ACR: Savella Brings Relief Long-Term in Fibromyalgia

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3 comment(s)

CHICAGO -- Patients diagnosed with fibromyalgia who remain on therapy can achieve long-term pain relief -- to at least three years -- from treatment with the selective serotonin and norepinephrine reuptake inhibitor milnacipran (Savella), researchers said here.

After obtaining about a 25% decrease in pain scores within three months of therapy with milnacipran, the 217 patients who stayed on open-label treatment maintained that relief level to at least 38 months, said Lesley Arnold, MD, professor of psychiatry at the University of Cincinnati College of Medicine.

"These findings provide support for sustained long-term efficacy of milnacipran for treatment of fibromyalgia," Arnold told *MedPage Today* at her poster presentation during the annual meeting of the American College of Rheumatology.

Of the patients who remained on the study, 70% demonstrated clinically significant improvements in global status after three years of treatment, she said.

She reported on a trial that originally included 1,268 patients, with 1,220 in an intention-to-treat status. The four-phase study included a two-week washout period, a two-week dose-escalation period, then eight weeks on a stable dose. That was followed by flexible dosing of 50 mg to 200 mg of milnacipran a day through the three-year run of the study.

Arnold illustrated that the relief achieved by the 820 patients who completed one year of the trial was similar to the pain relief achieved by the 462 patients who completed two years of therapy and by the 217 patients who were treated for three years.

In the original cohort, 1,212 evaluable patients achieved a mean decrease of 17.6 points in their Visual Analogue Pain Weekly Recall, or Visual Analogue Scale (VAS). At the three-year visit, the VAS score among the 217 patients still on medication showed a 23.9-point decrease. The responder rate to milnacipran remained about 70% of the population across all three years of the study.

"One of the major obstacles for treatment of patients with fibromyalgia is keeping them on therapy," said Eric Matteson, MD, chairman of rheumatology and professor of medicine at the Mayo Clinic School of Medicine.

"This study is encouraging because it shows that if you can keep the patients taking their medication, pain relief can be maintained for the long term."

The mean age of the patients in the study was 50.3 years, Arnold and colleagues reported. As common with fibromyalgia, 95.4% of the original intention-to-treat population were women, and 93.1% of the original cohort were white. The mean weight of the patients in the study was 82 kg, and their mean body mass index was 30.7 kg/m2.

On the VAS pain 24-hour recall, the mean score was 60.9; on the weekly recall, the mean score was 63.6, which Arnold said represented a pain that is difficult to ignore.

"We were able to lower this pain level by about a third with milnacipran," she said, "and that is as meaningful reduction. We observed improvements in pain, global status, and physical functioning that were maintained with long-term milnacipran treatment."

The study was funded by Forest Laboratories.

Arnold disclosed commercial interests with Eli Lilly, Pfizer, Cypress Bioscience, Boehringer Ingelheim, Forest Laboratories, Novartis, Takeda , AstraZeneca, sanofi-aventis, Grunenthal, and Johnson & Johnson. Co-authors included employees of Forest Research Institute.

Matteson disclosed commercial interests with Genentech and Biogen IDEC.

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Arnold L, et al "3-year efficacy of milnacipran in patients with fibromyalgia: an open-label, flexible-dosing study" Arthritis Rheum: 63(10); Abstract 1907.

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