



PharmaMar and Jazz Pharmaceuticals Announce FDA Acceptance and Priority Review of New Drug Application for Lurbinectedin in Relapsed Small Cell Lung Cancer

February 17, 2020

Prescription Drug User Fee Act (PDUFA) date set for August 16, 2020.

MADRID and DUBLIN, Feb. 17, 2020 /PRNewswire/ -- PharmaMar (MSE:PHM) and Jazz Pharmaceuticals plc (Nasdaq: JAZZ) announce that the U.S. Food and Drug Administration (FDA) accepted for filing with Priority Review the New Drug Application (NDA) seeking accelerated approval for lurbinectedin for the treatment of patients with Small Cell Lung Cancer (SCLC) who have progressed after prior platinum-containing therapy. The FDA has set a PDUFA target action date of August 16, 2020.

PharmaMar submitted the NDA to FDA in December 2019 based on data from the Phase II monotherapy basket trial, which included evaluation of lurbinectedin for the treatment of relapsed SCLC. A total of 105 patients from 39 centers were recruited in Europe and the United States. The trial met its primary endpoint of the Objective Response Rate (ORR) and the results were presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2019.

The FDA's accelerated approval pathway allowed for the submission of an NDA based on the results of Phase II drug investigations for the treatment of serious diseases that address an unmet medical need. There remains a critical unmet need for patients with relapsed SCLC, as the treatment landscape has not changed substantially in more than two decades since the last new chemical entity, topotecan, was approved.

As previously announced in December 2019, PharmaMar and Jazz Pharmaceuticals have entered into an exclusive license agreement, which became effective in January 2020, granting Jazz U.S. commercialization rights to lurbinectedin.

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.

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 with an R&D expansion into neuroscience, 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 Sunosi, Defitelio[®] (defibrotide), Erwinaze[®] 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 and follow us on Twitter at @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.

PharmaMar Media and Investor Relations Contact

Media Contact:

Alfonso Ortín – Communications Director aortin@pharmamar.com Mobile: +34 609493127
Miguel Martínez-Cava – Communication Manager mmartinez-cava@pharmamar.com
Mobile: +34 606597464
Phone: +34 918466000

Investor Relations:

José Luis Moreno – Capital Markets & Investor Relations Director
investorrelations@pharmamar.com

Phone: +34 914444500

Or please visit our website at 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



 View original content to download multimedia: <http://www.prnewswire.com/news-releases/pharmamar-and-jazz-pharmaceuticals-announce-fda-acceptance-and-priority-review-of-new-drug-application-for-lurbinectedin-in-relapsed-small-cell-lung-cancer-301005785.html>

SOURCE Jazz Pharmaceuticals plc