These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert in the country of prescription.

NAME OF SPONSOR/COMPANY:

Genzyme Corporation, 500 Kendall Street, Cambridge, MA 02142
Bone Care International, Inc., Middleton, WI 53652 (Bone Care was acquired by Genzyme Corporation July 2005)

TITLE OF STUDY:

Protocol BCI-CH-120: A Multicenter, Open-label, Parallel Design, Comparative Study of the Efficacy and Safety of Intravenous 1α -Hydroxyvitamin D_2 (Hectorol®) to Intravenous Calcitriol (Calcijex®) in Reducing Elevated Blood Parathyroid Hormone Levels in End Stage Renal Disease Patients on Hemodialysis

INVESTIGATORS AND STUDY CENTER(S):

This was a two-center study conducted in the United States.

STUDIED PERIOD:

First patient enrolled: 23 December 1998
Last patient completed: 16 June 1999

PHASE OF DEVELOPMENT:

Phase 3

OBJECTIVES:

The objective of this study was to compare the safety and efficacy of intravenous Hectorol® and intravenous calcitriol in the treatment of secondary hyperparathyroidism (SHPT) in patients with Stage 5 Chronic Kidney Disease (CKD) on hemodialysis (HD).

METHODOLOGY:

This was a Phase 3 study consisting of a 4-week washout period, a 16-week treatment period, and a 2-week post-treatment period. During the treatment period, subjects were randomly assigned to receive Hectorol® or calcitriol.

NUMBER OF PATIENTS (PLANNED AND ANALYZED):

No. Enrolled: 26
No. Treated: 6 (4 Hectorol®, 2 calcitriol)
No. Completed: 0
This study was terminated early due to sponsor's economics.

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION:

Patients with Stage 5 CKD on hemodialysis three times weekly for at least four months; age 18 years or older; history of plasma iPTH ≥ 400 pg/mL while not receiving vitamin D hormone therapy, or plasma iPTH ≥ 200 pg/mL while on vitamin D hormone therapy.

TEST PRODUCT, DOSE, AND MODE OF ADMINISTRATION:

Hectorol® (doxercalciferol injection) 4 mcg doxercalciferol/2 mL, 4 mcg three times weekly
Doses were administered intravenously at each dialysis session.

DURATION OF TREATMENT:

A 4-week Washout Period followed by a 16-week Treatment Period and 2-week Post-Treatment Period.

REFERENCE THERAPY, DOSE AND MODE OF ADMINISTRATION:

Calcitriol: Calcijex® (sterile aqueous solution of 1 mcg calcitriol/1 mL)
Dose: 1 mcg three times weekly
Doses were administered intravenously at each dialysis session.

CRITERIA FOR EVALUATION:

Criteria for Evaluation - Efficacy:
Plasma iPTH was evaluated for evidence of efficacy.

Criteria for Evaluation - Safety:
Safety was evaluated based on adverse events and laboratory parameters.

STATISTICAL METHODS:

Statistical Methods - Efficacy:
Baseline values for all evaluable parameters were defined as the average of the data collected at Weeks -1 and 0 (prior to receiving study drug). Changes from baseline data for iPTH were summarized by treatment group. Due to limited data, no formal statistical comparisons comparing treatment groups were performed.

Statistical Methods - Safety:
All adverse events were recorded and their frequencies were determined. Baseline values for all evaluable parameters were defined as the average of the data collected at Weeks -1 and 0 (prior to receiving study drug). Change from baseline data for laboratory parameters were summarized by treatment group. Due to limited data, no formal statistical comparisons comparing treatment groups were performed.

SUMMARY / CONCLUSIONS

Summary / Conclusions - Demographics:
Of the 6 patients who were randomized to treatment, 4 (3 male, 1 female) received Hectorol® and 2 (1 male, 1 female) received calcitriol. All were African Americans and the mean age was 51 years (range of 37 to 63 years) for the Hectorol® group and 46 years (range 40 to 51 years) for the calcitriol group.

Summary / Conclusions - Efficacy:
The data obtained indicate that both Hectorol® and calcitriol reduced iPTH levels during treatment.

Summary / Conclusions - Safety Results:
A total of 117 adverse events occurred in the six subjects treated with study drugs. Twelve of these events occurred before or during the washout period. All of the adverse events were judged to be not related or probably not related to the study drug. The majority of adverse events were assessed as mild to moderate in intensity. There were no adverse events that led to discontinuation of study drug and/or study withdrawal.
Four (4) serious adverse events occurred in two (2) patients on study drug during the study. No serious adverse events were assessed as related to study drug. One (1) patient death occurred in a patient hospitalized for necrotizing fasciitis and sepsis. The patient was on study drug calcitriol and the events were assessed as probably not related to study drug.
Clinical laboratory data**,** including serum calcium**,** phosphorus**,** other chemistry parameters and hematolog**y** parameters did not reveal any clinically significant changes from baseline for the six patients who received study drug.

Based on report prepared on: 06 July 2005

Synopsis prepared on: 06 August 2006