Jazz Pharmaceuticals to Present Compelling Clinical and Pre-Clinical Data Advancing Oncology Research at AACR 2026

March 18, 2026

Seven presentations deliver new insights into zanidatamab's differentiated HER2 biology, emerging pre-clinical data on dordaviprone and related imipridones, and advancing research on JZP898, a conditionally activated IFNα2b cytokine

For U.S. media and investors only

DUBLIN, March 18, 2026 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the company and its partners will present one oral and six poster presentations at the 2026 American Association for Cancer Research (AACR) Annual Meeting, taking place April 17-22, 2026, in San Diego.

The research highlights meaningful progress across Jazz's oncology portfolio, including new findings from company-sponsored research evaluating Ziihera® (zanidatamab-hrii), a HER2-targeted bispecific antibody; JZP898, an investigational, differentiated, conditionally activated interferon alpha-2b (IFNα2b) cytokine pro-drug designed for activation within the tumor microenvironment; and imipridone compounds including Modeyso™ (dordaviprone), a protease activator of the mitochondrial caseinolytic protease P (ClpP) and a dopamine D2 receptor (DRD2) inhibitor.

"Jazz is presenting research at AACR that highlights how we are advancing our oncology portfolio with pace and rigor to deliver differentiated science and new insights across multiple development programs," 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. "Zanidatamab is already delivering meaningful benefits for adult patients with previously treated, unresectable or metastatic HER2+ (IHC 3+) biliary tract cancer. We are advancing our program in first-line HER2+ locally advanced or metastatic gastroesophageal adenocarcinoma, and generating a robust body of evidence that characterizes its distinct HER2 biology and its potential across additional HER2-expressing tumors, including HER2+ breast cancer. The NeoZanHER trial data being presented at AACR provide supporting evidence for our ongoing research in early-stage breast cancer."

Highlights at the AACR Annual Meeting include:

- An oral presentation with results from the Phase 2 single-arm, open-label NeoZanHER trial (NCT05035836) evaluating zanidatamab for the investigational use as neoadjuvant monotherapy in patients with early-stage HER2+ breast cancer. At six weeks, zanidatamab treatment resulted in a statistically significant decrease in tumor size and volume from baseline, and 30% of patients (n=6) achieved pathologic complete response (pCR). Treatment with zanidatamab was manageable with no new safety signals.
- A poster presentation detailing mechanistic and multi-omics analyses characterizing zanidatamab's differentiated HER2 biology, including dual, domain-specific binding and downstream effects on key cellular signaling pathways, with insights into activity in models following trastuzumab deruxtecan (T-DXd) exposure.
- A poster presentation featuring preclinical data supporting the activity of JZP898 – currently in Phase 1 development – including evidence of tumor-localized interferon signaling and immune engagement in preclinical models.
- A presentation featuring preclinical research evaluating imipridones, inclusive of dordaviprone (formerly ONC201) and JZP3507 (formerly ONC206), across renal cell carcinoma and small-cell lung cancer models, including combination approaches and comparative analyses to further characterize activity and mechanism.

Additional presentations will further explore zanidatamab's utility across HER2-expressing solid tumors and within innovative biomarker-driven clinical trial designs, including adaptive organ-preservation strategies in gastroesophageal adenocarcinoma (GEA).

The AACR abstracts are available at: https://www.aacr.org/meeting/aacr-annual-meeting-2026/

The full list of Jazz- and partner-supported presentations at the 2026 AACR Annual Meeting are:

Zanidatamab Presentations:

Presentation Title	Authors	Presentation Details
A phase 2 single-arm open-label trial evaluating zanidatamab in patients with early stage HER2 positive breast cancer: The NeoZanHER Study	Valero V, Pohlmann PR, Mouabbi J, Huang X, Qiao W, Alonzo H, Murthy RK, Rauch GM, Adesoye T, Checka C, Symmans FW, Grachev D, Alajajyan F, Nwosu-Iheme A, Hassan A, Patel MM, Giordano SH, Hunt K, Tripathy D, Meric-Bernstam F	**Type:** Oral Presentation **Session:** Clinical Trials Minisymposium: Aiming for Cure: Perioperative Clinical Trials **Date/Time:** April 18, 2026, 12:30-2:30 p.m. PST **Presentation number:** CT012

Zanidatamab modulates multiple pathways involved in tumor growth and survival and is efficacious post T-DXd	Karmokar A, Loro E, Kyakulaga AH, Lau D, Weisser N, Desjardins G, Raghunatha P, Clark E, Humphreys R, and Vaidya K	**Type:** Poster **Session:** Experimental and Molecular Therapeutics: Next-Generation Targeted Therapies Directed Against Tumor Surface Antigens **Date/Time:** April 21, 2026, 9:00 a.m.-12:00 p.m. PST **Abstract number:** 4542
DiscovHER PAN-206: Phase 2 tumor-agnostic study of zanidatamab in patients with previously treated human epidermal growth factor receptor 2-overexpressing solid tumors	Subbiah V, Makker V, Oh DY, Gardener E, Gartner E, Meric-Bernstam F	**Type:** Poster **Session:** Phase II and Phase III Clinical Trials in Progress **Date/Time:** April 21, 2026, 9:00 a.m.-12:00 p.m. PST **Abstract number:** CT209
AACR adaptive biomarker-driven organ preservation trial in GE adenocarcinomas (AACR-ADOPT-GEA)	Elimova E, Ajani JA, Klempner SJ, Schalper K, Wainberg ZA, Yuan Y, Baranski JD, Boerner S, Durbin S, Gallagher D, Huh W, McLaughlin R, Strickland M, Rubin EH, Siu LL, Yap TA, LoRusso P	**Type:** Poster **Session:** Phase II and Phase III Clinical Trials in Progress **Date/Time:** April 21, 2026, 9:00 a.m.-12:00 p.m. PST **Abstract number:** CT223

Dordaviprone (formerly ONC201) Presentations:

Presentation Title	Authors	Presentation Details
Nuvisertib (TP-3654) and Dordaviprone (ONC201) synergize to reduce renal cell carcinoma cell viability	Meza KS, Holder SL, El-Deiry W	**Type:** Poster **Session:** Experimental and Molecular Therapeutics: Targeting Cell Surface Vulnerabilities to Overcome Therapeutic Resistance **Date/Time:** April 20, 2026, 2:00-5:00 p.m. PST **Abstract number:** 3174
Imipridones ONC201, ONC206, and ONC212 show potent killing and colony arrest of small-cell lung cancer cell lines	Su AY, Purcell C, Zhang S, Zhou L, Uruchurtu AS, El-Deiry WS	**Type:** Poster **Session:** Experimental and Molecular Therapeutics: Cellular Responses to Anticancer Drugs **Date/Time:** April 20, 2026, 2:00-5:00 p.m. PST **Abstract number:** 2937

JZP898 Presentation:

Presentation Title	Authors	Presentation Details
JZP898, a conditionally activated interferon alpha, generates efficacy and robust TME engagement in syngeneic mouse models	Karmokar A, Loro E, Zhang Z, Mukavilli R, Gupta A, Trouba K, Amber V, Humphreys RC	**Type:** Poster **Session:** Experimental and Molecular Therapeutics: RNA, Gene and Cell Therapies, and Enabling Assay Technologies **Date/Time:** April 19, 2026, 2:00-5:00 p.m. PST **Abstract number:** 470

About Ziihera® (zanidatamab-hrii)

Ziihera (zanidatamab-hrii) is a bispecific HER2-directed antibody that binds to two extracellular sites on HER2. Binding of zanidatamab-hrii with HER2 results in internalization leading to a reduction in HER2 expression of the receptor on the tumor cell surface. Zanidatamab-hrii induces complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC), and antibody-dependent cellular phagocytosis (ADCP). These mechanisms result in tumor growth inhibition and cell death in vitro and in vivo.[1] In the United States, *Ziihera* is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test.[1] The FDA

granted accelerated approval for this indication 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(s).[1]

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 BeOne under license agreements from Zymeworks, which first developed the molecule.

A supplemental biologics license application for zanidatamab was submitted to the FDA under Real Time Oncology Review in first-line HER2+ locally advanced or metastatic GEA. The FDA granted two Breakthrough Therapy designations for zanidatamab's development: one as a single agent for previously treated HER2 gene-amplified BTC, and one in combination with standard-of-care chemotherapy for first-line HER2+ locally advanced or metastatic GEA. The FDA also granted 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 the FDA for the treatment of BTC, gastric (including gastroesophageal junction) cancer, and esophageal cancer, as well as Orphan Drug designations from the European Medicines Agency for the treatment of BTC, gastric/gastroesophageal junction cancer and oesophageal cancer.

Important Safety Information for ZIIHERA

WARNING: EMBRYO-FETAL TOXICITY
Exposure to ZIIHERA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity
ZIIHERA can cause fetal harm when administered to a pregnant woman. In literature reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death.

Verify the pregnancy status of females of reproductive potential prior to the initiation of ZIIHERA. Advise pregnant women and females of reproductive potential that exposure to ZIIHERA during pregnancy or within 4 months prior to conception can result in fetal harm. Advise females of reproductive potential to use effective contraception during treatment with ZIIHERA and for 4 months following the last dose of ZIIHERA.

Left Ventricular Dysfunction
ZIIHERA can cause decreases in left ventricular ejection fraction (LVEF). LVEF declined by >10% and decreased to <50% in 4.3% of 233 patients. Left ventricular dysfunction (LVD) leading to permanent discontinuation of ZIIHERA was reported in 0.9% of patients. The median time to first occurrence of LVD was 5.6 months (range: 1.6 to 18.7). LVD resolved in 70% of patients.

Assess LVEF prior to initiation of ZIIHERA and at regular intervals during treatment. Withhold dose or permanently discontinue ZIIHERA based on severity of adverse reactions.

The safety of ZIIHERA has not been established in patients with a baseline ejection fraction that is below 50%.

Infusion-Related Reactions
ZIIHERA can cause infusion-related reactions (IRRs). An IRR was reported in 31% of 233 patients treated with ZIIHERA as a single agent in clinical studies, including Grade 3 (0.4%), and Grade 2 (25%). IRRs leading to permanent discontinuation of ZIIHERA were reported in 0.4% of patients. IRRs occurred on the first day of dosing in 28% of patients; 97% of IRRs resolved within one day.

Prior to each dose of ZIIHERA, administer premedications to prevent potential IRRs. Monitor patients for signs and symptoms of IRR during ZIIHERA administration and as clinically indicated after completion of infusion. Have medications and emergency equipment to treat IRRs available for immediate use.

If an IRR occurs, slow, or stop the infusion, and administer appropriate medical management. Monitor patients until complete resolution of signs and symptoms before resuming. Permanently discontinue ZIIHERA in patients with recurrent severe or life-threatening IRRs.

Diarrhea
ZIIHERA can cause severe diarrhea.

Diarrhea was reported in 48% of 233 patients treated in clinical studies, including Grade 3 (6%) and Grade 2 (17%). If diarrhea occurs, administer antidiarrheal treatment as clinically indicated. Perform diagnostic tests as clinically indicated to exclude other causes of diarrhea. Withhold or permanently discontinue ZIIHERA based on severity.

ADVERSE REACTIONS
Serious adverse reactions occurred in 53% of 80 patients with unresectable or metastatic HER2-positive BTC who received ZIIHERA. Serious adverse reactions in >2% of patients included biliary obstruction (15%), biliary tract infection (8%), sepsis (8%), pneumonia (5%), diarrhea (3.8%), gastric obstruction (3.8%), and fatigue (2.5%). A fatal adverse reaction of hepatic failure occurred in one patient who received ZIIHERA.

The most common adverse reactions in 80 patients with unresectable or metastatic HER2-positive BTC who received ZIIHERA (≥20%) were diarrhea (50%), infusion-related reaction (35%), abdominal pain (29%), and fatigue (24%).

USE IN SPECIFIC POPULATIONS

Pediatric Use
Safety and efficacy of ZIIHERA have not been established in pediatric patients.

Geriatric Use
Of the 80 patients who received ZIIHERA for unresectable or metastatic HER2-positive BTC, there were 39 (49%) patients 65 years of age and older. Thirty-seven (46%) were aged 65-74 years old and 2 (3%) were aged 75 years or older.

No overall differences in safety or efficacy were observed between these patients and younger adult patients.

The full U.S. Prescribing Information for ZIIHERA, including BOXED Warning, is available at: https://pp.jazzpharma.com/pi/ziihera.en.USPI.pdf

About Modeyso ™ (dordaviprone)
Modeyso (dordaviprone) is approved by FDA for the treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy.[2] *Modeyso* is an orally administered small molecule given once weekly. *Modeyso* is a protease activator of the mitochondrial ClpP and also inhibits DRD2. In vitro, dordaviprone activates the integrated stress response, induces apoptosis, and alters mitochondrial metabolism, leading to restored histone H3 K27 trimethylation in H3 K27M-mutant diffuse glioma.[2]

Modeyso received accelerated approval based on a pre-specified integrated efficacy analysis of 50 adult and pediatric patients with recurrent H3 K27M-mutant diffuse midline glioma enrolled across five open-label clinical studies (ONC006, ONC013, ONC014, ONC016, and ONC018). Continued approval may be contingent upon verification and description of clinical benefit in the ongoing Phase 3 ACTION trial (NCT05580562), which is evaluating the safety and clinical benefit of *Modeyso* in newly diagnosed patients with H3 K27M-mutant diffuse glioma following radiotherapy. The FDA granted dordaviprone Rare Pediatric Disease designation and Fast-Track designation, and dordaviprone received Orphan Drug Designation in the United States, Europe and Australia. *Modeyso* was developed by Chimerix prior to its acquisition by Jazz Pharmaceuticals in April 2025.

Modeyso (dordaviprone) is not approved anywhere else in the world.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
Hypersensitivity
MODEYSO can cause severe hypersensitivity reactions.

In the pooled safety population, Grade 3 hypersensitivity reactions occurred in 0.3% of patients receiving MODEYSO. Signs and symptoms of hypersensitivity may include rash, hives, fever, low blood pressure, wheezing, or swelling of the face or throat.

Inform patients about the signs and symptoms of hypersensitivity reactions and instruct them to seek immediate medical attention if symptoms occur.

If clinically significant hypersensitivity or anaphylaxis occur, immediately interrupt MODEYSO and initiate appropriate medical treatment and supportive care. Based on the severity of the adverse reaction, temporarily interrupt or permanently discontinue MODEYSO.

QTc Interval Prolongation
MODEYSO causes concentration-dependent QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g. torsades de pointes) or sudden death.

In patients who received MODEYSO and underwent at least one post baseline ECG, QTcF increase of >60 msec compared to baseline and QTcF >500 msec occurred in 6% and 1.2% of patients, respectively.

Monitor ECGs and electrolytes prior to initiation and periodically during treatment, as clinically indicated. Increase the frequency of monitoring in patients with congenital long QT syndrome, existing QTc prolongation, a history of ventricular arrhythmias, electrolyte abnormalities, heart failure, or who are taking strong or moderate CYP3A4 inhibitors.

Avoid concomitant use with other agents known to prolong the QT interval. If concomitant use cannot be avoided, increase the frequency of monitoring and separate administration of MODEYSO and QT-prolonging product.

Interrupt or reduce the dose of MODEYSO in patients who develop QT prolongation; permanently discontinue in patients with signs of life-threatening arrhythmias.

Embryo-Fetal Toxicity
MODEYSO can cause fetal harm when administered to a pregnant woman.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with MODEYSO and for 1 month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with MODEYSO and for 1 month after the last dose.

ADVERSE REACTIONS
Serious adverse reactions occurred in 33% of the 376 patients who received MODEYSO. Serious adverse reactions in >2% of patients included hydrocephalus (5%), vomiting (4.3%), headache (3.2%), seizure (2.4%), and muscular weakness (2.1%). Fatal adverse reactions occurred in 1% of patients who received MODEYSO, including cardiac arrest (0.5%), intracranial hemorrhage (0.3%), and encephalopathy (0.3%).

The most common adverse reactions (≥20%) reported in clinical trials with MODEYSO were fatigue (34%), headache (32%), vomiting (24%), nausea (24%), and musculoskeletal pain (20%). The most common (≥2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (7%), decreased calcium (2.7%), and increased alanine aminotransferase (2.4%).

DRUG INTERACTIONS
Strong and Moderate CYP3A4 Inhibitors
Avoid concomitant use of MODEYSO with strong and moderate CYP3A4 inhibitors. If concomitant use cannot be avoided, reduce the MODEYSO dose as recommended and monitor for toxicity.

Strong and Moderate CYP3A4 Inducers
Avoid concomitant use of strong and moderate CYP3A4 inducers with MODEYSO.

USE IN SPECIFIC POPULATIONS

Lactation

There are no data on the presence of MODEYSO in human milk because of the potential for serious adverse reactions from MODEYSO in breastfed children, advise women not to breastfeed during treatment with MODEYSO and for 1 week after the last dose.

Pediatric Use

The safety and effectiveness of MODEYSO have not been established in patients less than 1 year of age. Dosing has not been established for patients weighing less than 22 pounds (10 kg).

Please refer to the full Prescribing Information, including both Patient Information and Instructions for Use, for complete safety and administration information.

The full U.S. Prescribing Information for MODEYSO is available at: https://pp.jazzpharma.com/pi/modeyso.en.USPI.pdf

About JZP898

JZP898 is an investigational differentiated, conditionally-activated IFNα INDUKINE™ molecule, and is currently in Phase 1 development for the investigational use in solid tumors as monotherapy and in combination with a PD-1 inhibitor. 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.

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 rare disease — often with limited or no therapeutic options. We have a diverse portfolio of medicines, including leading therapies addressing epilepsies, cancers and sleep disorders. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics. 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.

Cautionary Note Concerning Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the potential therapeutic benefits of zanidatamab in HER2+ first-line GEA and other HER2-expressing cancers, JZP898 and dordaviprone, 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 the successful completion of regulatory activities and uncertain regulatory approval, risks related to failure or delays in successfully initiating or completing clinical trials and assessing patients 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' Securities and Exchange Commission filings and reports, including Jazz Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2025, 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.

Contacts:

Media Contact:
CorporateAffairsMediaInfo@jazzpharma.com
Ireland +353 1 637 2141
U.S. +1 215 867 4948

Investor Contact:
InvestorInfo@jazzpharma.com
Ireland +353 1 634 3211
U.S. +1 650 496 2717

[1] ZIIHERA (zanidatamab-hrii) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.)

[2] MODEYSO (dordaviprone) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

View original content to download multimedia:https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-to-present-compelling-clinical-and-pre-clinical-data-advancing-oncology-research-at-aacr-2026-302716697.html

SOURCE Jazz Pharmaceuticals plc