# Jazz Pharmaceuticals to Present Data at 2023 AACR Annual Meeting Showcasing New Zepzelca® (lurbinectedin) Data and Expanded Oncology Pre-Clinical and Clinical Pipeline

March 15, 2023

DUBLIN, March 15, 2023 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the company, along with its partners, will present five new abstracts at the American Association for Cancer Research (AACR) Annual Meeting from April 14-19, 2023. Research findings to be presented include data from company-sponsored and collaborative trials studying Zepzelca® (lurbinectedin), zanidatamab and JZP898.

"The data Jazz and our partners are presenting at AACR this year demonstrate our commitment to advancing the next generation of oncology care, including our ongoing research for lurbinectedin," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "Over the last year, Jazz has added promising new immuno-oncology and targeted therapy candidates to our pipeline – including zanidatamab, a novel late-stage HER2-targeted bispecific antibody – and progressed ongoing development programs with the goal of improving standards of care across multiple cancer types with significant unmet need and poor outcomes."

Data highlights at the AACR Annual Meeting include:

- A poster presentation evaluating the role of SLFN11 expression in predicting response to lurbinectedin, a DNA damaging agent, in human small cell lung cancer (SCLC) cell lines and *in vivo* models. Results demonstrate that efficacy may be correlated to SLFN11 protein expression, consistent with the RNA level association.[1]
- A poster presentation featuring data identifying MCL1 as a specific lurbinectedin target and demonstrating anti-tumor activity of lurbinectedin in combination with a specific BCL2 inhibitor and with a specific BCL2L1 inhibitor in *in vivo* and *in vitro* models.[2]
- A poster presentation titled "ERBB2 amplification detected in ctDNA as a surrogate for tumor tissue FISH analysis of HER2 status in phase 1 study with zanidatamab for the treatment of locally advanced or metastatic HER2 expressing cancers."

The AACR abstracts are available at: https://www.abstractsonline.com/pp8/#!/10828/

The full list of Jazz-supported presentations at the 2023 AACR Annual Meeting are:

**Zepzelca® (lurbinectedin) Presentations**

| Presentation Title | Author | Presentation Details |
|---|---|---|
| High SLFN11 expression correlates with sensitivity to lurbinectedin in small cell lung cancer (SCLC) models | Gupta A., et al. | **Type**: Poster<br>**Session:** Biomarkers of Therapeutic Benefit 2<br>**Date**: Monday, April 17, 2023, 9:00 AM - 12:30 PM<br>**Abstract number:** 2145 |
| Lurbinectedin exhibits combinatorial activity with BCL2/BCL2L1 inhibitors *in vitro* and *in vivo* by modulation of MCL1 expression | Vaidya K.S., et al. | **Type:** Poster<br>**Session:** Cell Death Pathways/ Molecular Classifications of Tumors for Diagnostics, Prognostics, and Therapeutic Outcomes<br>**Date:** Wednesday, April 19, 2023, 9:00 AM - 12:30 PM<br>**Abstract number**: 6155 |
| Lurbinectedin shows potent activity in all four molecular subtypes of small cell lung cancer (SCLC) and POU2F3 and SLFN11 are biomarkers for a better response | Diez M.M., et al. | **Type:** Poster<br>**Session:** DNA-reactive Agents, HDAC and Methyltransferase Inhibitors, and Tubulin Agents<br>**Date:** Wednesday, April 19, 2023, 9:00 AM - 12:30 PM<br>**Abstract number**: 6247 |

**Zanidatamab Presentation***

| Presentation Title | Author | Presentation Details |
|---|---|---|
| ERBB2 amplification detected in ctDNA as a surrogate for tumor tissue FISH analysis of HER2 status in phase 1 study with zanidatamab for the treatment of locally advanced or metastatic HER2 expressing cancers | Shpektor D., et al. | **Type:** Poster<br>**Session:** Phase I Clinical Trials 2<br>**Date:** Tuesday, April 18, 2023, 1:30 PM - 5:00 PM<br>**Abstract number**: CT278 |
| *Clinical trial abstract texts are embargoed until noon ET on April 14, 2023. | | |

**JZP898 Presentation**

| Presentation Title | Author | Presentation Details |
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|---|---|---|
| WTX-613, (JZP898) a selectively activated IFNα INDUKINE™ molecule, reprograms the tumor microenvironment and generates robust anti-tumor immunity as a monotherapy and in combination with checkpoint inhibitors | Nirschl CJ, et al. | **Type:** Poster<br>**Session:** Immunomodulatory Agents and Interventions 1<br>**Date:** Monday April 17, 2023 9:00 AM - 12:30 PM<br>**Abstract number:** 1817 |

**About Zanidatamab**

Zanidatamab is an investigational bispecific antibody, based on Zymeworks' Azymetric™ platform, 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 potent effector function leading to encouraging antitumor activity in patients. Zymeworks, along with collaborators Jazz and BeiGene, Ltd. (BeiGene), are developing zanidatamab in multiple clinical trials as a targeted treatment option for patients with solid tumors that express HER2.

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 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 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 some transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death.[3]

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 successful, LAGOON will serve as the confirmatory trial for *Zepzelca* to support full approval in the U.S.

*Zepzelca* is a prescription medicine used to treat adults with 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. *Zepzelca* is not approved as part of a combination therapy or as a first-line maintenance treatment for patients with extensive-stage small cell lung cancer.

**Important Safety Information for Patients**

**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.**

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

**About JZP898**

JZP898 (also known as WTX-613) is an investigational differentiated, conditionally-activated interferon alpha (IFNα) INDUKINE™ molecule. JZP898 is an engineered IFNα2b cytokine pro-drug that is activated specifically within the tumor microenvironment where it can stimulate IFNα receptors on cancer-fighting immune effector cells. JZP898 was created leveraging Werewolf Therapeutics' proprietary PREDATOR™ protein engineering technology, which integrates specialized protein design elements to enhance activity, stability and tumor selectivity within a single molecule, called INDUKINE molecules.

**About Jazz Pharmaceuticals plc**

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 paving the way for next-generation precision therapies for patients and improving the standard of care for these serious and life-threatening cancers 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 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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[2] https://www.abstractsonline.com/pp8/#!/10828/presentation/1964
[3] ZEPZELCA (lurbinectedin) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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