

News Capsules

WHAT'S NEW IN DRUG RESEARCH
AND MANAGED CARE PHARMACY

New agent reduces PTH levels in hemodialysis patients with secondary hyperparathyroidism

PHILADELPHIA, PA—The first agent in an investigational class of compounds known as the calcimimetics can control parathyroid hormone (PTH) levels in patients with end-stage renal disease who have secondary hyperparathyroidism, which occurs as a complication in half or more of all patients with chronic kidney disease.

The agent, cinacalcet (NPS Pharmaceuticals), rapidly reduces PTH secretion by increasing the sensitivity of the calcium-sensing receptor to extracellular calcium. Data were presented in Philadelphia at the 35th annual meeting of the American Society of Nephrology.

"Cinacalcet is a completely novel compound that modulates the sensitivity of the calcium-sensing receptor and allows us to manage hyperparathyroidism and control calcium-phosphorous product (Ca x P) in a way that we never could before," said Geoffrey A. Block, MD.

Cinacalcet was studied in a multicenter, double-blind trial of 82 patients on maintenance hemodialysis who had pre-study PTH levels of 300 pg/mL or greater despite standard therapies. Patients were randomized to cinacalcet (up to 180 mg/d) or placebo for 12 weeks.

At the study's conclusion, 54% of cinacalcet-treated patients had plasma

PTH reduced to the target level (≤ 250 pg/mL), compared with only 5% of placebo recipients ($P < .001$), according to Dr Block, who is director of clinical research at Denver Nephrologists. Cinacalcet reduced PTH levels by the first week of dose titration, and PTH levels remained significantly lower compared with placebo throughout the study.

"This agent allows us to control

PTH without exacerbating Ca x P," Dr Block said. "In fact, we're able to give less binder because we're not driving phosphorus absorption from the GI tract with cinacalcet."

Ca x P declined by 13.1% in cinacalcet-treated patients ($P = .003$) compared with only 5.6% in the placebo group ($P = .08$).

The rate of adverse events was similar between the two groups, with transient GI symptoms being most common. No symptomatic hypocalcemia events occurred during the study and no patient had to be withdrawn from the study because of low serum calcium concentrations.

Data from two 1-year studies support the benefit of long-term cinacalcet therapy in addition to standard therapy in reducing PTH levels. In these studies, cinacalcet 25 to 100 mg/d was compared with placebo in a total of 149 hemodialysis patients with PTH levels of 300 pg/mL or greater.

Fifty percent of patients in the cinacalcet group and 12% in the placebo

group had a 30% or greater reduction in their PTH levels from baseline, according to lead investigator Sharon Moe, MD, associate professor of medicine and assistant dean for research, Indiana University, Indianapolis, Ind.

Forty-nine patients

from these studies have completed a 1-year open-label extension study of cinacalcet. "For 2 years, we were able to maintain suppression of PTH using 30 to 180 mg/d of cinacalcet," Dr Moe said.

NPS Pharmaceuticals' licensee, Amgen Inc, has announced that it intends to file an NDA for cinacalcet during the second half of 2003.

■ The agent, cinacalcet, rapidly reduces PTH secretion by increasing the sensitivity of the calcium-sensing receptor.

Omalizumab appears effective in patients with poorly controlled allergic asthma

DENVER, COLO—Patients whose asthma was poorly controlled with conventional treatments and who received the investigational anti-immunoglobulin-E drug omalizumab experienced about half the number of asthma deterioration-related incidents as patients who did not receive the add-on medication.

Rob Niven, MD, a respiratory consultant at the North West Lung Research Centre, Manchester, United Kingdom,

said that in the yearlong open-label study, patients receiving add-on omalizumab had an annualized rate of 4.92 events per patient year, compared with 9.76 per patient year for patients who continued to receive baseline treatment for their asthma ($P < .001$).

In his presentation at the 60th anniversary meeting of the American Academy of Allergy, Asthma and Immunology, Dr Niven defined asthma

deterioration-related incidents as those events in which patients needed to take a course of oral steroids or antibiotics, in which they missed school or work attendance due to illness, in which they required an unscheduled physician visit, or in which they had to go to the emergency room or were hospitalized. Dr Niven said the need for antibiotics for lung infections was a surrogate marker for lung function.

The researchers enrolled 206 patients into the trial to receive omalizumab, a

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