FDA Approves Milnacipran for Fibromyalgia

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Milnacipran, a selective serotonin and norepinephrine dual reuptake inhibitor, has been approved by the Food and Drug Administration for the management of fibromyalgia in adults, the third drug approved for this indication.

Approval was based on the results of two phase III studies of a total of 2,084 patients with fibromyalgia, which found that during 3-6 months of treatment, those (1,460 patients) treated with 100 mg or 200 mg of milnacipran per day experienced statistically significant and clinically meaningful improvements in pain, patient global assessment, and physical function, compared with those on placebo.

A 30% or greater improvement in pain scores at 15 weeks was reported by 56% of patients on the 200-mg dose and 53% on the 100-mg dose, both significantly better than the 41% on placebo.

Milnacipran is expected to be available in pharmacies in March, according to Forest Laboratories Inc. and Cypress Bioscience Inc., which will market it under the trade name Savella.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) plan is necessary for milnacipran "to ensure that the benefits of the drug outweighs the risks," according to the FDA's approval letter, which notes that the serious risks associated with drugs in this class are serious psychiatric symptoms, including suicidal ideation, particularly in patients with depression. The letter noted that patients with fibromyalgia often have other other mood disorders, such as major depression. ■