Medical Xpress

FDA approves lumryz for narcolepsy

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The U.S. Food & Drug Administration has approved Lumryz for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy. Lumryz is an extended-release formulation of sodium

oxybate to be taken once at bedtime.

The approval was based on results from the REST-ON phase 3 trial, in which once-at-bedtime Lumryz led to significant and clinically meaningful improvement across the three coprimary end points of Maintenance of Wakefulness Test, Clinical Global Impression-Improvement, and mean weekly cataplexy attacks versus placebo for all three doses evaluated.

The most common adverse reactions (incidence of more than 5 percent and greater than placebo) were nausea, dizziness, enuresis, headache, and vomiting, which were reported for all doses.

"Today's landmark approval and receipt of Orphan Drug Exclusivity represents a major milestone for both Avadel and people living with narcolepsy. As we have heard from key stakeholders, previously approved narcolepsy therapies have the potential to disrupt sleep by either causing insomnia or through forced awakening during the middle of the night for their crucial second dose," Greg Divis, CEO of Avadel Pharmaceuticals, said in a statement.

"Lumryz can now offer people with narcolepsy the opportunity for an uninterrupted night sleep while receiving the full benefit of their prescribed treatment in one single bedtime dose that addresses their symptoms of narcolepsy."

Approval of Lumryz was granted to Avadel.

More information: Avadel press release