New Data for Zepzelca™ (lurbinectedin) to be Presented at IASLC 2020 North America Conference on Lung Cancer

October 14, 2020

Updated second-line SCLC analysis from Phase 2 basket trial previously published in The Lancet Oncology among study results to be presented

DUBLIN, Oct. 14, 2020 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and its partner PharmaMar (MSE: PHM) today announced they will present new data for Zepzelca™ (lurbinectedin) in small cell lung cancer (SCLC) at the International Association for the Study of Lung Cancer (IASLC) 2020 North America Conference on Lung Cancer, which will be held October 16-17, 2020 as a virtual event.

"Jazz is committed to improving outcomes for patients with SCLC where there continues to be a high unmet need despite research and treatment advancements," said Robert Iannone, M.D., M.S.C.E., executive vice president, research and development of Jazz Pharmaceuticals. "At this year's IASLC virtual meeting, we look forward to presenting, along with our partner PharmaMar, data on lurbinectedin, our newest oncology medicine to be approved by the U.S. FDA."

Highlights at the 2020 North America Conference on Lung Cancer include:

- A poster presentation of the outcomes in patients treated with lurbinectedin who were candidates for platinum re-challenge in the relapsed SCLC cohort from the Phase 2 basket trial, including those with a chemotherapy-free interval (CTFI) ≥180 days
- A poster presentation of the outcomes by baseline patient characteristics for the relapsed SCLC cohort from the Phase 2 basket trial
- A poster presentation featuring the results in the subset of patients who achieved a response to lurbinectedin in the relapsed SCLC cohort from the Phase 2 basket trial

The IASLC 2020 North America Conference on Lung Cancer presentations will be presented on October 16 from 5 – 6 p.m. CDT at https://naclc2020.iaslc.org/.

A full list of presentations follows below:

Presentation Title	Author	Abstract Number
Activity of Lurbinectedin in Second-line SCLC Patients Who Are Candidates for Platinum Re-challenge	Subbiah et al.	109
Phase 2 Basket Trial of Lurbinectedin in Small Cell Lung Cancer: Analysis of Efficacy by Baseline Characteristics	Sands et al.	110
Phase 2 Basket Trial of Lurbinectedin in Second-line Small-Cell Lung Cancer: Characteristics and Outcomes in Treatment Responders	Subbiah et al.	111

Zepzelca is approved in the U.S. for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. Zepzelca was approved by the U.S. Food and Drug Administration (FDA) under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1]

About Zepzelca™(lurbinectedin)
Zepzelca, also known as PM1183, is an alkylating drug that binds guanine residues within DNA. This triggers a cascade of events that can affect the activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death.[1]

Zepzelca for injection 4 mg is a prescription medicine used to treat adults with a kind of lung cancer called small cell lung cancer that has spread to other parts of the body (metastatic) and who have received treatment with chemotherapy that contains platinum, and it did not work or is no longer working. *Zepzelca* is approved based on response rate and how long the response lasted. Additional studies will further evaluate the benefit of *Zepzelca* for this use.

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

Important Safety Information

Before receiving ZEPZELCA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- are pregnant or plan to become pregnant. ZEPZELCA can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with ZEPZELCA.
- You should use effective birth control (contraception) during treatment with and for 6 months after your final dose of ZEPZELCA.
- Tell your healthcare provider right away if you become pregnant or think that you are pregnant during treatment with ZEPZELCA.

Males with female partners who are able to become pregnant should use effective birth control during treatment with and for 4 months after your final dose of ZEPZELCA.

- are breastfeeding or plan to breastfeed. It is not known if ZEPZELCA passes into your breastmilk. Do not breastfeed during treatment with ZEPZELCA and for 2 weeks after your final dose of ZEPZELCA. Talk to your healthcare provider about the best way to feed your baby during treatment with ZEPZELCA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain other medicines may affect how ZEPZELCA works.

What should I avoid while using ZEPZELCA?

Avoid eating or drinking grapefruit, or products that contain grapefruit juice during treatment with ZEPZELCA.

ZEPZELCA can cause serious side effects, including:

- **Low blood cell counts.** Low blood counts including low neutrophil counts (neutropenia) and low platelet counts (thrombocytopenia) are common with ZEPZELCA, and can also be severe. Some people with low white blood cell counts may get fever, or an infection throughout the body (sepsis), that can cause death. Your healthcare provider should do blood tests before you receive each treatment with ZEPZELCA to check your blood cell counts.
  Tell your healthcare provider right away if you develop:
  - fever or any other signs of infection
  - unusual bruising or bleeding
  - tiredness
  - pale colored skin
- **Liver problems.** Increased liver function tests are common with ZEPZELCA, and can also be severe. Your healthcare provider should do blood tests to check your liver function before you start and during treatment with ZEPZELCA.
  Tell your healthcare provider right away if you develop symptoms of liver problems including:
  - loss of appetite
  - nausea or vomiting
  - pain on the right side of your stomach area (abdomen)

Your healthcare provider may temporarily stop treatment, lower your dose, or permanently stop ZEPZELCA if you develop low blood cell counts or liver problems during treatment with ZEPZELCA.

The most common side effects of ZEPZELCA include:

- tiredness
- low white and red blood cell counts
- increased kidney function blood test (creatinine)
- increased liver function blood tests
- increased blood sugar (glucose)
- nausea
- decreased appetite
- muscle and joint (musculoskeletal) pain
- low level of albumin in the blood
- constipation
- trouble breathing
- low levels of sodium and magnesium in the blood
- vomiting
- cough
- diarrhea

These are not all of the possible side effects of ZEPZELCA.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Jazz Pharmaceuticals at 1-800-520-5568.

More information about Zepzelca, including Full Prescribing Information and Patient Information, is available here.

ZEPZELCA is a trademark of PharmaMar, S.A. used by Jazz Pharmaceuticals under license.

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) is a global biopharmaceutical company dedicated to developing and commercializing life-changing medicines that transform the lives of patients with serious diseases - often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep and movement disorders, and in oncology, including hematologic malignancies and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in more than 90 countries. For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.

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References:

1. ZEPZELCA (lurbinectedin) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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