Jazz Pharmaceuticals Provides Update on Phase 2 Trial of Investigational JZP150 in Adult Patients with Post-Traumatic Stress Disorder

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DUBLIN, Dec. 21, 2023 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced top-line results from the Phase 2 trial (NCT05178316) evaluating JZP150, an investigational small molecule selective fatty acid amide hydrolase (FAAH) inhibitor, on efficacy and safety in adults with post-traumatic stress disorder (PTSD). The trial did not meet the primary endpoint. There was not a statistically significant decrease in total PTSD symptom severity as measured by the Clinician Administered PTSD Scale (CAPS-5) between JZP150 (4mg or 0.3mg) compared to placebo from baseline to week 12. The trial also did not meet the key secondary endpoints of mean change from baseline to week 12 on the Clinical Global Impression of Severity (CGI-S) and the Patient Global Impression of Severity (PGI-S) scales.

"We are deeply grateful to all those who supported and made this trial possible, including the patients who were enrolled, their families, our investigators and trial staff," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "We plan to fully evaluate these data; however, based on top-line results we do not anticipate moving forward with additional JZP150 development in PTSD. We recognize the significant unmet need for PTSD patients and plan to share the findings from this trial with the medical community at a future date."

No new safety signals for JZP150 were observed. The most common treatment emergent adverse events (TEAEs) were headache, nausea and urinary tract infection. These were predominately mild to moderate in severity, and also occurred in placebo-treated participants.

About the JZP150 Phase 2 Trial
The multicenter, double-blind, placebo-controlled randomized, clinical trial (NCT05178316) evaluated two doses (4mg and 0.3mg) of JZP150. The trial randomized 282 adults aged 18 to 70 diagnosed with PTSD using the criteria of the American Psychiatric Association's Diagnostic and Statistical Manual for Mental Disorders, 5th edition (DSM-5).[1]

The primary endpoint of the trial measured participants' changes from baseline to week 12 using the total score from CAPS-5, a structured clinical interview that is considered the gold standard for diagnosing and assessing patients with PTSD. It includes 30 items with which physicians can make PTSD diagnoses and evaluate the severity of the symptoms as well as the impact on social and occupational functioning.[2] The trial had several secondary endpoints, including changes in scores on the CGI-S and PGI-S scales from baseline to the end of treatment.

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.

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References:

[1] American Psychiatric Association (APA). Diagnostic and Statistical Manual for Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Publishing; 2013.

[2] Weathers FW, Blake DD, Schnurr PP, Kaloupek DG, Marx BP, Keane TM. *The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)*. [Assessment] 2013. Available from www.ptsd.va.gov.

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