

1.0 Abstract

<p>Title: Long-Term Therapy Outcomes when treating CKD-patients with paricalcitol in German and Austrian Clinical Practice</p>
<p>Keywords: Observational study, paricalcitol, Treatment of Hyperparathyroidism, Chronic kidney disease stage 3, 4 and 5 (CKD stage 3, 4 and 5), dialysis, Chronic Kidney Disease, Zemplar sHPT, Secondary Hyperparathyroidism</p>
<p>Rationale and Background: Secondary hyperparathyroidism is a common complication in patients with chronic kidney disease (CKD) and appropriate and prompt treatment with vitamin D receptor activators (VDRA) is an effective way to prevent further complications. Studies have shown the importance of keeping serum calcium and phosphate levels low in patients with chronic kidney disease in order to avoid cardiovascular complications and reduce mortality [REDACTED]</p> <p>Experimental and clinical studies indicate that paricalcitol inhibits parathormone (PTH) synthesis at the transcription level, with less effect on calcium and phosphate serum levels compared to the current standard treatment with calcitriol and alphacalcidol.</p> <p>Postmarketing observational studies with a well-planned study design, defined study protocol and biometrical estimates are necessary for a more profound understanding of the effectiveness and adverse drug reactions of paricalcitol, especially those that are unknown or rare.</p>
<p>Research Question and Objectives: The purpose of this study was to obtain data on the safety and effectiveness of Zemplar® injection and Zemplar® capsules in real-life clinical practice. In this study, Zemplar® was prescribed on an on-label basis in an everyday setting. A period of 12 months had been consciously chosen in order to also obtain experience on the maintenance dose and treatment optimization with Zemplar® injection and Zemplar® capsules in long-term use.</p> <p>Primary study objectives were:</p> <ul style="list-style-type: none"> • to determine the percentage of patients achieving an iPTH level within the target range of K/DOQI (Kidney Disease Quality Outcome Initiative) treatment guidelines (CKD 3: 35 – 70 pg/mL; CKD 4: 70 – 110 pg/mL; CKD 5: 150 – 300 pg/mL) during 12-month treatment with Zemplar® • to determine the time until that level of response is achieved and whether it is sustained <p>Secondary objectives were:</p> <ul style="list-style-type: none"> • Analysis of episodes of hypercalcemia, hyperphosphatemia and elevated calcium phosphate product during the first 12 months of treatment with Zemplar® • Health economics investigations (i.e. days off disability, days of hospitalizations). • Safety Analysis
<p>Study Design: This was a multi-center, single-arm non-interventional study.</p>
<p>Setting: Participating sites were facilities specialized in the treatment of chronic kidney disease and offices of community-based specialists/nephrologists in Germany and Austria. The study population was comprised of patients with chronic kidney disease and a diagnosis of secondary hyperparathyroidism.</p>
<p>Subjects and Study Size: The study population comprised of patients with chronic kidney disease and a diagnosis of secondary hyperparathyroidism: 761 subjects were enrolled in the study. 2 subjects lacked information necessary for assignment to one of the analysis groups. Hence, the analysis was conducted with 759 subjects.</p>
<p>Variables and Data Sources:</p> <p>Key variables: iPTH, serum-calcium, serum-phosphate, calcium-phosphate-product</p> <p>Data sources: Case report form (CRF), electronic data report form (eDRF)</p>
<p>Results: Both application of paricalcitol led to comparable lower parathormone levels (iPTH). The IV application of paricalcitol</p>

