[Journal of Clinical Oncology](#)", in their September and November issues, respectively; both having published the positive results of PharmaMar's phase II trial.

This trial intended to assess the clinical activity of lurbinectedin in patients affected by metastatic breast cancer in BRCA 1 and/or BRCA 2 gene mutations.

It is important to highlight that in the patients with BRCA2 mutations, the confirmed overall response rate (ORR) was observed to be 61%, the median progression-free survival (PFS) was observed to be 5.9 months and the median overall survival (OS) was observed to be 26.6 months.

In the prior, untreated PARP population, the confirmed ORR was 72%, this being the highest reported figure in this tumor setting so far.

The 54 breast cancer patients with mutations in the BRCA 1 and/or BRCA 2 genes included in the trial were recruited from 11 research centers in the United States and Spain.

*"Lurbinectedin is a selective inhibitor of active transcription of protein-coding genes,"* explained by Judith Balmaña (Vall d'Hebron Institute of Oncology) in [The Lancet](#)

[Oncology](#). "In this phase II trial, it showed a notable efficacy in patients with metastatic breast cancer and a germline BRCA1/2 mutation."

#### **Legal warning**

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#### **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 ty-pes 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); and a chemical enterprise, Zelnova Zeltia. To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://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.

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