# Jazz Pharmaceuticals to Present New Data Highlighting Advancements in Solid Tumors and Rare Blood Cancers at Upcoming Oncology Meetings

November 30, 2023

*New trial results of investigational bispecific antibody zanidatamab presented at SABCS in HER2+/HR+ metastatic breast cancer*

*Strong presence at ASH includes 11 presentations spanning Jazz's portfolio, advancing research into difficult-to-treat blood cancers and diseases*

*Real-world data at NACLC reinforce clinical impact of Zepzelca® (lurbinectedin) in small cell lung cancer*

DUBLIN, Nov. 30, 2023 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the Company and its partners will present two abstracts at the 2023 San Antonio Breast Cancer Symposium (SABCS) from December 5-9; 11 abstracts at the 65th Annual American Society of Hematology (ASH) Annual Meeting from December 9-12; and two abstracts at the International Association for the Study of Lung Cancer (IASLC) 2023 North America Conference on Lung Cancer (NACLC) from December 1-3. New data include updated findings from a Phase 2a trial of the investigational HER2-targeted bispecific antibody zanidatamab in combination with palbociclib and fulvestrant as a chemotherapy-free option for HER2+/ HR+ metastatic breast cancer (mBC).

"Following recent trial results showing the potential of zanidatamab to treat HER2-expressing gastric and biliary tract cancers at ASCO GI, ASCO and ESMO this year, we're excited to share updated data at SABCS in HER2-amplified and hormone receptor-positive metastatic breast cancer when zanidatamab is used in combination to target the HER2, CDK4/6 and hormone receptor pathways," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "SABCS will also feature data from a trial of zanidatamab in neoadjuvant breast cancer. Additionally, we look forward to sharing new data through numerous presentations at ASH 2023 that underscore our commitment to improving standards of care in blood cancer and other hematologic diseases, as well as real-world findings at NACLC that provide evidence of Zepzelca's safety in clinical practice for the treatment of second-line small cell lung cancer."

Notable presentations at this year's SABCS, ASH and NACLC meetings include:

- A SABCS oral presentation (late-breaking abstract) featuring primary results from a Phase 2a study for a chemotherapy-free option in heavily pretreated patients with HER2+/HR+ mBC treated with the combination of zanidatamab plus palbociclib and fulvestrant.
- An investigator-sponsored (MD Anderson Cancer Center) SABCS poster presentation featuring results of a Phase 1 trial evaluating neoadjuvant zanidatamab in patients with stage 1 node-negative HER2+ breast cancer as a single-agent chemotherapy-free option.
- An ASH poster presentation of the complete pivotal, Phase 2/3 trial results of Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn) in acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL), which includes efficacy, safety and population pharmacokinetic modeling from intramuscular (IM) and intravenous (IV) dosing. The combination of observed and modeled results demonstrates *Rylaze* achieved therapeutic nadir serum asparaginase activity (NSAA) levels in the vast majority of patients via multiple dosing schedules with a safety profile consistent with prior studies and no new safety signals identified. Treatment-related adverse events (TRAEs) ≥ grade 3 occurred in 126/228 (55%) patients with no TRAEs that led to death.[1]
- Two NACLC poster presentations of real-world data for Zepzelca® (lurbinectedin) in the second-line and later settings for the treatment of small cell lung cancer (SCLC).

The Jazz and partner-supported presentations at SABCS 2023 are:

**Zanidatamab Presentations**

| **Presentation Title** | **Author** | **Presentation Details** (All times CDT) |
|---|---|---|
| Primary Results From a Phase 2a Study of Zanidatamab (zani) + Palbociclib (palbo) + Fulvestrant (fulv) in HER2+/HR+ Metastatic Breast Cancer (mBC) | Santiago Escrivá-de-Romani, et al. | **Type:** Oral<br>**Session:** Late Breaking Abstracts<br>**Presentation Number**: LBO1-04<br>**Date/Time**: Friday, December 8, 2023, 12:20 PM – 12:25 PM |
| Neoadjuvant Zanidatamab for Stage 1 Node Negative HER2 Positive Breast Cancer (BC)<br>[IST] | V. Valero, et al. | **Type:** Poster<br>**Session:** Spotlight poster session<br>**Presentation Number**: PS09-03<br>**Date / Time**: Wednesday, December 6, 2023, 5:30 PM – 6:30 PM |

The Jazz-supported presentations at the 2023 ASH Annual Meeting are:

**Rylaze Presentations**

| Presentation Title | Author | Presentation Details (All times PDT) |
|---|---|---|
| Efficacy and Safety of Recombinant *Erwinia* Asparaginase in Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL): Complete Follow-up of the Children's Oncology Group (COG) AALL1931 study | Luke Maese, et al. | **Type:** Poster<br>**Number:** 1498<br>**Session:** 614. Acute Lymphoblastic Leukemias: Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster I<br>**Date/Time:** Saturday, December 9, 5:30-7:30 PM<br>Abstract Link |
| A Meta-analysis Comparing the Relative Efficacy of Pediatric-Inspired Regimens Versus Hyper-CVAD for the Treatment of Acute Lymphoblastic Leukemia/Lymphoblastic Lymphoma in Adolescents, Young Adults and Adults | Wenqing Su, et al. | **Type:** Poster<br>**Number:** 3779<br>**Session:** 905. Outcomes Research—Lymphoid Malignancies: Poster II<br>**Date/Time:** Sunday, December 10, 6:00-8:00 PM<br>Abstract Link |

**Asparaginase Collaboration Studies**

| Presentation Title | Author | Presentation Details |
|---|---|---|
| Overcoming Venetoclax (Ven) Resistance Through Glutamine (Gln) Depletion: Final Analysis of the Phase 1 Trial of Ven and Pegcrisantaspase (PegC) Combination in Relapsed and Refractory (R/R) Acute Myeloid Leukemia (AML) | Yuchen Liu, et al. | **Type:** Oral<br>**Number:** 60<br>**Session:** 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Upcoming Therapies in Newly Diagnosed and Relapsed/Refractory AML<br>**Date/Time:** Saturday, December 9, 10:45 AM<br>Abstract link |

**Vyxeos Presentations**

| Presentation Title | Author | Presentation Details |
|---|---|---|
| Population Pharmacokinetic-Pharmacodynamic Modeling of Neutrophil and Platelet Count for Lower-Intensity Therapy of CPX-351 Combined With Venetoclax in Acute Myeloid Leukemia | Yali Liang, et al. | **Type:** Poster<br>**Number:** 2902<br>**Session:** 615. Acute Myeloid Leukemias: Commercially Available Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster II<br>**Date/Time:** Sunday, December 10, 6:00-8:00 PM<br>Abstract Link |
| CPX-351 With Venetoclax in Patients with Relapsed/Refractory Acute Myeloid Leukemia: Results of a Phase Ib Study | Alex Bataller, et al. | **Type:** Poster<br>**Number:** 4259<br>**Session:** 615. Acute Myeloid Leukemias: Commercially Available Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III<br>**Date/Time:** Monday, December 11, 6:00-8:00 PM<br>Abstract link |
| Phase 2 Study of CPX-351 in Combination with Venetoclax in Patients with Newly Diagnosed, High Risk Acute Myeloid Leukemia | Wei-Ying Jen, et al. | **Type:** Poster<br>**Number:** 4273<br>**Session:** 615. Acute Myeloid Leukemias: Commercially Available Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III<br>**Date/Time:** Monday, December 11, 6:00-8:00 PM<br>Abstract link |
| Results of a Phase 1/2 Study of Lower Dose CPX-351 for Patients with Int-2 or High Risk IPSS Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia after Failure to Hypomethylating Agents | Guillermo Montalban-Bravo, et al. | **Type:** Poster<br>**Number:** 1873<br>**Session:** 637. Myelodysplastic Syndromes Clinical and Epidemiological: Poster I<br>**Date/Time:** Saturday, Dec. 9, 5:30 PM-7:30 PM<br>Abstract link |
| CRISPR/Cas9 Screen Identifies CPX-351 and 7+3 Regimens Response Modulators with Distinct Sensitive and Resistant Profiles [IST] | Nam Nguyen, et al. | **Type:** Poster<br>**Number:** 1412<br>**Session:** 604. Molecular Pharmacology and Drug Resistance: Myeloid Neoplasms: Poster I<br>**Date/Time:** Saturday, Dec. 9, 5:30-7:30 PM |

| | | |
|---|---|---|
| | | Abstract link |
| CPX-351 in Patients with Newly Diagnosed Post Myeloproliferative Neoplasms Acute Myeloid Leukemia [IST] | Sylvain Garciaz, et al. | **Type:** Poster<br>**Number:** 2917<br>**Session:** 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster II<br>**Date/Time:** Sunday, Dec. 10, 6:00-8:00 PM<br>Abstract link |

**Defitelio Presentations**

| Presentation Title | Author | Presentation Details |
|---|---|---|
| Resolution of Veno-occlusive Disease/Sinusoidal Obstruction Syndrome (VOD/SOS) With Defibrotide Following HCT in Adult and Pediatric Patients: Pooled Analysis of DEFIFrance and EBMT PASS Registries | Mohamad Mohty, et al. | **Type:** Poster<br>**Number:** 3527<br>**Session:** 721. Allogeneic Transplantation: Conditioning Regimens, Engraftment and Acute Toxicities: Poster II<br>**Date/Time:** Sunday, December 10, 6:00-8:00 PM<br>Abstract link |
| A Phase II Study to Evaluate the Safety and Efficacy of Defibrotide and Changes in Plasma Biomarkers in Sickle Cell Disease-Related Acute Chest Syndrome (IND 127812) [IST] | Edo Schaefer, et al. | **Type:** Poster<br>**Number:** 2520<br>**Session:** 114. Sickle cell Disease, Sickle Cell Trait and Other Hemoglobinopathies, Excluding Thalassemias: Clinical and Epidemiological: Poster II<br>**Date/Time:** Sunday, December 10, 6:00-8:00 PM<br>Abstract link |

The Jazz-supported presentations at NACLC 2023 are:

**Zepzelca Presentations**

| Presentation Title | Author | Presentation Details (All times CDT) |
|---|---|---|
| Real-World Use of Lurbinectedin in Patients with Small Cell Lung Cancer: Jazz EMERGE 402 Updated Analysis | Balazs Halmos, et al. | **Type:** Poster<br>**Number:** PP01.119<br>**Session:** Poster Viewing Reception<br>**Date/Time:** Saturday, December 2, 5:40-6:55 PM CT |
| Real-World Effectiveness and Safety Profile of Lurbinectedin and Other Second-Line Treatments in Small Cell Lung Cancer | Apar Ganti, et al. | **Type:** Poster<br>**Number:** PP01.117<br>**Session:** Poster Viewing Reception<br>**Date/Time:** Saturday, December 2, 2023/5:40-6:55 PM CT |

**About Zanidatamab**
Zanidatamab is an investigational bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. This unique design results in multiple mechanisms of action including dual HER2 signal blockade, increased binding and removal of HER2 protein from the cell surface, and immune-mediated cytotoxicity leading to encouraging antitumor activity in patients. 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 Breakthrough Therapy designation for zanidatamab in patients with previously treated HER2 gene-amplified biliary tract cancers (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 first-line 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 RYLAZE® (asparaginase erwinia chrysanthemi (recombinant)-rywn)**
RYLAZE, also known as JZP458, is approved in the U.S. for use as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients one month or older who have developed hypersensitivity to *E. coli*-derived asparaginase. RYLAZE has orphan drug designation for the treatment of ALL/LBL in the United States. RYLAZE, or recombinant E*rwinia* is a short-acting distinct asparaginase derived from a novel *Pseudomonas fluorescens* expression platform to help ensure robustness of supply to meet patient needs. JZP458 was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in October 2019 for the treatment of this patient population. RYLAZE was approved as part of the Real-Time Oncology Review program, an initiative of the FDA's Oncology Center of Excellence designed for efficient delivery of safe and effective cancer treatments to patients.[2]

The full U.S. Prescribing Information for RYLAZE is available at:

https://pp.jazzpharma.com/pi/rylaze.en.USPI.pdf

**Important Safety Information for Rylaze**
**RYLAZE should not be given to people who have had:**

- Serious allergic reactions to RYLAZE
- Serious swelling of the pancreas (stomach pain), serious blood clots, or serious bleeding during previous asparaginase treatment

**RYLAZE may cause serious side effects, including:**

- Allergic reactions (a feeling of tightness in your throat, unusual swelling/redness in your throat and/or tongue, or trouble breathing), some of which may be life-threatening
- Swelling of the pancreas (stomach pain), which, if left untreated, may be fatal
- Blood clots (may be experienced as headache, arm or leg swelling, shortness of breath, or chest pain), which may be life-threatening
- Bleeding, which may be life-threatening
- Liver problems

**Contact your doctor immediately if any of these side effects occur.**

**Some of the most common side effects with RYLAZE include:** liver problems, nausea and vomiting, bone and muscle pain, infection, tiredness, headache, fever with low white blood cell count, fever, bleeding, mouth swelling (sometimes with sores), pain in the abdomen, decreased appetite, allergic reactions, high blood sugar levels, diarrhea, swelling of the pancreas, and low levels of potassium in your blood.

RYLAZE can harm your unborn baby. Inform your doctor if you are pregnant, planning to become pregnant, or nursing. Females of reproductive potential should use effective contraception (other than hormonal contraceptives) during treatment and for 3 months following the final dose. Do not breastfeed while receiving RYLAZE and for 1 week after the final dose.

**Tell your healthcare provider if there are any side effects that are bothersome or that do not go away.**

**These are not all the possible side effects of RYLAZE. For more information, ask your healthcare provider.**

**Call your doctor for medical advice about any 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 (1-800-332-1088).***

**About Vyxeos® (daunorubicin and cytarabine) liposome for injection**
*Vyxeos* is a liposomal combination of daunorubicin, an anthracycline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor.

In the U.S., *Vyxeos* (daunorubicin and cytarabine) liposome for injection is indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older.[3]

**More information about Vyxeos in the United States, including Full Prescribing Information and BOXED Warning, is available here.**

**Important Safety Information for VYXEOS®**

**WARNING: VYXEOS has different dosage recommendations from other medications that contain daunorubicin and/or cytarabine. Do not substitute VYXEOS for other daunorubicin and/or cytarabine-containing products.**

VYXEOS should not be given to patients who have a history of serious allergic reaction to daunorubicin, cytarabine, or any of its ingredients.

**VYXEOS can cause a severe decrease in blood cells** (red and white blood cells and cells that prevent bleeding, called platelets) which can result in serious infection or bleeding and possibly lead to death. Your doctor will monitor your blood counts during treatment with VYXEOS. Patients should tell the doctor about new onset fever or symptoms of infection or if they notice signs of bruising or bleeding.

**VYXEOS can cause heart-related side effects.** Tell your doctor about any history of heart disease, radiation to the chest, or previous chemotherapy. Inform your doctor if you develop symptoms of heart failure such as:
shortness of breath or trouble breathing
swelling or fluid retention, especially in the feet, ankles, or legs
unusual tiredness

**VYXEOS may cause allergic reactions including anaphylaxis.** Seek immediate medical attention if you develop signs and symptoms of anaphylaxis such as:
trouble breathing
severe itching
skin rash or hives
swelling of the face, lips, mouth, or tongue

**VYXEOS contains copper and may cause copper overload** in patients with Wilson's disease or other copper-processing disorders.

**VYXEOS can damage the skin if it leaks out of the vein.** Tell your doctor right away if you experience symptoms of burning, stinging, or blisters and skin sores at the injection site.

**VYXEOS can harm your unborn baby.** Inform your doctor if you are pregnant, planning to become pregnant, or nursing. Do not breastfeed while receiving VYXEOS. Females and males of reproductive potential should use effective contraception during treatment and for 6 months following the last dose of VYXEOS.

The most common side effects are bleeding events, fever, rash, swelling, nausea, sores in the mouth or throat, diarrhea, constipation, muscle pain, tiredness, stomach pain, difficulty breathing, headache, cough, decreased appetite, irregular heartbeat, pneumonia, blood infection, chills, sleep disorders, and vomiting.

**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.**

**About Defitelio® (defibrotide sodium)**

In the U.S., Defitelio® (defibrotide sodium) injection 80mg/mL received U.S. Food and Drug Administration (FDA) marketing approval on March 30, 2016, and it is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT) and is the first and only FDA-approved therapy for patients with this rare, potentially fatal complication. *Defitelio* is not approved for the prevention of VOD.[6]

**Please see full Prescribing Information for Defitelio in the United States.**

In Europe, defibrotide is marketed under the name Defitelio® ▼ (defibrotide). In October 2013, the European Commission granted marketing authorization to *Defitelio* under exceptional circumstances for the treatment of severe VOD in patients after HSCT therapy. In Europe, *Defitelio* is indicated in patients over one month of age. It is not indicated in patients with hypersensitivity to defibrotide or any of its excipients or with concomitant use of thrombolytic therapy.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system found under section 4.8 of the SmPC (http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/human/medicines/002393/human_med_001646.jsp)

**The full Summary of Product Characteristics of Defitelio in Europe is available here.**

**Important Safety Information for Defitelio**

Defitelio should not be given to patients who are:

- Currently taking anticoagulants or fibrinolytics
- Allergic to Defitelio or any of its ingredients

Defitelio may increase the risk of bleeding in patients with VOD and should not be given to patients with active bleeding. During treatment with Defitelio, patients should be monitored for signs of bleeding. In the event that bleeding occurs during treatment with Defitelio, treatment should be temporarily or permanently stopped.

Patients should tell the doctor right away about any signs or symptoms of hemorrhage such as unusual bleeding, easy bruising, blood in urine or stool, headache, confusion, slurred speech, or altered vision.

Defitelio may cause allergic reactions including anaphylaxis. Patients who develop signs and symptoms of anaphylaxis such as trouble breathing, severe itching, skin rash or hives, or swelling of the face, lips, mouth or tongue should seek medical attention immediately.

The most common side effects of Defitelio are decreased blood pressure, diarrhea, vomiting, nausea and nose bleeds.

**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 some transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death.[4]

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 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.
Females who 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.**



**About Jazz Pharmaceuticals**

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharmaceutical 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 and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. Please visit www.jazzpharmaceuticals.com for more information.

**Caution Concerning Forward-Looking Statements**
This press release contains forward-looking statements, including, but not limited to, statements related to improving standards of care in blood cancer and other hematologic diseases 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 other risks and uncertainties affecting Jazz Pharmaceuticals and its development programs, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including Jazz Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, and future filings and reports by Jazz Pharmaceuticals. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect Jazz Pharmaceuticals' 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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**References**

[1] Maese L, et al. Efficacy and Safety of Intramuscular (IM) Recombinant Erwinia Asparaginase in Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL): The Children's Oncology Group (COG) AALL1931 study. American Society of Hematology. 2023. Available at https://ash.confex.com/ash/2023/webprogram/Paper172577.html

[2] Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

[3] Vyxeos (daunorubicin and cytarabine) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

[4] ZEPZELCA (lurbinectedin) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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