



## PharmaMar and Jazz Pharmaceuticals Sign Exclusive License Agreement for Lurbinectedin in the U.S.

December 19, 2019

- Jazz to pay an upfront payment of \$200 million to PharmaMar
- Opportunity for Jazz to expand its oncology portfolio with lurbinectedin, a late stage asset in relapsed small cell lung cancer (SCLC)
- PharmaMar is also eligible to receive up to \$800 million in potential milestone payments in addition to royalties on net sales
- Lurbinectedin New Drug Application (NDA) submitted to FDA in December 2019 with the potential to launch in 2020
- Collaboration emphasizes Jazz and PharmaMar's commitments to providing differentiated medicines to patients in areas of high unmet need

MADRID and DUBLIN, Dec. 19, 2019 /PRNewswire/ -- PharmaMar (MSE:PHM) and Jazz Pharmaceuticals plc (Nasdaq:JAZZ) today announced that PharmaMar and Jazz Pharmaceuticals Ireland Limited have entered into an exclusive license agreement for lurbinectedin in the United States.

Under the terms of this agreement, PharmaMar will receive an upfront payment of \$200 million with potential regulatory milestone payments of up to \$250 million upon the achievement of accelerated and/or full regulatory approval of lurbinectedin by FDA within certain timelines.

PharmaMar is also eligible to receive up to \$550 million in potential commercial milestone payments, as well as incremental tiered royalties on future net sales of lurbinectedin ranging from the high teens up to 30 percent. PharmaMar may receive additional payments on approval of other indications. PharmaMar retains production rights for lurbinectedin and will supply the product to Jazz.

Lurbinectedin was granted orphan drug designation for SCLC by FDA in August 2018. In December 2019, PharmaMar submitted an NDA to FDA for accelerated approval of lurbinectedin for relapsed SCLC, based on data from its Phase 2 basket trial, following positive interactions with FDA.

The lurbinectedin Phase 2 monotherapy basket trial enrolled a total of 105 patients at 39 centers in eight Western European countries in addition to the U.S. The primary endpoint was Overall Response Rate (ORR) as measured by investigator review assessment. Secondary endpoints included Duration of Response, Progression-Free Survival, Overall Survival, and safety. In relapsed SCLC, lurbinectedin showed an ORR of 35.2%, which compares favorably to topotecan's historical ORR of 16.9%<sup>1</sup> by investigator assessment. In addition, lurbinectedin demonstrated a favorable safety, tolerability and administration profile versus historical standard of care.

*"We are very pleased with the lurbinectedin agreement with our new U.S. partner Jazz," said José María Fernández Sousa-Faro, PhD, President of PharmaMar. "We are convinced that with Jazz, we have found a partner deeply committed to providing lurbinectedin to patients in the U.S. Lurbinectedin has the potential to become a therapeutic alternative for patients with relapsed small cell lung cancer, who have limited treatment options."*

*"Lurbinectedin represents a strong strategic fit and an exciting opportunity for Jazz to expand our oncology portfolio with a late stage asset," said Bruce C. Cozadd, Chairman and CEO of Jazz Pharmaceuticals. "We are looking forward to commercializing lurbinectedin in the U.S., as SCLC is an area of significant unmet medical need given limited late-stage treatment options and we believe lurbinectedin may offer patients with relapsed SCLC a meaningful treatment option."*

SCLC is a very aggressive cancer that usually is diagnosed with advanced, often metastatic, disease, thus limiting the role of traditional approaches and often posing a worse prognosis when compared to other lung cancers<sup>2</sup>. In the U.S., approximately 10-15% of lung cancers are small cell.<sup>2</sup> Approximately 30,000 new cases of SCLC are recorded in the U.S. every year<sup>3</sup>.

Closing of the agreement is subject to expiration or termination of the waiting period under the Hart-Scott-Rodino Act.

### PharmaMar Conference Call for Investors and Analysts

PharmaMar management will host a conference call and webcast for investors and analysts on January 9<sup>th</sup>, 2020, at 14:00 CET (08:00 AM, New York time) as follows. The numbers to connect to the teleconference are 877-407-3102 (from USA or Canada) and +1 201-493-6790 (other countries). Interested parties can also follow the conference call live via the following link: <https://78449.themediaframe.com/dataconf/productusers/phm/mediaframe/33803/index1.html>

The recording of the teleconference will be available for thirty days and it can be accessed on PharmaMar's website by visiting the [Events Calendar](#) section of the Company's website [www.pharmamar.com](http://www.pharmamar.com).

### Jazz Pharmaceuticals Conference Call for Investors and Analysts

Jazz Pharmaceuticals will host an investor conference call and live audio webcast on Friday, January 10, 2020 at 8:30 a.m. EST (1:30 p.m. GMT) to discuss the transaction. The live webcast may be accessed from the Investors section of Jazz Pharmaceuticals' website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com). Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 855 353 7924 in the U.S., or +1 503 343 6056 outside the U.S., and entering passcode 4069667.

A replay of the conference call will be available through January 17, 2020 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S.,

and entering passcode 4069667. An archived version of the webcast will be available for at least one week in the Investors section of Jazz Pharmaceuticals' website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.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 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 Jazz Pharmaceuticals**

Jazz Pharmaceuticals plc (Nasdaq: JAZZ), a global biopharmaceutical company, is dedicated to developing life-changing medicines for people with limited or no options. As a leader in sleep medicine and with a growing hematology/oncology portfolio, Jazz has a diverse portfolio of products and product candidates in development, and is focused on transforming biopharmaceutical discoveries into novel medicines. Jazz Pharmaceuticals markets Sunosi® (solriamfetol), Xyrem® (sodium oxybate) oral solution, Defitelio® (defibrotide sodium), Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Defitelio® (defibrotide), Erwinase® and Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion in countries outside the U.S. For country-specific product information, please visit <https://www.jazzpharmaceuticals.com/medicines>. For more information, please visit [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) and follow us on Twitter at [@JazzPharma](https://twitter.com/JazzPharma).

#### **PharmaMar Legal Statement**

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.

#### **Jazz Pharmaceuticals "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995**

This press release contains forward-looking statements, including, but not limited to, statements related to potential accelerated FDA approval of lurbinectedin in the U.S. during 2020; potential regulatory, sales and development milestones under the licensing agreement between Jazz Pharmaceuticals and PharmaMar and related potential future payments by Jazz Pharmaceuticals to PharmaMar; the potential for lurbinectedin to become a therapeutic alternative for patients with relapsed SCLC; Jazz's potential commercialization of lurbinectedin in the U.S. and its belief that lurbinectedin may offer patients with relapsed SCLC an important therapeutic option; and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: the ability to obtain U.S. antitrust clearance for the licensing agreement; Jazz Pharmaceuticals' ability to achieve the expected benefits (commercial or otherwise) from the license agreement; pharmaceutical product development and clinical success thereof; the regulatory approval process; effectively commercializing any product candidates; and other risks and uncertainties affecting Jazz Pharmaceuticals, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 and future filings and reports by the company. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect the company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

#### **PharmaMar Media and Investor Relations Contact**

##### **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

##### **Investor Relations:**

José Luis Moreno Martínez-Losa – Capital Markets & Investor Relations Director  
[investorrelations@pharmamar.com](mailto:investorrelations@pharmamar.com)  
Phone: +34 914444500

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

#### Jazz Pharmaceuticals Media and Investor Relations Contact

**Media Contact:**

Jacqueline Kirby, Vice President, Corporate Affairs & Government Relations  
Ireland +353 1 697 2141 U.S. +1 215 867 4910

**Investor Contact:**

Kathee Littrell, Vice President, Investor Relations  
Ireland +353 1 634 7887 U.S. +1 650 496 2717

<sup>1</sup> von Pawel et al. *J Clin Oncol* 32:4012-4019

<sup>2</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>3</sup> SEER Cancer Stat Facts – Lung and Bronchus Cancer, <https://seer.cancer.gov/statfacts/html/lungb.html> (accessed December 17, 2019)



View original content to download multimedia: <http://www.prnewswire.com/news-releases/pharmamar-and-jazz-pharmaceuticals-sign-exclusive-license-agreement-for-lurbinectedin-in-the-us-300977579.html>

SOURCE Jazz Pharmaceuticals plc