# Jazz Pharmaceuticals to Highlight Breadth of Research in Narcolepsy and Excessive Sleepiness in Obstructive Sleep Apnea at SLEEP 2018 Annual Meeting

May 10, 2018

**Twenty abstracts including eight oral presentations to showcase Jazz's breadth and depth of sleep medicine innovation**

DUBLIN, May 10, 2018 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) announced today that it will present 20 abstracts spanning the company's sleep portfolio at the 32nd Annual Meeting of the Associated Professional Sleep Societies, known as "SLEEP", in Baltimore from June 3-6, 2018.

"Jazz continues to invest in its pipeline and portfolio to deliver therapeutic options for the sleep community, and the breadth of data we are presenting at SLEEP is a testament to our substantial commitment to sleep medicine," said Jed Black, M.D., senior vice president, Sleep and CNS Medicine at Jazz Pharmaceuticals and adjunct professor, Stanford University Medical Center, Stanford Center for Sleep Sciences and Medicine. "We are particularly enthusiastic about our investigational medicine solriamfetol, which, if approved by the U.S. Food and Drug Administration, will offer patients a new and robust treatment option, and the first new chemical entity for the treatment of excessive sleepiness in narcolepsy and OSA in the U.S. in nearly 10 years."

On March 2, 2018, Jazz announced that the U.S. Food and Drug Administration (FDA) accepted for filing with standard review the company's New Drug Application (NDA) seeking marketing approval for solriamfetol (JZP-110), an investigational medicine for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA).

Highlights at SLEEP will include:

- Oral and poster presentations on results from an open-label, long-term safety and maintenance of efficacy study (TONES 5) of solriamfetol in the treatment of excessive sleepiness in patients with narcolepsy or OSA.
- Oral and poster presentations examining the impact of solriamfetol on wakefulness throughout the day from the Phase 3 TONES 2 and TONES 3 studies.
- Oral and poster presentations on post-hoc efficacy and safety analyses from the Phase 3 TONES 2 study for solriamfetol for excessive sleepiness in OSA, stratified by baseline cataplexy status.
- Oral and poster presentations regarding the impact of narcolepsy and OSA on work productivity and quality of life.
- Oral and poster presentations on the long-term safety and efficacy data from the Phase 2/3 study evaluating sodium oxybate in the treatment of pediatric patients with narcolepsy.
- Poster on supporting safety for patients diagnosed with narcolepsy by restricting distribution of sodium oxybate to a central pharmacy using a central database and longitudinal monitoring.

A full list of Jazz-supported oral and poster presentations covering solriamfetol and sodium oxybate follows below:

**Solriamfetol (JZP-110) Oral and Poster Presentations**

| **Presentation Title** | **Author** | **Date / Time / Session/ Presentation Number/ Location** |
|---|---|---|
| A Long-Term Safety and Maintenance of Efficacy Study of Solriamfetol (JZP-110) in the Treatment of Excessive Sleepiness in Subjects with Narcolepsy or Obstructive Sleep Apnea | Malhotra et al. | June 3 5:00-7:00 p.m.<br>Poster Session P12<br>Poster 331<br><br>June 5 1:30–2:30 p.m.<br>Oral Session O18<br>Abstract 620 |
| Solriamfetol (JZP-110) in the Treatment of Excessive Sleepiness in Narcoleptic Patients With and Without Cataplexy: Results From a Randomized, Phase 3, Clinical Trial | Dauvilliers et al. | June 3 5:00-7:00 p.m.<br>Poster Session P12<br>Poster 332<br><br>June 5 1:30–2:30 p.m.<br>Oral Session O18<br>Abstract 619 |
| Solriamfetol (JZP-110) in the Treatment of Excessive Sleepiness in Narcolepsy and Obstructive Sleep Apnea: Maintenance of Wakefulness Test Results Across the Day | Schweitzer et al. | June 3 5:00-7:00 p.m.<br>Poster Session P12<br>Poster 329<br><br>June 5 1:30–2:30 p.m.<br>Oral Session O18 |

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| | | Abstract 622 |
| Measures of Function, Work Productivity, and Quality of Life From a Phase 3 Study of Solriamfetol (JZP-110) in Patients with Narcolepsy | Emsellem et al. | June 3 5:00-7:00 p.m. Poster Session P12 Poster 330<br><br>June 5 1:30–2:30 p.m. Oral Session O18 Abstract 621 |
| Impacts of Excessive Sleepiness Associated With Obstructive Sleep Apnea on Work Productivity | Waldman et al. | June 3 5:00-7:00 p.m. Poster Session P02 Poster 59<br><br>June 4 1:45–2:45 p.m. Oral Session O09 Abstract 462 |
| Using Multiple Anchor-based And Distribution-based Estimates To Determine The Minimal Important Difference (MID) For The FOSQ-10 | Weaver et al. | June 3 5:00-7:00 p.m. Poster Session P12 Poster 343<br><br>June 4 3:00-5:00 p.m. Oral Session O12 Abstract 612 |
| US Healthcare Claims Analysis of Obstructive Sleep Apnea Comorbidities and Their Association with Stimulant Drug Use | Ohayon et al. | June 5 5:00-7:00 p.m. Poster Session P28 Abstract 1085 Poster 140 |

**Sodium oxybate / Narcolepsy-related Oral and Poster Presentations**

| **Presentation Title** | **Author** | **Date / Time / Session/ Presentation Number/ Location** |
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| Sodium Oxybate Treatment of Pediatric Narcolepsy: Effects on Weight, Height, and Pubertal Development | Dauvillier et al. | June 4 5:00-7:00 p.m. Poster Session P13 Abstract 0785 Poster 021 |
| Sodium Oxybate Treatment of Narcolepsy in Pediatric Patients: Long-term Efficacy and Safety | Mignot et al. | June 3 5:00-7:00 p.m. Poster Session P12 Poster 352<br><br>June 5 2:45–4:45 p.m. Oral Session O20 Abstract 813 |
| Pharmacokinetics of Sodium Oxybate in Children and Adolescents with Narcolepsy with Cataplexy | Rosen et al. | June 4 5:00-7:00 p.m. Poster Session P13 Abstract 0837 Poster 019 |
| Clinical and Patient Global Impression in a Phase 2/3 Study of Sodium Oxybate in Children and Adolescents with Narcolepsy with Cataplexy | Ruoff et al. | June 4 5:00-7:00 p.m. Poster Session P13 Abstract 0838 Poster 020 |
| Injuries, Motor Vehicle Accidents, and Near Misses in Narcolepsy: Results from the Nexus Narcolepsy Registry | Ohayon et al. | June 3 5:00-7:00 p.m. Poster Session P12 Abstract 0629 Poster 344 |
| Disease Burden in Pediatric Narcolepsy: a Claims-based Analysis of Healthcare Utilization and Costs, and Medical Comorbidity | Reiss<br>Reddy et al. | June 3 5:00-7:00 p.m. Poster Session P10 Poster 297<br><br>June 5 2:45–4:45 p.m. Oral Session O20 Abstract 812 |

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| Predictors of Time to Narcolepsy Diagnosis in Participants with Adult Onset of Symptoms: Results from the Nexus Narcolepsy Registry | Thorpy et al. | June 3 5:00-7:00 p.m. Poster Session P12 Abstract 0636 Poster 351 |
| US Prevalence of Narcolepsy and Other Sleep Disorders From 2013-2016: a Retrospective, Epidemiological Study Utilizing Nationwide Claims | Hess et al. | June 3 5:00-7:00 p.m. Poster Session P12 Abstract 0625 Poster 335 |
| Supporting Safety for Patients Diagnosed with Narcolepsy by Restricting Distribution of Sodium Oxybate to a Central Pharmacy Using a Central Database and Longitudinal Monitoring | Strunc et al. | June 5 5:00-7:00 p.m. Poster Session P28 Abstract 1088 Poster 143 |

**Additionally, the following investigator-sponsored trials focusing on sodium oxybate will be presented:**

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| Defining Disrupted Nighttime Sleep in Pediatric Narcolepsy | Maski et al. | June 4 5:00-7:00 p.m. Poster Session P13 Abstract 0784 Poster 018 |
| Role of diet in modulating the effects of sodium oxybate on weight gain in male Sprague-Dawley rats | Houser et al. | June 4 5:00-7:00 p.m. Poster Session P19 Abstract 0125 Poster 187 |
| Diagnostic Accuracy and Validity of the Swiss Narcolepsy Scale for the Diagnosis of Type 1 and Type 2 Narcolepsy Against Other Central Disorders of Hypersomnolence | Bargiotas et al | June 3 5:00–7:00 p.m. Poster Session P12 Abstract 0631 Poster 346 |
| The Bern Sleep-Wake Registry: | Calle et al | June 5 5:00–7:00 p.m. |
| Demographics And Clinical Characteristics of the First 6,831 Patients | | Poster Session P38 Abstract 0733 Poster 334 |

**About Solriamfetol**
Solriamfetol (JZP-110) is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) in development for treatment of excessive sleepiness in adult patients with narcolepsy, OSA, and Parkinson's disease. In 2014, Jazz Pharmaceuticals acquired a license to develop and commercialize solriamfetol from Aerial Biopharma. Jazz Pharmaceuticals has worldwide development, manufacturing, and commercialization rights to solriamfetol, excluding certain jurisdictions in Asia. SK Biopharmaceuticals, the discoverer of the compound (also known as SKL-N05), maintains rights in 12 Asian markets, including Korea, China and Japan. Solriamfetol has orphan drug designation in the United States for narcolepsy.

**About Xyrem**
Xyrem® (sodium oxybate) oral solution, CIII, is indicated for the treatment of cataplexy in narcolepsy and for the treatment of excessive daytime sleepiness in narcolepsy. Xyrem may only be dispensed to patients enrolled in the Xyrem REMS Program. Xyrem was first approved in the U.S. in 2002, based on clinical trial data in adults. The current United States Product Insert for Xyrem indicates that safety and effectiveness in pediatric patients have not been established. On April 27, 2018, Jazz submitted a supplemental NDA to FDA with revised proposed labeling to include data for use in pediatric patients, consistent with the FDA's pediatric written request.

**IMPORTANT SAFETY INFORMATION**

**Xyrem is a central nervous system (CNS) depressant. In clinical trials at recommended doses obtundation and clinically significant respiratory depression occurred in Xyremtreated patients. Almost all of the patients who received Xyrem during clinical trials in narcolepsy were receiving central nervous system stimulants.**

**Xyrem is the sodium salt of gamma hydroxybutyrate (GHB). Abuse of GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.**

**Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem REMS Program, using the central pharmacy that is specially certified. Prescribers and patients must enroll in the program. For further information go to www.XYREMREMS.com or call 1-866-XYREM88® (1-866- 997-3688).**

Xyrem is contraindicated in combination with sedative hypnotics or alcohol and in patients with succinic semialdehyde dehydrogenase deficiency.

Caution should be used when considering the concurrent use of Xyrem with other CNS depressants. Healthcare providers should caution patients

against hazardous activities requiring complete mental alertness or motor coordination within the first 6 hours of dosing or after first initiating treatment until certain that Xyrem does not affect them adversely. The rapid onset of sedation, coupled with the amnestic features of Xyrem, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (e.g. assault victim). Patients should be monitored for emergent or increased depression and suicidality and for impaired motor/cognitive function. Episodes of sleepwalking should be fully evaluated and appropriate interventions considered. The amount of daily sodium intake in each dose of Xyrem should be considered in patients sensitive to salt intake. The most common adverse reactions were nausea, dizziness, vomiting, somnolence, enuresis, and tremor.

**Please click here to see the full Prescribing Information for Xyrem, including BOXED Warning.**

**About the Nexus Narcolepsy Registry**
The Nexus Narcolepsy Registry is an effort by Wake Up Narcolepsy and the narcolepsy research and advocacy communities, in collaboration with Jazz Pharmaceuticals, to collect deidentified data from a large group of people with narcolepsy over several years in order to shed light on the impact of the condition on people's lives. To learn more about the registry, please visit www.narcolepsyregistry.com.

**About Jazz Pharmaceuticals plc**
Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem®(sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Defitelio® (defibrotide sodium) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For country-specific product information, please visit www.jazzpharmaceuticals.com/products. For more information, please visit www.jazzpharmaceuticals.com and follow us on Twitter at @JazzPharma.

**"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995** This press release contains forward-looking statements, including, but not limited to, statements related to solriamfetol (JZP-110) as a potential treatment for excessive sleepiness in adult patients with narcolepsy or OSA and other statements that are not historical facts. These forward-looking statements are based on the company's 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 regulatory approval process, including the risk that the company is unable to obtain FDA approval for solriamfetol in a timely manner or at all; and effectively commercializing solriamfetol; and other risks and uncertainties affecting the company 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 the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and future filings and reports by the company. Other risks and uncertainties of which the company is not currently aware may also affect the company's 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 the company on its website or otherwise. The company 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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SOURCE Jazz Pharmaceuticals plc

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