

## PharmaMar and Bionical Emas launch Expanded Access Program for lurbinectedin in relapsed Small Cell Lung Cancer in the U.S.

**Madrid, January 27<sup>th</sup>, 2020.-** PharmaMar (PHM:MSE) and Bionical Emas, a global specialist Clinical Research Organization (CRO) have today announced the launch of an Expanded Access Program (EAP) for lurbinectedin to treat patients in the United States (U.S.) with relapsed Small Cell Lung Cancer (SCLC), who are unable to enter clinical trials and there are no appropriate alternative treatments.

**Dr. Jack West**, Associate Clinical Professor, City of Hope Cancer Center, Duarte, CA, said: *"I welcome the availability of lurbinectedin through the EAP as an option for patients. This disease has few compelling alternatives in this setting, so this would be a very welcome option for physicians and patients alike."*

SCLC is a very aggressive cancer that is usually diagnosed with advanced, often metastatic disease, thus limiting the role of traditional approaches and usually posing a worse prognosis when compared to other lung cancers<sup>1</sup>. In the U.S., approximately 10-15% of lung cancers are small cell<sup>1</sup>. Approximately 30,000 new cases of SCLC are recorded in the U.S. every year<sup>2</sup>. The treatment of relapsed SCLC has not changed substantially in more than two decades.

SCLC is one of PharmaMar's priority research areas. In December 2019, the Company announced the filing of lurbinectedin's New Drug Application (NDA) for the treatment of relapsed SCLC with the FDA under the "accelerated approval" program.

*"SCLC is a devastating disease for patients and their families, having limited effective treatment options. We are excited to be able to provide access to lurbinectedin to eligible patients across the U.S."*, said **Tom Watson**, Executive Vice President, Bionical Emas.

*"I am happy to see the launch of the lurbinectedin EAP in the U.S. today. Relapsed SCLC is a very aggressive disease with existing second line treatments showing only limited effectiveness. As oncology physicians, we are constantly looking for new treatment options for our patients. There is only one approved drug for the*

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<sup>1</sup> American Cancer Society, <https://www.cancer.org/cancer/small-cell-lung-cancer/about/what-is-small-cell-lung-cancer.html> (accessed December 17, 2019)

<sup>2</sup> SEER Cancer Stat Facts – Lung and Bronchus Cancer, <https://seer.cancer.gov/statfacts/html/lungb.html> (accessed December 17, 2019)

*second line treatment which has modest benefit and significant side effects, and there are currently no other open EAPs. Providing access to this new option for patients requires time and investment from the Company and it is greatly appreciated by physicians in the clinic”, said **Dr. William Jeffrey Petty**, Professor, Hematology and Oncology, Wake Forest Baptist Health, Winston-Salem, North Carolina.*

Healthcare professionals wishing to request access to lurbinectedin under the EAP or who would like to find out more should do so by emailing [Lurbinectedin.EAP@Bionical-Emاس.com](mailto:Lurbinectedin.EAP@Bionical-Emاس.com).

Further details concerning the EAP in the U.S. can be found on [Clinicaltrials.gov](https://Clinicaltrials.gov).

#### **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 Bionical Emاس**

Bionical Emاس is a specialist CRO combining Clinical Development, Early Access Programs and Clinical Trial Supply.

Its Early Access Programs provide companies a route to allow access to pre-approved medicines to help patients with unmet medical needs.

Access is provided in response to physician requests, where no alternative treatment options are available, and the patient is not eligible for clinical trials for the condition.

<https://bionicaemas.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.

**Bionical Emاس contact:**

Tom Watson, Executive Vice President, Early Access Programs

[tom.watson@bionical-emas.com](mailto:tom.watson@bionical-emas.com)

**PharmaMar 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

**PharmaMar Investor Relations:**

José Luis Moreno Martínez-Losa – Capital Markets & Investor Relations Director

[investorrelations@pharmamar.com](mailto:investorrelations@pharmamar.com)

Phone: +34 914444500

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