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In accordance with the provisions of article 227 of the Spanish Securities Markets and Investment Services Act (*Ley de los Mercados de Valores y de los Servicios de Inversión*), approved by Law 6/2023, of 17 March, and concordant provisions, is hereby reported the following:

**OTHER RELEVANT INFORMATION**

Pharma Mar, S.A. announces together with its partner Luye Pharma Group Ltd. that the New Drug Application (NDA) submission of lurbinectedin has been accepted by the Centre for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in the People's Republic of China (China) for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression on or after receiving platinum-based chemotherapy.

Please find attached press release that Pharma Mar, S.A. will distribute to the media.

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# PharmaMar and Luye Pharma announce the acceptance of New Drug Application for lurbinectedin in China

**Madrid, June 6th, 2023.** – PharmaMar (MSE:PHM) and Luye Pharma Group Ltd. have announced today that the New Drug Application (NDA) submission of lurbinectedin has been accepted by the Centre for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in the People's Republic of China (China) for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression on or after receiving platinum-based chemotherapy.

In April 2019, PharmaMar and Luye Pharma signed an agreement for the development and commercialization of lurbinectedin in Small Cell Lung Cancer (SCLC), and potentially in other indications in mainland China, Hong Kong and Macao.

In 2020, lurbinectedin received Accelerated Approval from the U.S. Food and Drug Administration (FDA) and subsequently received approvals in 9 other countries for the treatment of metastatic SCLC, and has been filed in several countries.

The NDA is based on data from a single-arm, dose-escalation, and dose-expansion clinical study conducted in China. The study was designed to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of lurbinectedin in Chinese patients with advanced solid tumors including relapsed SCLC. The results of the study show efficacy and a manageable safety profile of the drug as a second-line therapy at a dose of 3.2mg/m2 in Chinese SCLC patients, the same dose that has been approved in the United States and in other countries. It was confirmed by an Independent Review Committee that the Overall Response Rate (ORR) was 45.5% in subjects with relapsed SCLC.

The clinical study conducted in China was the first study evaluating the efficacy and safety of lurbinectedin in Chinese patients. The preliminary results of this study were presented at the 2022 annual meeting of the American Society of Clinical Oncology (ASCO), as well as the 25th National Clinical Oncology Conference and the 2022 annual meeting of the Chinese Society of Clinical Oncology.

In addition to mainland China, lurbinectedin is also being reviewed for its NDA in the Hong Kong and Macao SAR of China and has the –authorization for urgent clinical use in Hainan region and Hong Kong.

Lung cancer was China's No.1 cancer in 2020 in terms of morbidity and mortality, with approximately 815,000 new cases and 714,000 deaths that year. Specifically, SCLC accounted for 13%-17% of all lung cancer cases[1]. Most SCLC patients were already at the advanced stage upon diagnosis, resulting in poor prognosis. Their five-year survival rate was only 7% or as low as 3% for those patients with the extensive stage of the disease. Although SCLC is very sensitive to initial treatments, most patients would experience a relapse or develop drug resistance after initial treatments. According to statistics, approximately 75% of the patients with locally advanced SCLC and more than 90% of those with metastatic SCLC would relapse within two years after receiving treatment. The high relapse rate of SCLC poses a significant challenge to its treatment, and innovative therapies are urgently needed in clinical practice.



**About Zepzelca®**

Zepzelca® (lurbinectedin), 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.

**About PharmaMar**

PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation.

[1] Data Monitor: Small Cell Lung Cancer (SCLC) Globocan 2020. All ages, both genders.

PharmaMar has developed and now commercializes Yondelis® in Europe by itself, as well as Zepzelca® (lurbinectedin), in the US; and Aplidin® (plitidepsin), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectedin, ecubectedin, PM534 and PM54. It also has a preclinical and clinical program in virology. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland and The United States. PharmaMar also wholly owns Sylentis, a company dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

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