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**Etelcalcetide, A Novel Synthetic, D-Amino Acid Peptide –
Results from Placebo-Controlled Studies**

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Secondary hyperparathyroidism (SHPT) is a common complication of mineral metabolism in patients with end stage renal disease receiving hemodialysis. Characterized initially by hyperphosphatemia, hypocalcemia, and vitamin D deficiency, SHPT is often treated with phosphate binders, vitamin D analogs, and the oral calcimimetic cinacalcet. Studies have shown that cinacalcet is an effective treatment for safely reducing parathyroid hormone (PTH), blood calcium (Ca), and phosphorus (P) levels. However, additional data have shown inconsistent adherence to cinacalcet and frequent early discontinuation following initiation. Etelcalcetide is a novel, D-amino acid peptide calcimimetic administered intravenously three-times per week at the end of each hemodialysis session. Data from two etelcalcetide pivotal phase 3 studies have shown >30% reductions in serum PTH from baseline for 74.7% (n=380/509) and 8.9% (n=46/514) patients in the etelcalcetide and placebo arms, respectively (p<0.001). Additional endpoints achieved include sustained reductions in PTH from baseline over time, decreased albumin-corrected Ca, and decreased P levels in adult patients treated with etelcalcetide compared to placebo. In the two pivotal trials, there were no apparent effect modifications by demographic characteristics. Biomarker mean baseline characteristics were PTH 847 pg/mL, cCa 9.64 mg/dL, and P 5.86 mg/dL; and PTH 836 pg/mL, cCa 9.65 mg/dL, and P 5.80 mg/dL in the etelcalcetide and placebo arms, respectively. The most common (>8%) adverse events in the etelcalcetide groups include decreased blood calcium levels, muscle spasms, diarrhea, nausea and vomiting. Symptomatic hypocalcemia remains a concern for calcimimetic therapy with approximately 7% reported in the two pivotal trials. Calcium-containing binders and vitamin D were higher in the etelcalcetide group. Mean cCa reached a nadir at 10 to 12 weeks of a 26-week trial, which may explain the increased dialysate calcium concentrations approximately 25% of patients received in the etelcalcetide and placebo (3%) groups. Together, these data suggest that IV etelcalcetide is an effective treatment for reducing PTH levels in patients with SHPT on hemodialysis.

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