disorder (20.0%), depression (16.0%), attention-deficit/hyperactivity disorder (ADHD; 12.0%), and panic attacks (8.0%). Misdiagnosis of narcolepsy was reported in 32.0% of participants; alternative diagnoses included anxiety disorder, ADHD, sleep apnea (all 8.0%), and obsessive-compulsive disorder (4.0%). Physician specialties that confirmed narcolepsy diagnosis included neurologists and pediatricians (each 24.0%), pulmonologists (16.0%), pediatric neurologists (12.0%), general practitioners/internists (8.0%), and endocrinologists (4.0%). In participants with NT1 (n=16), warning symptoms for cataplexy were reported by 43.8% and included a sense that cataplexy was imminent without physical symptoms, a sense that time had somewhat suspended, fear/fright, and a feeling of warmness (all 6.3%). At diagnosis, the number of cataplexy episodes per day in order of frequency was 2 (37.5%), 3 (25.0%), 4 (18.8%), and 1 (12.5%). Current medications for narcolepsy included stimulants (60.0%), wake-promoting agents (40.0%), sodium oxybate (32.0%), serotonin-norepinephrine reuptake inhibitors (16.0%), and selective serotonin reuptake inhibitors (8.0%).

Conclusion: Interim baseline data from CATNAP provide valuable information on the experience and management of pediatric narcolepsy that will facilitate education of patients and caregivers, inform clinical decision-making, and potentially improve treatment strategies.

Support (If Any): Jazz Pharmaceuticals.

0386

LONG-TERM SAFETY DURING A CLINICAL TRIAL OF LOWER-SODIUM OXYBATE IN PARTICIPANTS WITH NARCOLEPSY WITH CATAPLEXY

Richard Bogan[1], Nancy Foldvary-Schaefer[2], Roman Skowronski[3], Abby Chen[3], Michael Thorpy[4]

University of South Carolina School of Medicine [1] Cleveland Clinic Lerner College of Medicine [2] Jazz Pharmaceuticals [3] Albert Einstein College of Medicine [4]

Introduction: Treatment-emergent adverse events (TEAEs) were analyzed during a 6-month open-label extension (OLE) of a double-blind, placebo-controlled, randomized withdrawal trial (NCT03030599) of lower-sodium oxybate (LXB; Xywav™). LXB is FDA approved for treating cataplexy or excessive daytime sleepiness in patients with narcolepsy aged ≥7 years and for treating idiopathic hypersomnia in adults.

Methods: Participants entered the OLE following rescreening (re-entry) after discontinuing LXB treatment or directly after completing the main study (rollover). Re-entry participants initiated LXB (4.5 g/night) or, if taking sodium oxybate (SXB) during rescreening, transitioned to identical LXB doses (gram-for-gram). Participants titrated (1–1.5 g/night/week) to a maximum of 9 g/night. TEAEs were assessed in all participants receiving ≥1 LXB dose. TEAE duration represents time from TEAE start to end date (or end of OLE, if TEAE end date unrecorded).

Results: In the analysis population (N=74, mean±SD age=37.6±12.6 years, 66.2% female, 91.9% White), 27 (36.5%) re-entered (after a median [range] of 15.0 [4.0–33.0] days), and 47 (63.5%) rolled over. Most reported ≥1 TEAE (overall, 58.1%; re-entry, 59.3%; rollover, 57.4%). Overall, the most commonly reported TEAEs were headache (n=7, 9.5%; peak incidence was month 3 [n=5/72]; median [range] duration=1.0 [1–25] day), nasopharyngitis (n=6, 8.1%; peak incidence was month 6 [n=2/69]; median [range] duration=9.0 [1–24] days), and dizziness (n=5, 6.8%; peak incidence was month 1 [n=3/74]; median [range] duration=26.0 [1–181] days). TEAEs were most prevalent in month 3 (n=11/72 [15.3%] reporting a TEAE). No participant reported fall or enuresis; 1 reported nausea (rollover). Most TEAEs were mild or moderate; 2 participants had severe TEAEs (invasive ductal carcinoma [IDC], n=1; dizziness, n=1). Few participants (14.9%) had LXB-related TEAEs, most frequently dizziness (overall, 5.4%; re-entry, 7.4%; rollover, 4.3%). LXB-related TEAEs were more common in participants who re-entered (re-entry, 22.2%; rollover, 10.6%). Seven participants discontinued (re-entry, n=2; rollover, n=5), 3 due to TEAEs (IDC, n=1; apathy, n=1; sleep apnea syndrome, n=1); only apathy was treatment related.

Conclusion: In this long-term study of LXB, safety and tolerability profiles were generally consistent with the known safety profile of SXB. The most common TEAEs were headache, nasopharyngitis, and dizziness.

Support (If Any): Jazz Pharmaceuticals.

0387

WEIGHT CHANGES DURING TREATMENT WITH LOWER-SODIUM OXYBATE IN A PHASE 3 CLINICAL STUDY IN PATIENTS WITH IDIOPATHIC HYPERSOMNIA

Yves Dauvilliers[1], Patricia Chandler[2], Luke Hickey[2], Abby Chen[2], Teresa Steininger[2], Nancy Foldvary-Schaefer[3]

Sleep and Wake Disorders Centre, Department of Neurology, Gui de Chauliac Hospital and University of Montpellier, INSERM Institute Neuroscience Montpellier [1] Jazz Pharmaceuticals [2] Sleep Disorders Center, Department of Neurology, Cleveland Clinic [3]

Introduction: Treatment with sodium oxybate (SXB) has been associated with weight loss in patients with narcolepsy. Lower-sodium oxybate (LXB) contains the same active moiety as SXB, with 92% less sodium, and is approved in the United States for the treatment of idiopathic hypersomnia in adults. This analysis assessed weight changes during LXB treatment in a phase 3 clinical study (NCT03533114).

Methods: Participants 18–75 years of age with idiopathic hypersomnia (treatment naive or taking an alerting agent [with or without SXB] at study entry) began LXB treatment in a 10- to 14-week, open-label, optimized treatment and titration period. After a 2-week stable-dose period (SDP) on their optimized dose of LXB, participants were randomized (1:1) to LXB or placebo for a 2-week, double-blind, randomized withdrawal period, followed by a 24-week open-label extension (OLE).

Results: Study participants (N=154) had a mean (SD) age of 40.3 (13.7) years; baseline mean (SD) weight was 76.9 (18.6) kg, and baseline mean (SD) body mass index (BMI) was 27.1 (5.9) kg/m2. At baseline, 1.3% (2/154) of participants were underweight (BMI <18.5 kg/m2), 40.3% (62/154) of participants had a normal weight (BMI 18.5 to <25 kg/m2), 33.8% (52/154) were overweight (BMI 25 to <30 kg/m2), and 24.7% (38/154) were obese (BMI ≥30 kg/m2). At the end of the SDP, 28.7% (31/108) of participants had weight loss ≥5%. Mean (SD) change in weight at the end of the SDP (n=108) was −2.5 (4.1) kg. Mean (SD) decreases in weight at the end of SDP were numerically greater in participants with higher baseline BMI (normal baseline BMI, −1.8 [3.0] kg; overweight baseline BMI, −2.8 [3.1] kg; obese baseline BMI, −3.2 [5.9] kg).

Conclusion: In this phase 3 clinical trial, adults with idiopathic hypersomnia treated with LXB experienced weight loss, including weight loss ≥5% in 28.7% of participants. Mean weight loss was greater in participants with a higher baseline BMI.

Support (If Any): Jazz Pharmaceuticals.