New Publication Presents Comparative Efficacy Data For Abbott's Zemplar® (Paricalcitol) In Treating Secondary Hyperparathyroidism In Hemodialysis Patients

Study Provides Head-to-Head Comparison of Treatment with Zemplar Against Treatment with Cinacalcet Plus Low-Dose Vitamin D

Abbott Park, Illinois (NYSE: ABT) — Abbott today announced the publication of a Phase 4 clinical trial comparing the efficacy of Zemplar against cinacalcet plus low-dose vitamin D in treating secondary hyperparathyroidism (SHPT) in patients on kidney dialysis (hemodialysis). In the study, more patients treated with intravenous Zemplar achieved their treatment goal, compared to patients treated with cinacalcet plus low-dose vitamin D. SHPT occurs frequently in chronic kidney disease patients and can cause an imbalance in calcium and phosphorus levels in the body.

Data from the study, called IMPACT-SHPT, were published online recently in Nephrology Dialysis Transplantation. IMPACT-SHPT was an international, multi-center, open-label Phase 4 study that investigated 272 patients over 28 weeks. Patients were randomly assigned to receive either intravenous or oral Zemplar or cinacalcet plus low-dose vitamin D, either intravenously or orally.

"IMPACT-SHPT is an important study to the field of nephrology because for the first time, it gives us clinical data that directly compare the efficacy of the leading treatments currently used to manage elevated intact parathyroid hormone (iPTH) levels in hemodialysis patients. In this study, more patients reached the target iPTH level with paricalcitol monotherapy compared to a combination treatment with cinacalcet," said Dr. Markus Ketteler, professor of medicine and head, division of nephrology, Klinikum Coburg, and the lead author of the study.

In the study, significantly more patients in the intravenous Zemplar group achieved the primary end point (57.7%) of a mean iPTH level of 150-300 pg/mL during weeks 21-28 than patients in the cinacalcet group (32.7%; $p = 0.016$). More patients in the oral Zemplar group (54.4%) achieved the primary endpoint than patients in the cinacalcet group (43.4%; $p = 0.260$), but the results did not reach statistical significance.

"Abbott is pleased with the results of this study, which underscore our commitment to patients by making continued contributions to advancing the scientific and clinical understanding of the treatment of kidney disease and its complications," said Dr. Samina Kahn, medical director, Abbott.

The most common adverse events classified as at least probably related to study drug in the intravenous and oral Zemplar treatment groups were hypercalcemia, or high calcium levels, (8.1 and 16.7%) and hyperphosphatemia, or high phosphate levels (0 and 5.6%). The most common adverse events classified as at least probably related to study drug in the cinacalcet treatment groups were hypocalcemia, or low calcium levels, (14.1 and 25.7%), nausea (7.8 and 5.7%) and vomiting (6.3 and 2.9%). Most adverse event rates reported did not significantly differ between the Zemplar and cinacalcet groups. Major adverse cardiac events were more common in the Zemplar group than in the cinacalcet group. The reason for this imbalance is not known, but could be due to a higher rate of cardiovascular comorbidities in the Zemplar group at baseline. Four treatment-emergent deaths were reported in the Zemplar group, but none were considered related to treatment.

Elevated iPTH levels caused by secondary hyperparathyroidism in chronic kidney disease patients are generally treated with either a vitamin D receptor activator like Zemplar or a calcimimetic like cinacalcet, or additionally, may be treated with the combination of a vitamin D receptor activator plus a calcimimetic.

Intended Use[1][2]

ZEMPLAR® (paricalcitol) Capsules are an active form of vitamin D used to prevent and treat secondary hyperparathyroidism (increased parathyroid hormone levels) in people with Stage 3 or Stage 4 chronic kidney disease and in people with Stage 5 kidney failure on dialysis.

Before starting ZEMPLAR Capsules in people who have Stage 5 kidney failure and are on dialysis, their doctor should make sure the level of calcium in their blood is 9.5 mg/dL or lower to help lower the chance of getting symptoms of high calcium in their blood.

ZEMPLAR® (paricalcitol) Injection is an active form of vitamin D used to prevent and treat secondary hyperparathyroidism (increased parathyroid hormone levels) in people with Stage 5 kidney failure on dialysis.

Important Safety Information[3][4]

People should not start or continue to take ZEMPLAR if they have symptoms of high calcium or vitamin D or if they are allergic to any product ingredient. Taking too much vitamin D or taking it for a long time can cause very high calcium or vitamin D levels which may cause serious health problems and the need for emergency medical care. Signs of high calcium include feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination and weight loss. People should tell their doctor if they are having any of these signs.

Before and while taking ZEMPLAR, people should tell their doctor about all medications that they are taking, including prescription and nonprescription drugs, aluminum-containing compounds, supplements, and herbal preparations, or any change in their medical condition.

Before starting people on and while they are taking ZEMPLAR their doctor should measure their blood levels of PTH, calcium, and phosphorus. Their doctor may order the tests more often when they begin ZEMPLAR or if their dose is changed. Their doctor may adjust their dose based on the results of their blood tests.

It is important that people follow their ZEMPLAR medication plan exactly as their doctor has ordered and follow any instructions they were given about their diet and phosphorus restrictions.

The most common side effects with the use of ZEMPLAR Capsules include diarrhea, nausea, swelling, allergic reaction, viral infection, high blood pressure, vomiting, inflammation of the throat and nose, and dizziness.

The most common side effects with the use of ZEMPLAR Injection include vomiting, swelling and nausea.

Please see Full Prescribing information

For Zemplar® (paricalcitol) Injection at rxabbott.com/pdf/zemplarivpi.pdf

For Zemplar® (paricalcitol) Capsules at rxabbott.com/pdf/Zemplarcappi.pdf

About Abbott

Abbott (NYSE: ABT) is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 91,000 people and markets its products in more than 130 countries.

[1] ZEMPLAR® (paricalcitol) Capsules [package insert]. North Chicago, IL: Abbott Laboratories.

[2] ZEMPLAR® (pariclcitol) Injection [package insert]. North Chicago, IL: Abbott Laboratories.

[3] ZEMPLAR® (paricalcitol) Capsules [package insert]. North Chicago, IL: Abbott Laboratories.

[4] ZEMPLAR® (paricalcitol) Injection [package insert]. North Chicago, IL: Abbott Laboratories.

Media:
Andrew Lewis
847 937-6616