

Daridorexant safe, effective for insomnia disorder

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(HealthDay)—Daridorexant (50 mg) improves both nighttime symptoms



and daytime functioning in people with insomnia disorder, according to a study published in the Feb. 1 issue of *The Lancet Neurology*.

Emmanuel Mignot, M.D., from the Stanford Center for Sleep Research and Medicine in Palo Alto, California, and colleagues conducted two phase 3 randomized controlled trials at 156 sites in 17 countries. The authors randomly assigned 930 adults with insomnia disorder (1:1:1) to receive either daridorexant (50 mg, 25 mg) or placebo in study 1 and 924 adults to receive either daridorexant (25 mg, 10 mg) or placebo in study 2 every evening for three months.

The researchers found that in study 1, wake time after sleep onset (WASO) and latency to persistent sleep (LPS) were significantly reduced among participants in the daridorexant 50-mg group versus participants in the placebo group at month 1 and month 3. Similar results for WASO and LPS were seen among those receiving daridorexant 25 mg versus the placebo group. The daridorexant 50-mg group also had significantly improved self-reported total sleep time and Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ) scores at month 1 and month 3 compared with placebo. However, the daridorexant 25-mg group only saw significant improvements in self-reported total sleep, not IDSIQ sleepiness domain scores. In study 2, WASO was significantly reduced in the daridorexant 25-mg group versus placebo at month 1 and month 3, but there were no significant differences seen in LPS. The daridorexant 25-mg group saw significant improvement in selfreported total sleep time at month 1 and month 3, but not in IDSIQ sleepiness domain scores at either timepoint. No significant improvements for any measures were seen for the daridorexant 10-mg group versus placebo. The overall incidence of adverse events was similar between treatment groups across studies.

"It is exciting to see that insomnia is finally not solely viewed as a nighttime problem but as a cause of daytime suffering," Mignot said in a



statement.

Several authors disclosed financial ties to <u>pharmaceutical companies</u>, including Idorsia Pharmaceuticals, which manufactures daridorexant and funded the study.

More information: <u>Abstract/Full Text (subscription or payment may be required)</u>

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