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-112: Effect of Oral 1α -Hydroxyvitamin D_2 on Elevated Blood Parathyroid Hormone Levels in Elderly Subjects with Secondary Hyperparathyroidism

INVESTIGATORS AND STUDY CENTER(S):

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

STUDIED PERIOD:

First patient enrolled: 21 July 1997
Last patient completed: 14 November 1997

PHASE OF DEVELOPMENT:

Phase 2

OBJECTIVES:

To explore the efficacy and safety of oral Hectorol® as a therapy for elderly subjects with secondary hyperparathyroidism (SHPT).

METHODOLOGY:

This was a Phase 2, randomized, open-label study conducted at one center. The study consisted of two periods: a 1- to 6-week baseline (pre-treatment) period and a 12-week treatment period. Subjects were randomly assigned to one of four treatment groups: 1 mcg Hectorol® daily, 1 mcg Hectorol® daily plus 800 mg elemental calcium (2000 mg calcium carbonate) daily, 2.5 mcg Hectorol® daily, or 7.5 mcg Hectorol® weekly plus 800 mg elemental calcium (2000 mg calcium carbonate) daily.

NUMBER OF PATIENTS (PLANNED AND ANALYZED):

No. Enrolled and Treated: 14
No. Treated: 5
No. Completed: 3
This study was terminated by the sponsor early due to difficulties in subject enrollment.

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION:

Subjects included in this study were age 60 to 100 years with secondary hyperparathyroidism, intact parathyroid hormone (iPTH) levels of ≥50 pg/mL, and femoral neck osteopenia defined as bone mineral density of ≤0.82 g/cm^2 for women and ≤0.92 g/cm^2 for men.

TEST PRODUCT, DOSE, AND MODE OF ADMINISTRATION:

Hectorol® : 0.5 mcg or 2.5 mcg soft gelatin capsules.
Doses of Hectorol® were 1 mcg or 2.5 mcg daily; or 7.5 mcg weekly.
Calcium carbonate: tablets containing 200 mg calcium as 500 mg calcium carbonate (e.g., Tums®).
Doses of calcium carbonate were 2000 mg daily.
Doses were administered orally

DURATION OF TREATMENT:

1- to 6-week baseline period followed by up to 12 weeks of treatment with an optional 12-week extension period.

REFERENCE THERAPY, DOSE AND MODE OF ADMINISTRATION:

Not applicable.

CRITERIA FOR EVALUATION:

Criteria for Evaluation - Efficacy:
Serum iPTH was to be evaluated for evidence of the test drug's efficacy.

Criteria For Evaluation - Safety:
Safety was evaluated based on serum and urine calcium and phosphorus, as well as adverse events.

STATISTICAL METHODS:

Statistical Methods - Efficacy:
No formal statistical methods were conducted due to early study termination.

Statistical Methods - Safety:
No formal statistical analyses were conducted due to early study termination.

SUMMARY / CONCLUSIONS

Summary / Conclusions - Demographics:
Of the 5 subjects, 4 were women and all were Caucasian. The mean age was 80 years (range, 76 to 86 years).

Summary / Conclusions - Efficacy:
Efficacy data were not summarized due to early study termination. However, all three subjects who completed the treatment period had reduced iPTH levels from baseline at the end of the treatment period.

Summary / Conclusions - Safety Results:
A total of eight treatment emergent adverse events occurred in three patients. All adverse events were mild to moderate in intensity and considered not related or probably not related to study drug by the Investigator.

No patient deaths occurred during the study. Three serious adverse events occurred in a single patient. The events were assessed as not related to study drug by the Investigator.

Clinical laboratory analyses were not performed due to early study termination.

Based on report prepared on:
1998 (Data included in 1998 Annual Report to IND 31,423 (Serial No. 100)
Synopsis prepared on: 24 June 2006