Jazz Pharmaceuticals Provides Update on Phase 2b Trial of Investigational Suvecaltamide (JZP385) in Essential Tremor

June 20, 2024

DUBLIN, June 20, 2024 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced top-line results from the Phase 2b clinical trial (NCT05122650) evaluating the efficacy and safety of suvecaltamide (JZP385), an investigational, highly selective and state-dependent modulator of T-type calcium channels, in adult patients with essential tremor (ET). Suvecaltamide did not achieve statistical significance at 30mg versus placebo on the primary endpoint of change from baseline to week 12 on the Essential Tremor Rating Assessment Scale (TETRAS) modified composite outcome score and key secondary endpoint of Clinical Global Impression-Severity (CGI-S) scale.

While not statistically significant, numeric improvements were observed on the primary endpoint and key secondary endpoint at 30mg versus placebo. The improvement in placebo from baseline to week 12 also exceeded the Company's expectations and was higher than what was observed for placebo in the prior T-CALM trial of suvecaltamide.

"We are disappointed that the trial did not meet its primary endpoint. We recognize the significant unmet need for people living with ET, and we are grateful to the patients, their families and the investigators that participated in the trial," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "We are evaluating the data to better understand the trial results and await the results of the suvecaltamide trial in Parkinson's disease tremor to determine next steps for the program. The Phase 2 Parkinson's disease tremor trial is ongoing with results expected first quarter 2025."

Suvecaltamide was well tolerated and the overall safety profile was consistent with previous studies with no new safety signals observed. The most common treatment-emergent adverse events (TEAEs) were dizziness, headache, paresthesia, diarrhea and insomnia. These were predominately mild to moderate in severity. One participant experienced a serious adverse event considered treatment related by the investigator.

About the Phase 2b Trial
The Phase 2b clinical trial (NCT05122650) is a 12-week, multicenter, double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of suvecaltamide in a once-daily oral dose of 10, 20 and 30mg or placebo. The primary endpoint (modified TETRAS composite outcome score) represents items 1-11 from the TETRAS-ADL combined with items 6+7 (spiral and handwriting assessments, respectively) from the TETRAS-PS with scoring modifications. The key secondary endpoint in the trial measured the percentage of participants with ≥1 point improvement on CGI-S. The trial randomized 420 participants from four countries.

About Suvecaltamide
Suvecaltamide (JZP385) is an investigational, highly selective and state-dependent modulator of T-type calcium channels (Ca_V3). T-type calcium channels play a role in the brain's control of muscle movement.[1] Suvecaltamide preferentially binds to stabilize a specific conformation of the channel and reduce activity. The suvecaltamide Phase 2 proof-of-concept trial in Parkinson's disease tremor is ongoing (NCT05642442).

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, 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.

Caution Concerning Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to potential timing of data availability from the JZP385 trial in Phase 2 Parkinson's disease tremor 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, 2023, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, 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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