

# PharmaMar and Jazz Pharmaceuticals Announce the U.S. License Agreement for Lurbinectedin is Effective with the Expiration of the HSR Waiting Period

January 22, 2020

- PharmaMar and Jazz signed an exclusive license agreement on 19 December 2019 for lurbinectedin in the United States
  Jazz to pay an upfront payment of \$200 million to PharmaMar
- PharmaMar is also eligible to receive up to \$800 million in potential milestone payments in addition to royalties on net sales

MADRID and DUBLIN, Jan. 22, 2020 /PRNewswire/ -- PharmaMar (MSE:PHM) and Jazz Pharmaceuticals plc (Nasdaq: JAZZ) announce that the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended "HSR", with respect to the exclusive license agreement for lurbinectedin in the United States expired as of January 21, 2020 at 11:59 p.m. ET.

As previously announced, on 19 December 2019, PharmaMar and Jazz Pharmaceuticals signed an exclusive license agreement for U.S. rights to lurbinectedin, the effectiveness of which was subject to the expiration or early termination of the applicable HSR waiting period. With the expiration of the HSR waiting period, the agreement became effective, and PharmaMar will receive the initial upfront payment of \$200 million in the forthcoming days.

Under the terms of the agreement, PharmaMar is also eligible to receive, in the following months, 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%.

PharmaMar retains production rights for lurbinectedin and will supply the product to Jazz.

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.

### **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<sup>®</sup> 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 <a href="https://www.pharmamar.com">www.pharmamar.com</a>.

#### **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<sup>®</sup> (solriamfetol), Xyrem<sup>®</sup> (sodium oxybate) oral solution, Defitelio<sup>®</sup> (defibrotide sodium), Erwinaze<sup>®</sup> (asparaginase *Erwinia chrysanthemi*) and Vyxeos<sup>®</sup> (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Sunosi, Defitelio<sup>®</sup> (defibrotide), Erwinase<sup>®</sup> and Vyxeos<sup>®</sup> 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 <a href="https://www.jazzpharmaceuticals.com/medicines">https://www.jazzpharmaceuticals.com/medicines</a>. For more information, please visit <a href="https://www.jazzpharmaceuticals.com/medicines">www.jazzpharmaceuticals.com/medicines</a>. For more information, please visit <a href="https://www.jazzpharmaceuticals.com/medicines">www.jazzpharmaceuticals.com/medicines</a>. For more information, please visit <a href="https://www.jazzpharmaceuticals.com/medicines">www.jazzpharmaceuticals.com/medicines</a>.

# 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 regulatory, sales and development milestones under the licensing agreement between Jazz Pharmaceuticals and PharmaMar and related potential future payments by Jazz Pharmaceuticals to PharmaMar; 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: 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 plo'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.

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