

CRITERIA: INCLUSION-EXCLUSION STUDY: HYPOPARATHYROIDISM

Inclusion

 \bigcirc Adults ≥18 years of age at the time of the Screening visit.

- Have a diagnosis of one of the following types of hypoparathyroidism for at least 26 weeks prior to the Screening visit:
 - a. Chronic post-surgical hypoparathyroidism
 - b. Idiopathic hypoparathyroidism
 - c. Autoimmune hypoparathyroidism
- ✓ Have thyroid-stimulating hormone (TSH) within normal laboratory limits at the Screening visit. If receiving thyroid medication, the dose must be stable for at least 4 weeks prior to the Screening visit. If receiving suppressive therapy for a history of thyroid cancer (differentiated), the TSH level must be ≥0.2 mIU/L at the Screening visit.
- Understand and be willing to sign an informed consent form (ICF) and abide by study restrictions, visits, and procedures.

Exclusion

- Known history of pseudohypoparathyroidism (impaired response to PTH, characterized as PTH resistance, with elevated PTH levels in the setting of hypocalcemia).
- Having any disease (other than hypoparathyroidism) that may affect calcium metabolism or calciumphosphate homeostasis or PTH levels (e.g., calcium-sensing receptor disorders [e.g., autosomal dominant hypocalcemia type 1] are exclusionary).

O Using any of the following therapies:

a. Loop diuretics, thiazide diuretics, phosphate binders (other than calcium carbonate or calcium citrate), digoxin, lithium, methotrexate, raloxifene citrate), digoxin, lithium, methotrexate, raloxifene hydrochloride, or acute systemic corticosteroids within 4 weeks prior to the screening visit. a.1 Chronic use of systemic corticosteroids is permitted if the dose has been stable for 4 weeks prior to the Screening visit.

b. Drugs containing PTH or PTH-related proteins, such as PTH(1-84) and PTH(1-34), within 4 weeks prior to the Screening visit;

c. Oral or intravenous bisphosphonates, denosumab, or romosozumab-aqqg within 18 months of the Screening visit;

d. Other drugs known to influence calcium and bone metabolism, such as calcitonin, fluoride tablets fluoride tablets (>0.5 mg daily), strontium, or cinacalcet hydrochloride within 3 months prior to the Screening visit.

Had a non-hypocalcemic seizure within 6 months of the Screening visit. Note: A history of seizures occurring in the setting of hypocalcemia is not exclusionary.

Has a clinically abnormal 12-lead ECG in the opinion of the investigator at the Screening visit that suggests underlying cardiac disease.