Investigational Drug Being Studied for Osteoarthritis of Knee

Nektar Therapeutics announced the preliminary topline results from a Phase II study of NKTR-181 for the treatment of moderate-to-severe chronic pain in patients with osteoarthritis of the knee. The study utilized a double-blind, placebo-controlled, randomized withdrawal study design to assess the efficacy, safety, and tolerability of NKTR-181. Of the 295 patients who entered the study, only 9 (3%) patients were unable to achieve meaningful pain relief with NKTR-181. Fifty-three (18%) patients discontinued treatment during the titration period because of adverse events, most of which are those commonly associated with opioid agents. A total of 213 patients achieved an average 40% reduction in pain and entered the randomized phase of the study.

Following the titration period, patients were randomized 1:1 to either continue to receive their analgesic dose of NKTR-181 or to receive placebo for 21 days. NKTR-181 performed as expected as an opioid analgesic agent throughout the study with patients continuing to show a reduction in pain scores throughout the randomized phase of the study. However, patients who were randomized to placebo did not show the expected increase in pain scores observed in similar enriched enrollment, randomized withdrawal studies. This unusual lack of a placebo rebound caused the Phase II study to miss the primary endpoint in the study, which was based on the average change in a patient’s pain score from pre-randomization baseline to the end of the double-blind, randomized treatment period of the study.

Nektar is carefully evaluating the lack of post-randomization rebound in the placebo arm to design the optimal pivotal trials for this drug. Based on the data from this trial, the company reported, it is clear that NKTR-181 provides pain relief on par with existing opioid agents while achieving a favorable safety profile that differentiates it from standard opioid agents.

Drug Approved to Treat Hot Flashes, Prevent Osteoporosis

The U.S. Food and Drug Administration (FDA) recently approved Duavee® (conjugated estrogens/bazedoxifene) for women with moderate-to-severe hot flashes (vasomotor symptoms) associated with menopause and to prevent osteoporosis after menopause.

Duavee is the first FDA-approved medication that combines estrogen with an estrogen agonist/antagonist (bazedoxifene). The bazedoxifene component of Duavee reduces the risk of endometrial hyperplasia (excessive growth of the lining of the uterus) that can occur with the estrogen component of Duavee.

Duavee is intended only for postmenopausal women who still have a uterus. Like other products containing estrogen, Duavee should be used for the shortest duration consistent with treatment goals and risks for the individual woman. When using Duavee only for the prevention of osteoporosis, such use should be limited to women who are at significant risk of osteoporosis after carefully considering alternatives that do not contain estrogen.

The most common side effects observed in patients receiving Duavee were muscle spasms, nausea, diarrhea, dyspepsia, upper abdominal pain, oropharyngeal pain, dizziness, and neck pain. Because Duavee contains estrogen, it is being approved with the same Boxed Warning and otherWARNINGS and Precautions that have been approved with estrogen products.