



## **PharmaMar announces that lurbinectedin has received acceptance for its clinical trial application in China**

**Madrid, June 29<sup>th</sup>, 2020.-** PharmaMar (MSE:PHM) has announced today along with its partner in China, Luye Pharma Group Ltd., that the clinical trial application of lurbinectedin for Small Cell Lung Cancer (SCLC) has received formal acceptance from the Centre for Drug Evaluation (CDE) of the People's Republic of China.

In April 2019, PharmaMar and Luye Pharma entered into a license development and commercialization agreement with respect to lurbinectedin, by which PharmaMar received an upfront of \$5 million. Pursuant to the terms of the agreement, Luye Pharma is committed to develop lurbinectedin in SCLC in China, while PharmaMar retains exclusive production rights for the compound.

According to data from the World Health Organization (WHO), China has the highest number of cancer cases in the world, due to an aging population, tobacco and pollution. China is also the country with the highest mortality rate in Asia for lung cancer. Lung cancer affects a larger number of people in China than in the U.S., Europe and Japan combined. The WHO estimates that in 2020, 800,000 new cases of lung cancer will be diagnosed and will cause nearly 700,000 deaths. It is estimated that SCLC represents approximately 18% of all lung cancers in China.

Lurbinectedin was approved on June 15<sup>th</sup>, 2020, by the US Food and Drug Administration (FDA) for the treatment of adult patients with metastatic SCLC cancer with disease progression, after platinum-based chemotherapy. This approval is based on monotherapy clinical data from an open-label, multi-center, single-arm study in 105 adult platinum-sensitive and platinum-resistant patients with relapsed SCLC<sup>1</sup>. The data, which appeared in the May 2020 issue of *The Lancet Oncology*, showed that in relapsed SCLC, lurbinectedin demonstrated an Overall Response Rate (ORR) of 35% and a median Duration of Response (DoR) of 5.3 months as measured by investigator assessment (30% and 5.1 months respectively, as measured by an independent review committee (IRC).

**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 Luye Pharma Group**

Luye Pharma Group is an international pharmaceutical company dedicated to the R&D, manufacturing and sale of innovative medications. The company has a robust pipeline of 40 drug candidates in China and more than 10 drug candidates overseas. The company currently has a number of new drugs and new formulations in the central nervous system and oncology therapeutic areas under study in the U.S. and Europe. Luye Pharma has set up 7 manufacturing sites with over 30 production lines in total, establishing GMP quality management and international standard control systems. The company offers more than 30 products covering the four largest and fastest growing therapeutic areas — oncology, cardiovascular, metabolism and central nervous system, with business conducted in over 80 countries and regions around the world, including the largest pharmaceutical markets - China, the U.S., Europe and Japan, as well as fast growing emerging markets.

#### **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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<sup>1</sup> Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncol.* 2020 May;21(5):645-654.