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New Drug Application Submitted For Excessive Sleepiness Therapy

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Jazz Pharmaceuticals Submits New Drug Application for Solriamfetol (JZP-110) for Excessive Sleepiness

Jazz Pharmaceuticals declared about the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration.

The company is looking for marketing approval of solriamfetol (JZP-110), an investigational medicine for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA).

The solriamfetol Phase 3 clinical program includes one study evaluating excessive sleepiness in adult patients with narcolepsy (TONES 2),two studies evaluating excessive sleepiness in adult patients with OSA (TONES 3 and TONES 4), and an open-label, long-term safety and maintenance of efficacy study (TONES 5) in the treatment of excessive sleepiness in patients with narcolepsy or OSA.

"Excessive sleepiness due to narcolepsy or OSA can affect a person's ability to function at work or at home, and many patients unfortunately might suffer for years before their condition is properly addressed," said Karen Smith, M.D., executive vice president, research and development and chief medical officer at Jazz Pharmaceuticals.

"Jazz is committed to addressing unmet needs in this area by improving awareness and accurate diagnosis of these conditions and by delivering meaningful treatment option." He added