Industry Spotlight

New Drug for SHPT in CKD Stages 3–4

The US Food and Drug Administration (FDA) approved Rayaldee (calcifediol) (OPKO Health, Miami, FL) extended-release capsules for treatment of secondary hyperparathyroidism (SHPT). The approval applies only to treating adults with SHPT who have CKD stage 3 or 4 and serum total 25-hydroxyvitamin D <30 ng/mL.

Rayaldee has a patented design intended to increase serum total 25-hydroxyvitamin D (prohormone) levels to targeted levels and also to decrease elevated intact parathyroid hormone (iPTH). It is the first drug approved for this specific purpose.

"Rayaldee is an important new option for treating SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency," Kevin J. Martin, Director of Research, Division of Nephrology, at Saint Louis University School of Medicine, stated in the company media release. "The great majority of SHPT cases in this patient population are associated with vitamin D insufficiency, a problem that Rayaldee can correct."

The FDA approval was based on data from two 26-week placebo-controlled, double-blind phase 3 trials that showed a greater proportion of CKD stage 3 or 4 patients with SHPT and vitamin D insufficiency achieved reductions of >30% in plasma iPTH after treatment with Rayaldee vs. placebo. More than 80% of patients receiving Rayaldee were able to correct their vitamin D insufficiency compared with <7% of patients receiving placebo.

Over-administration of calcifediol can cause hypercalciuria, hypercalcemia, hyperphosphatemia, or oversuppression of intact PTH, the company noted.

Rayaldee extended-release capsules will be available in the second half of 2016.

New Combo Drug for Hypertension

A combination therapy called Byvalson has been approved by the FDA to treat high blood pressure.

Taken together once a day in a fixed dose pill from Allergan (Parsippany, NJ; Dublin, Ireland), the two drugs—Nebivolol and Valsartan—work by using different mechanisms to lower blood pressure.

Nebivolol (marketed in the US as Bystolic) is a beta-adrenergic receptor blocking agent. While the drug's mechanism of action "has not been definitively established," the company suggested that its actions might include vasodilation and decreased peripheral vascular resistance (PVR), reduced heart rate, and myocardial contractility and renin suppression.

Valsartan (brand name Diovan) is an angiotensin II receptor blocker that blocks the binding of angiotensin II to the AT1 receptor in many tissues.

Allergan noted that Byvalson is the first and only fixed-dose combination of a beta blocker and angiotensin II receptor blocker available in the US.

FDA approval was based on a phase 3, double-blind, placebo-controlled, dose-escalating, 8-week efficacy and safety study, published in *The Lancet*.

The study randomized approximately 4100 patients with stage 1 or 2 hypertension to the drug. In an efficacy and safety study, treatment with the combination of Nebivolol and Valsartan for 4 weeks was associated with statistically significant reductions from baseline in diastolic and systolic blood pressure versus either Nebivolol or Valsartan alone. The overall rate of adverse events was similar across treatment groups and placebo.

Allergan said it expects Byvalson to be available in the second half of 2016.

Fresenius Enters Regenerative Medicine Field

The world's largest provider of dialysis services now has a new business: a regenerative medicine company. Frensenius Medical Care (Bad Homburg, Germany) has opened the doors of Unicyte AG, a subsidiary that will undertake research into kidney and liver diseases, diabetes, and cancer.

Fresenius' primary partner in Unicyte is the Molecular Biology Center at the University of Turin in Italy. The center specifically focuses on the study of the molecular mechanisms underlying the physiopathological processes that result in cardiovascular diseases, inflammation, and cancer, as well as on the intricacies of stem cell biology. The research efforts are aimed at developing advanced molecular imaging technology and bioinformatic analysis, and generating mouse and zebrafish models.

Fresenius, which has collaborated with the University of Turin since 2003, says it will work with additional partners as needed to advance these projects. One of the first successes between the partners was the isolation and characterization of a human stem cell population from an adult liver.

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