

Brief summaries of recent drug approvals, interactions, and adverse events

## Help for Sarcoidosis-Related Fatigue

More than half of sarcoidosis patients say fatigue is debilitating, and most studies of sarcoidosis identify fatigue as a major cause of impaired quality of life. Armodafinil significantly reduces fatigue in patients with sarcoidosis, according to a small study by researchers from the University of Cincinnati in Cincinnati, Ohio, and Harvard Medical School in Boston, Massachusetts.

In this double-blind crossover study, patients received armodafinil or placebo with 8 weeks of therapy for each arm and a 2-week washout period. Armodafinil was started at 150 mg; the dose was increased to 250 mg after 4 weeks. Patients underwent polysomnography and multiple sleep latency testing (MSLT) after each treatment arm. (Sleep apnea is more common in sarcoidosis patients than in the general population.) Fatigue was assessed using the Fatigue Assessment Scale (FAS).

Of 30 patients with persistent fatigue, 10 patients were unable or unwilling to do the sleep studies; another 5 patients were excluded. The remaining 15 patients had baseline sleep studies revealing an apnea-hypopnea index (the sum of apnea and hypopnea events per hour of sleep) of  $\leq$  5 per hour. Those patients received at least 1 dose of therapy. One patient withdrew after 4 days of armodafinil treatment due to severe anxiety that resolved with drug discontinuation.

After 8 weeks of therapy, 9 patients treated with armodafinil reported a clinically significant  $\geq$  4-point decrease in the FAS score, vs only 1 patient on placebo (*P* = .0295). The FAS score (the only sarcoidosis-specific fatigue score) decreased for the drug-treated patients and increased for the placebo-treated patients throughout the study. Similarly, 7 patients treated with 4 weeks of armodafinil reported a clinically significant  $\geq$  4-point increase in their Functional Assessment of Chronic Illness Therapy—Fatigue (FACIT-F) scores (showing reduced fatigue), vs no placebo patients (*P* = .0149). Scores on FACIT-F continued to increase for drug-treated patients and dropped for the placebo patients after 8 weeks of therapy (*P* = .004)

Nine patients with significant persistent fatigue, either at the time of screening or in the past—despite adequate positive airway pressure treatment—all improved with armodafinil. And the improvements in fatigue were not just improvements in sleepiness: The effect was seen in patients with and without objective sleepiness based on the MSLT. Moreover, the improved sleepiness scores led to better vitality scores. ● Source: Lower EE, Malhotra A, Surdulescu V, Baughman RP. J Pain Symptom Manage. 2013;45(2): 159-169.

doi: 10.1016/j.jpainsymman.2012.02.016.