Supplementary Material

One-Year Safety and Efficacy of Intravenous Etelcalcetide in Patients on Hemodialysis with Secondary Hyperparathyroidism

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Table S1. Inclusion and Exclusion Criteria

Inclusion Criteria
• Patients understood the trial procedures and agreed to participate in the trial by giving written informed consent.
• Patient must have completed the treatment and follow-up period, or have been discontinued for rising PTH, from an etelcalcetide phase 3 parent trial before the start of dosing in this trial.
• Patient agreed to not participate in another trial of an investigational agent during the trial.
• Dialysis prescription dialysate calcium concentration must have been ≥2.25 mEq/L.
• Female patient who was postmenopausal (defined as no menses for the previous 1 year and over the age of 50 years), surgically sterilized, has a medical condition that prevents pregnancy, remains abstinent, or is willing to use highly effective contraception during the trial and for 3 months after the last dose. Women of childbearing potential must have had a negative serum pregnancy test within 2 weeks before the first dose of etelcalcetide.
• Patient's legally acceptable representative had provided informed consent when the patient had any kind of condition that, in the opinion of the Investigator, might compromise the ability of the patient to give written informed consent.
Exclusion Criteria
• Was currently receiving treatment in another investigational device or drug trial.
• Was currently receiving other investigational procedures while participating in this trial.
• Patient had known sensitivity to any products or components to be administered during dosing.
• Patient had received cinacalcet between the last dose of investigational product in the parent study and the start of dosing with etelcalcetide in the current study.
• Patient had an unstable medical condition based on medical history, physical examination, and routine laboratory tests, or was otherwise unstable in the judgment of the Investigator.
• Patient had a history of any illness that, in the opinion of the Investigator, might have confounded the results of the trial or posed additional risk to the patient.
• Patient had a serious concurrent medical condition (e.g., malignancy) likely to result in death during the 12 months after enrollment.
• Patient was pregnant or nursing.
• Patient had a history or evidence of any other clinically significant disorder, condition, or disease (with the exception of those outlined above) that, in the opinion of the Investigator or Amgen physician, if consulted, would pose a risk to subject safety or interfere with the trial evaluation, procedures, or completion.

Figure S1. Incidence of Hypocalcemia by Visit.