National Comprehensive Cancer Network® adds Zepzelca™ (lurbinectedin) to Clinical Practice Guidelines in Oncology

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DUBLIN, July 13, 2020 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that Zepzelca ™(lurbinectedin) was added by the National Comprehensive Cancer Network (NCCN®) to the Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for small cell lung cancer (SCLC) on July 7, 2020.

The U.S. Food and Drug Administration (FDA) approved *Zepzelca* under accelerated approval on June 15, 2020 for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.[1] The approval was based on the data from the open-label, single-arm monotherapy trial. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

The NCCN Guidelines for SCLC now include lurbinectedin as a recommended regimen for both patients who relapse six months and less after prior systemic therapy and for patients who relapse more than six months after prior systemic therapy. For patients who relapse six months and less, lurbinectedin is a preferred regimen.

"We appreciate the decision by the NCCN to quickly incorporate *Zepzelca* into the Clinical Practice Guidelines in Oncology as it supports our commitment to ensuring that patients with relapsed small cell lung cancer are able to access this important new treatment option," said Robert Iannone M.D., M.S.C.E., executive vice president, research and development of Jazz Pharmaceuticals. "*Zepzelca* has the potential to fill an unmet need in relapsed SCLC where treatment options have been limited."

The NCCN, a not-for-profit alliance of 30 leading U.S. cancer centers devoted to patient care, research, and education, is dedicated to improving and facilitating quality, effective, efficient, and accessible cancer care so patients can live better lives. The intent of the NCCN Guidelines is to assist in the decision-making process of individuals involved in cancer care—including physicians, nurses, pharmacists, payers, patients and their families—with the ultimate goal of improving patient care and outcomes.

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.

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.

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About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharmaceutical company dedicated to developing life-changing medicines for people 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 medicine and movement disorders, and in oncology, including hematologic 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.

References:

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

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