News From the Food and Drug Administration

Relief From Heavy Bleeding Due to Uterine Fibroids

A new drug that combines estrogen and progestin has received approval for premenopausal women who experience heavy menstrual bleeding from uterine fibroids—the most common type of benign tumor that affects women of reproductive age.

Marketed as Oriahnn, the treatment consists of dual capsules. One containing elagolix, estradiol, and norethindrone acetate is taken in the morning. The other, with only elagolix, is taken at night. Women shouldn't use the drug for more than 24 months because of an increased risk of potentially irreversible bone loss.

In 2 identical phase 3 clinical trials, a total of 790 women were randomized to receive the dual capsule therapy, elagolix alone, or placebo. The primary end point in the 6-month trials was menstrual blood loss less than 80 mL during the final month of treatment and a 50% or greater reduction in menstrual blood loss from baseline to the final month of the studies.

About two-thirds of women in the first trial and three-fourths in the second trial who received the dual capsule therapy met the primary end point compared with about 10% of the women in the placebo groups. The 2 treatment groups were compared only to determine changes in bone mineral density. Bone loss was significantly less among women who received dual capsule treatment. The most common adverse events were hot flashes and metrorrhagia.

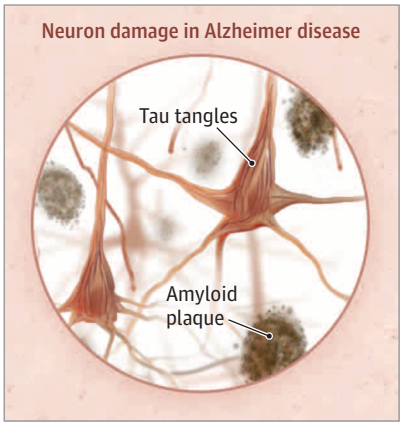
New Diagnostic Agent Detects Tau Pathology in the Brain

The FDA has approved a new imaging drug to help detect tau pathology—a distinctive characteristic of Alzheimer disease in the brain.

Flortaucipir F 18, marketed as Tauvid, is a radioactive diagnostic agent used for adults with cognitive impairment who are being evaluated for Alzheimer disease. The drug is indicated for positron emission tomography (PET) imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles.

"While there are FDA approved imaging drugs for amyloid pathology, this is the first drug approved for imaging tau pathology, 1 of the 2 neuropathological hallmarks of Alzheimer's disease," Charles Ganley, MD, director of the FDA's Office of Specialty Medicine, said in a statement.

When administered intravenously, flortaucipir F 18 binds to sites in the brain associated with tau protein misfolding. Subsequent imaging with a PET scan can help determine whether tau pathology is present. Currently, the only way to definitively diagnose Alzheimer disease is through a postmortem examination of the brain.



Flortaucipir F 18 was evaluated in 2 clinical studies in which 5 independent readers who were blinded to clinical information interpreted imaging performed with the drug. In the first study, 156 patients who were terminally ill agreed to undergo imaging with flortaucipir F 18 and to participate in a postmortem brain donation program. Independent readers evaluated scans from 64 of these patients—49 who had dementia, 1 with mild cognitive impairment, and 14 with no cognitive impairment. Their analyses were compared with those from pathologists who examined tau pathology in the patients' brains at autopsy. In the readers' evaluations of scans, sensitivity ranged from 92% to 100% and specificity varied from 52% to 92%.

The second study included the 64 patients evaluated in the first study as well as an additional 18 of the patients who were terminally ill and 159 with cognitive impairment who were being evaluated for Alzheimer disease. Analyses of PET scans from the first group of independent readers were compared with those from 5 new independent readers. They came to the same conclusions 87% of the time.

FDA officials cautioned that PET scans with flortaucipir F 18 were used to evaluate patients with severe dementia and that the test's accuracy could be lower for patients in earlier stages of cognitive decline. Common adverse reactions were headache, injection site pain, and high blood pressure.

Expanded Indication for Triple-Drug Antibiotic

An antibiotic already available for patients with complicated urinary tract infections or complicated intra-abdominal infections has received approval to treat adults with hospital-acquired or ventilator-associated bacterial pneumonia who have limited or no treatment options.

Sold under the brand name Recarbrio, the drug is a combination of imipenem, cilastatin, and relebactam. It is given intravenously by a health care professional.

In a phase 3 clinical trial involving 535 hospitalized patients who were treated for 14 days, the triple-drug antibiotic was compared with piperacillin and tazobactam, a common treatment for bacterial pneumonia. About half of the patients were ventilated at enrollment. The primary end point was death due to any cause at 28 days and a secondary end point was early clinical response 7 to 14 days after starting treatment.

Results showed that the triple-drug combination was noninferior to piperacillin and tazobactam for both all-cause mortality and early clinical response, according to manufacturer Merck & Co Inc. Common adverse reactions were diarrhea, nausea, and headache. **– Rebecca Voelker, MSJ**

Note: Source references are available through embedded hyperlinks in the article text online.