



## Jazz Pharmaceuticals to Host Modeyso™ (dordaviprone) Investor Webcast on August 27, 2025

August 20, 2025

DUBLIN, Aug. 20, 2025 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) will host an investor webcast on Wednesday, August 27, 2025, at 4:30 p.m. EDT / 9:30 p.m. IST to provide an overview of clinical data, patient need and commercialization strategy for Modeyso™ (dordaviprone). Modeyso was approved under accelerated approval by the U.S. Food and Drug Administration (FDA) on August 6, 2025, 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.<sup>1</sup> Modeyso is the first and only treatment option approved by the FDA for this ultra-rare and aggressive brain tumor.

Jazz senior management will provide an overview of Modeyso and commercial launch plans. Timothy Cloughesy, M.D., distinguished professor of neurology, co-director, UCLA Brain Tumor Center; director, UCLA Neuro-Oncology Program, will provide clinical perspectives on Modeyso and discuss clinical data.

### Audio webcast/conference call:

Interested parties may register for the call in advance [here](#) or via the Investors section of the Jazz Pharmaceuticals website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com). To ensure a timely connection, it is recommended that participants register at least 15 minutes prior to the scheduled webcast.

A replay of the webcast will be available via the Investors section of the Jazz Pharmaceuticals website at <https://investor.jazzpharma.com/investors/events-presentations>.

### About Modeyso™ (dordaviprone)

Modeyso (dordaviprone) is approved by the U.S. Food and Drug Administration (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.<sup>1</sup> Modeyso is an orally administered small molecule given once weekly. Modeyso is a protease activator of the mitochondrial caseinolytic protease P (ClpP) and also inhibits dopamine D2 receptor (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.<sup>1</sup>

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](https://clinicaltrials.gov/ct2/show/study/NCT05580562)), which is evaluating the safety and clinical benefit of Modeyso in newly diagnosed patients with H3 K27M-mutant diffuse glioma following radiotherapy.<sup>2</sup> 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.

#### **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](http://www.jazzpharmaceuticals.com) for more information.

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#### **References:**

<sup>1</sup> MODEYSO (dordaviprone) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

<sup>2</sup> [ClinicalTrials.gov](#). ONC201 in H3 K27M-mutant Diffuse Glioma Following Radiotherapy (the ACTION Study) (ACTION). Updated June 6, 2025. Accessed July 23, 2025. [Study Details | ONC201 in H3 K27M-mutant Diffuse Glioma Following Radiotherapy \(the ACTION Study\) | ClinicalTrials.gov](#)



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