

## PharmaMar announces the initiation of a study of lurbinectedin in combination with immunotherapy

- **This is a Phase I-II study to determine the recommended dose and efficacy of lurbinectedin in combination with atezolizumab (Roche) in patients with advanced Small Cell Lung Cancer (SCLC).**

**Madrid, January 14<sup>th</sup>, 2020.-** PharmaMar (MSE:PHM) has announced the start of a Phase I-II clinical trial in Spain to determine the recommended dose and efficacy of lurbinectedin in combination with atezolizumab (Roche) in patients with advanced SCLC whose disease has progressed following previous platinum-based chemotherapy. The first patient has already been enrolled.

This is a prospective, open-label, multi-center study which will include two parts: a Phase I study with primary objective to determine the Recommended Dose (RD) of the lurbinectedin-atezolizumab combination, followed by a Phase II, single-arm study, with an expansion cohort of patients treated at the RD, this being determined during the Phase I part. The primary endpoint of the Phase II part is to evaluate the efficacy of the combination in terms of Overall Response Rate (ORR). Secondary objectives include Duration of Response (DoR), Progression-Free Survival (PFS) and Overall Survival (OS), in addition to the safety profile and tolerability of the combination.

Lurbinectedin has shown in [pre-clinical studies](#) that its mechanism of action induces cell death, reinstates and enhances systemic anticancer immune responses, resulting in a long-term immunological memory effect, underlining the potency of lurbinectedin combination with immunotherapy.

According to **Dr. Luis Paz-Ares**, Head of the Oncology Department at the 12 de Octubre University Hospital in Madrid and principal investigator of the study, *"the efficacy demonstrated by lurbinectedin as a single agent in the Phase II Basket trial and the results seen in preclinical combinations with immunotherapy make us optimistic about the start of this new trial, with which we hope to provide a new treatment option for patients with small-cell lung cancer"*.

SCLC is a very aggressive cancer that is usually diagnosed with advanced, often metastatic disease, limiting the role of traditional approaches and posing a worse prognosis when compared to other lung cancers. About 14% of lung cancers are

Small Cell<sup>1</sup>, with about 30,000 new cases in the United States alone each year<sup>2</sup>. This tumor is strongly associated with smoking, which is a major public health problem.

#### **Legal warning**

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

#### **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](http://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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<sup>1</sup> NCCN Guidelines US 2019

<sup>2</sup> GLOBOCAN 2018



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