Jazz Pharmaceuticals to Present Advancements in Solid Tumor Oncology Research at ESMO 2024

September 09, 2024

New and updated data from an ongoing Phase 2 trial of zanidatamab, an investigational dual HER2-targeted bispecific antibody, in combination with chemotherapy for first-line treatment of HER2-positive metastatic gastroesophageal adenocarcinoma (mGEA)

DUBLIN, Sept. 9, 2024 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the Company, along with its partners, will present five abstracts at the European Society for Medical Oncology (ESMO) Congress 2024 from September 13-17, 2024, in Barcelona, Spain. Presentations include data from trials of zanidatamab and Zepzelca® (lurbinectedin).

New and updated data with longer follow-up, including overall survival findings, will be presented from an ongoing Phase 2 trial of zanidatamab, an investigational dual HER2-targeted bispecific antibody, in combination with chemotherapy for the first-line treatment of HER2-positive metastatic gastroesophageal adenocarcinoma (mGEA). Additional data from a Phase 2 study evaluating zanidatamab in combination with chemotherapy and bevacizumab as first-line treatment in HER2-positive metastatic colorectal cancer demonstrating encouraging antitumor activity will be presented as a mini-oral presentation at the congress.

"We look forward to presenting new and more mature data from our oncology solid tumor clinical development program at this year's ESMO congress, in particular for zanidatamab in HER2-positive metastatic gastroesophageal adenocarcinoma," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development, and chief medical officer of Jazz Pharmaceuticals. "We look forward to continuing to advance our clinical development program for zanidatamab in GEA, including the Phase 3 clinical trial expected to read out in the second quarter of 2025 that could support global regulatory submissions."

Data on Zepzelca will also be presented at the congress, including findings from a Phase 2 trial evaluating the safety and efficacy of lurbinectedin and irinotecan in relapsed small cell lung cancer (SCLC) patients, including those with CTFI (Chemotherapy-Free Interval) 30-90 days, who typically have a poor prognosis. These findings support the rationale for this combination in the ongoing LAGOON confirmatory trial.

The full ESMO abstracts for posters are available at:
https://cslide.ctimeetingtech.com/esmo2024/attendee/confcal_2/presentation

The full ESMO abstracts for presentations are available at: ESMO Congress 2024 - Conference Calendar - ESMO Congress 2024 (ctimeetingtech.com)

The full list of Jazz or partner-supported presentations at the 2024 ESMO Congress includes:

Zanidatamab Presentations

Topic	Author	Presentation Details
Zanidatamab + Chemotherapy for First-Line (1L) Treatment of HER2+ Advanced or Metastatic Gastro-oesophageal Adenocarcinoma (mGEA): New and Updated Data From a Phase 2 Trial	Elena Elimova, et al.	**Type:** Poster **Date:** Monday, September 16 **Presentation Number:** 1432P
Zanidatamab (Zani) + Chemotherapy (CT) in First-Line (1L) Human Epidermal Growth Factor Receptor 2-Positive (HER2+) Advanced/Metastatic Colorectal Cancer (mCRC)	Sun Young Rha, et al.	**Type:** Mini Oral session **Date:** Saturday, September 14, 2:50-2:55 p.m. CEST **Presentation Number:** #516MO
HERIZON-BTC-02: A Phase 3 Study of Zanidatamab With Standard-of-Care (SOC) Therapy vs SOC Alone For First-Line (1L) Treatment of Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Advanced/Metastatic Biliary Tract Cancer (BTC)	Tesca Macarulla, et al.	**Type:** Poster **Date:** Monday, September 16 **Presentation Number:** 62TiP

Zepzelca Presentations

Topic	Author	Presentation Details
Phase 2 data of lurbinectedin and irinotecan in relapsed SCLC: efficacy and safety results in patients with CTFI>30 days [PharmaMar]	Jon Zugazagoitia, et al.	**Type:** Poster **Date:** Saturday, September 14 **Presentation Number:** 1790P

LINNOVATE: A phase 1/2 study of safety/efficacy of lurbinectedin combined with ipilimumab and nivolumab for advanced soft tissue sarcoma [IST]	Erlinda Gordon et al.	**Type:** Poster **Date:** Saturday, September 14 **Presentation Number:** 1739P

About Zanidatamab
Zanidatamab is an investigational dual HER2-targeted bispecific antibody that simultaneously binds to two distinct sites on HER2, known as biparatopic binding. This unique design and enhanced binding results in multiple mechanisms of action, including HER2 and HER3 signal inhibition, removal of HER2 protein from the cell surface and enhanced immune effector functions, such as complement-dependent cytotoxicity (CDC), which leads to encouraging antitumor activity. Zanidatamab is being developed in multiple clinical trials as a targeted treatment option for patients with solid tumors that express HER2. Zanidatamab is being developed by Jazz and BeiGene, Ltd. (BeiGene) under license agreements from Zymeworks, which first developed the molecule.

The U.S. Food and Drug Administration (FDA) has granted priority review for the Biologics License Application (BLA) for zanidatamab for the treatment of previously treated, unresectable, locally advanced, or metastatic HER2-positive biliary tract cancer (BTC) with a Prescription Drug User Fee Act (PDUFA) target action date of November 29, 2024. The FDA granted Breakthrough Therapy designation for zanidatamab development in patients with previously treated HER2 gene-amplified BTC, and two Fast Track designations for zanidatamab: one as a single agent for refractory BTC and one in combination with standard of care chemotherapy for 1L gastroesophageal adenocarcinoma (GEA). Additionally, zanidatamab has received Orphan Drug designations from FDA for the treatment of BTC and GEA, as well as Orphan Drug designation from the European Medicines Agency for the treatment of BTC and gastric cancer. Zanidatamab was also granted Breakthrough Therapy designation from the Center for Drug Evaluation (CDE) in China.

About Zepzelca® (lurbinectedin)
Zepzelca 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 transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death.[1]

The FDA approved *Zepzelca* under accelerated approval in June 2020 for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. The approval is based on overall response rate (ORR) and duration of response demonstrated in an open-label, monotherapy clinical study. In December 2021, Jazz and PharmaMar announced the initiation of LAGOON, a confirmatory Phase 3 clinical trial of *Zepzelca* for the treatment of patients with relapsed small cell lung cancer. If positive, LAGOON could confirm the benefit of *Zepzelca* in the treatment of small cell lung cancer (SCLC) when patients progress following 1L treatment with a platinum-based regimen and support full approval in the U.S.

Zepzelca is a prescription medicine used to treat adults with SCLC 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 for ZEPZELCA

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 last 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 their last 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 last 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, Seville oranges, or products that contain grapefruit juice and Seville oranges 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)
- **Leakage of ZEPZELCA out of your vein during the infusion.** If ZEPZELCA leaks into the tissues around your infusion site, it can cause damage and death of tissue cells around the infusion site. You may need to have surgery to remove any dead tissue. Tell your healthcare provider right away if you see any ZEPZELCA leaking out of your vein or around the catheter during your infusion, or if you notice any redness, swelling, itching or discomfort at the infusion site at any time.
- **Severe muscle problems (rhabdomyolysis).** Tell your healthcare provider if you have severe muscle pain or weakness.

Your healthcare provider may temporarily stop treatment, lower your dose, or permanently stop ZEPZELCA if you develop serious side effects 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.

Please see full Prescribing Information including Patient Information, and discuss with your doctor.

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

About Jazz Pharmaceuticals
Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharma company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases—often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience. Jazz is headquartered in Dublin, Ireland with research and development laboratories, manufacturing facilities and employees in multiple countries committed to serving patients worldwide. Please visit www.jazzpharmaceuticals.com for more information.

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