



National Securities Market Commission  
Markets Directorate General  
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Colmenar Viejo (Madrid), May 16, 2019

Pursuant to Article 17 of Regulation (EU) n° 596/2014 on market abuse and Article 226 of the consolidated text of the Spanish Securities Market Act, approved by Royal Legislative Decree 4/2015, of 23 October, we hereby make the following **REGULATORY ANNOUNCEMENT**:

“In relation to Significant Facts n° 276.396 and 276.625 dated March 25, 2019 and April 1, 2019, respectively, Pharma Mar, S.A. announces that ASCO (American Society of Clinical Oncology) has published the abstracts that will be presented in its 19° annual congress, to be held in Chicago (EE.UU.) from May 31 to June 4, 2019, including the abstract titled “ Efficacy and safety profile of lurbinectedin in second-line SCOLC patients: results from a phase II single-agent trial “ that was selected by ASCO for oral presentation.

According to the referred abstract, Lurbinectedin showed an Overall Response Rate (ORR) of 35.2% in the overall population and 46.6% and 21.3% in sensitive (CTFI $\geq$ 90 days, this meaning those patients who have suffered a relapse of the disease in a period greater than or equal to 90 days) and resistant patients (CTFI $<$ 90 days, this meaning those patients who have suffered a relapse of the disease in a period of less than 90 days), respectively. The median Duration of Response (DOR) was 5.3 months in the overall population and 6.2 and 4.7 months, respectively, in sensitive and resistant patients.

The oral presentation will take place on 1<sup>st</sup> June at 1:15 PM (CST). Luis G. Paz-Ares, MD, PhD, Professor of Medicine at the Hospital Universitario 12 de Octubre in Madrid and lead author of the study, will present updated results of lurbinectedin as a single agent in second line small cell lung cancer. In addition to the efficacy data, relevant safety data will also be presented. Dr. Paz-Ares and PharmaMar's management will organize a conference with investors after the presentation of the data, information for which PharmaMar announce at a later time.

Please find attached press release that will be distribute to the media today”.

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## **ASCO releases abstracts and publishes PharmaMar's lurbinectedin data in second line small cell lung cancer**

- **The phase II single-arm trial of Lurbinectedin in second line small cell lung cancer has met its primary endpoint, showing an Overall Response Rate (ORR) of 35.2%. In patients with sensitive disease the ORR was 46.6%.**
- **The Duration of Response (DOR) was a median of 6.2 months in sensitive patients, and a median of 5.3 months in the overall population.**
- **ASCO has selected PharmaMar's abstract for an oral presentation on June 1st, where updated study data will be presented**

**Madrid, 16<sup>th</sup> of May, 2019.-** ASCO (American Society of Clinical Oncology) has published the data obtained in the study of lurbinectedin (PharmaMar - MSE:PHM) as a single agent for the treatment of second line small cell lung cancer. These data will be presented orally at the 19<sup>th</sup> Annual ASCO Congress, to be held from 31<sup>st</sup> May to 4<sup>th</sup> June in Chicago (USA).

Lurbinectedin showed an Overall Response Rate (ORR) of 35.2% in the overall population and 46.6% and 21.3% in sensitive (CTFI $\geq$ 90 days, this meaning those patients who have suffered a relapse of the disease in a period greater than or equal to 90 days) and resistant patients (CTFI $<$ 90 days, this meaning those patients who have suffered a relapse of the disease in a period of less than 90 days), respectively. The median Duration of Response (DOR) was 5.3 months in the overall population and 6.2 and 4.7 months, respectively, in sensitive and resistant patients.

ASCO has selected PharmaMar's abstract for an oral presentation at its 19<sup>th</sup> Annual Congress. The presentation will take place on 1<sup>st</sup> June at 1:15 PM (CST) during the Oral Abstract Session: Lung Cancer-Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers. Luis G. Paz-Ares, MD, PhD, Professor of Medicine at the Hospital Universitario 12 de Octubre in Madrid and lead author of the study, will present updated results of lurbinectedin as a single agent in second line small cell lung cancer.

In addition to the efficacy data, relevant safety data will also be presented.

Dr Paz-Ares and PharmaMar's management will organize a conference with investors after the presentation of the data, information for which PharmaMar announce at a later time.

The single-agent lurbinectedin study is a single-arm, Phase II, multicenter trial, involving 105 patients recruited from 39 centers in nine countries in Western Europe along with the USA, studying the safety and efficacy of lurbinectedin in second line small cell lung cancer.

The conclusions of the abstract are that the data presented demonstrate that lurbinectedin in monotherapy is active for the treatment of second-line small cell lung cancer in both resistant and sensitive patients and has an acceptable and manageable tolerability profile.

In addition, **Dr. Paz-Ares** says *"After more than two decades of disappointments, lurbinectedin is emerging as a potential new alternative treatment for second line small cell lung cancer."*

*"To be selected to present our data in an oral session at such an international congress is an enormous honor and milestone for any pharmaceutical company. These results show that lurbinectedin may have the potential to become a therapeutic alternative for patients with small cell lung cancer, a pathology in which no second-line product has been approved for more than 20 years, so therefore, it is a unmet medical need",* says **Luis Mora**, General Manager of the Oncology Business Unit at PharmaMar.

Different studies with Yondelis® (trabectedin) will also be presented at the Congress.

The studies presented at the Congress are available at <http://abstracts.asco.org>.

## **Studies to be highlighted at ASCO 2019**

### **Lurbinectedin**

- **Efficacy and safety profile of lurbinectedin in second-line SCLC patients: results from a phase II single-agent trial.** (Abstract 8506).  
Oral presentation: Saturday, 1<sup>st</sup> June 2019, from 1:15 PM to 4:15 PM in Hall D2. Oral Abstract Session: Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers.  
Firs Author: Luis G. Paz-Ares, MD., PhD., Hospital Universitario 12 de Octubre, CiberOnc, Universidad Complutense and CNIO.

## Yondelis® (trabectedin)

- **Trabectedin for recurrent WHO grade II or III meningioma: a randomized phase II study of the EORTC Brain Tumor Group (EORTC-1320-BTG).** (Abstract 2007).  
Oral Presentation: Monday, 3<sup>rd</sup> June 2019, from 1:15 PM to 4:15 PM in S102: Oral Abstract Session: Central Nervous System Tumors.  
First Author: Matthias Preusser, MD., Medical University of Vienna, Comprehensive Cancer Center.
- **SAINT: Results of a phase 1/2 study of safety/efficacy using safe amounts of ipilimumab, nivolumab, and trabectedin as first-line treatment of advanced soft tissue sarcoma.** (Abstract 11016).  
Poster Board: #339. Poster Discussion Session, Saturday, 1<sup>st</sup> June 2019, from 3:00 PM to 4:30 PM in S404, Hall A.  
First Author: Erlinda Maria Gordon, MD., Sarcoma Oncology Research Center.
- **Exploration of tumor genetic alterations and associations with clinical outcomes: Retrospective genomic analysis of archived liposarcoma (LPS) and leiomyosarcoma (LMS) samples from phase III trial of trabectedin (T) versus dacarbazine (D).** (Abstract 11019).  
Poster Board: #342. Poster Discussion Session, Saturday, 1<sup>st</sup> June 2019, from 3:00 PM to 4:30 PM in S404, Hall A.  
First Author: Shibu Thomas, PhD., Janssen Research and Development.
- **A Single-Center Retrospective Study Of Patients Treated With Trabectedin (TRB) with Long-Term Follow Up.** (Abstract 11061).  
Poster Board: #384. Saturday, 1<sup>st</sup> June 2019, from 8:00 AM to 11:00 AM, in Hall A.  
First Author: Brett Schroeder, MD., Fred Hutchinson Cancer Research Center

### 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); and a chemical enterprise, Zelnova Zeltia. 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.

#### **About Yondelis®**

Yondelis® (trabectedin) is a novel, synthetically produced antitumor agent originally isolated from *Ecteinascidia turbinata*, a type of sea squirt. Yondelis® exerts its anticancer effects primarily by inhibiting active transcription, a type of gene expression on which proliferating cancer cells are particularly dependent.

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