



CNMV  
Markets Directorate General  
C/ Edison núm. 4  
28006 Madrid

Madrid, September 1, 2021

In accordance with article 227 of the recast Spanish Securities Market Act (*texto refundido de la Ley del Mercado de Valores*), approved by Royal Legislative Decree 4/2015, of 23 October, and related provisions, is hereby reported the following:

#### **OTHER RELEVANT INFORMATION**

Pharma Mar, S.A. announces that its licensing partner, Immedica Pharma AB (Immedica) has received marketing approval for Zepzelca® (lurbinectedin) by the Ministry of Health and Prevention of the United Arab Emirates (UAE) for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression after platinum-based chemotherapy.

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

**Pharma Mar S.A.**  
**Avda. de los Reyes, 1**  
**P.I. La Mina**  
**28770 Colmenar Viejo**  
**(Madrid) Spain**  
**[www.pharmamar.com](http://www.pharmamar.com)**



## PharmaMar announces the approval of Zepzelca<sup>®</sup> (lurbinectedin) for the treatment of metastatic Small Cell Lung Cancer in the United Arab Emirates

- This approval is based on overall response rate and duration of response, demonstrated in the open-label, monotherapy clinical trial.
- Approval represents an important advance for adult patients with Small Cell Lung Cancer (SCLC) that have progressed after platinum-based chemotherapy.

Madrid, September 1<sup>st</sup>, 2021. – PharmaMar (MSE:PHM) has announced today that its licensing partner, Immedica Pharma AB (Immedica) has received marketing approval for Zepzelca<sup>®</sup> (lurbinectedin) by the Ministry of Health and Prevention of the United Arab Emirates (UAE) for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression after platinum-based chemotherapy.

The approval of lurbinectedin by UAE Ministry of Health and Prevention is based on results from the open label, multi-center, single-arm clinical trial in 105 adults with relapsed SCLC<sup>1</sup>. The data, which appeared in *The Lancet Oncology*, in the May 2020 issue, showed that in relapsed SCLC, monotherapy with lurbinectedin had an overall response rate of 35% and a median duration of response of 5.3 months according to investigator assessments. The FDA approval was based on the same data.

This approval will allow Immedica to make lurbinectedin commercially available in the UAE in the following months.

PharmaMar has a strategic alliance/partnership with Immedica, both companies are committed to bringing innovative therapies to patients worldwide.

*"This is the second authorization of lurbinectedin from a regulatory agency, which will provide relapsed SCLC patients with a new treatment option in UAE,"* said **Luis Mora**, Managing Director of the PharmaMar's Oncology & Virology Business Units.



**Anders Edvell**, CEO at Immedica Pharma, said: *"Small cell lung cancer is a disease with limited treatment options. The approval of lurbinectedin in United Arab Emirates represents an important treatment option for patients whose metastatic SCLC has progressed after traditional chemotherapy such as platinum-based therapy"*.

#### **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**

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. 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 and PM14. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar also wholly owns other companies: GENOMICA, a molecular diagnostics company; and 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 Immedica AB**

Immedica is a fast-growing private niche pharma group with headquarter in Stockholm, Sweden and commercial coverage across Europe and the Middle East.

Immedica has significant know-how and experience in commercialization of niche/specialty care products across Europe and the Middle East, and the company's management team has an outstanding track record of operating niche pharma products internationally. Immedica has capabilities to provide optimal access of specialty care medicines to patients with significant medical needs, including key areas such as regulatory affairs, pharmacovigilance, medical affairs, pricing & reimbursement, quality, and product distribution.

Immedica's main owner is Impilo AB, a private Nordic investment company established in 2017.

More information is available at [www.immedica.com](http://www.immedica.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.

**Media Contact:**

Alfonso Ortín – Communications Director [aortin@pharmamar.com](mailto:aortin@pharmamar.com) Mobile: +34 609493127  
Miguel Martínez-Cava – Communication Manager [mmartinez-cava@pharmamar.com](mailto:mmartinez-cava@pharmamar.com) Mobile: +34 606597464

Phone: +34 918466000

**Capital Markets & Investor Relations:**

José Luis Moreno– Capital Markets & Investor Relations Director  
María Marín de la Plaza – Capital Markets & Investor Relations  
[investorrelations@pharmamar.com](mailto:investorrelations@pharmamar.com)  
Phone: +34 914444500



Or please visit our website at [www.pharmamar.com](http://www.pharmamar.com)

---

<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.