The CALIBRATE Study is the first Phase 3 study conducted for patients with ADH1, and we are incredibly excited to reach this milestone.

Dear Hypoparathyroidism Community,

We are happy to announce the **completion of enrollment for patients with Autosomal Dominant Hypocalcemia Type 1 (ADH1)** in the global Phase 3 clinical study called CALIBRATE. While the enrollment goal has been achieved, the study is actively ongoing to determine whether the investigational study medication, called encaleret, a tablet taken by mouth, can effectively and safely balance calcium levels in participants diagnosed with ADH1, a common genetic form of hypoparathyroidism.

Information about the CALIBRATE Study

- Enrolled ~ 70 participants with ADH1 at 25 investigational sites in 10 countries.
- Participants are randomly assigned to one of two groups: One group will continue with Standard of Care (which includes calcium and/or active Vitamin D supplements), and the other group (approximately two-thirds of the participants) will receive the investigational study drug.
- Phase 3 data will be announced in the second half of 2025.
- If the CALIBRATE study is successful, it could support an application for regulatory approval for encaleret.

"The complications arising from ADH1, such as seizures, heart abnormalities, muscle cramping, low calcium, and high urine calcium, can be very difficult to live with on a daily basis. We look forward to further evaluation of encaleret in the ongoing CALIBRATE study."

Patty Keating

Executive Director
HypoPARAthyroidism Association (HPA)

About ADH1

ADH1 is caused by an abnormal change in the **ca**lcium-**s**ensing **r**eceptor gene *(CASR)*.[1] It is estimated that changes in the *CASR* gene account for over 20% of nonsurgical hypoparathyroidism cases, with approximately 13,000 carriers in the United States alone.[2,3] ADH1 is often inherited from a parent but can also occur without a family history of the disease.[1] Diagnosis of ADH1 is confirmed through genetic testing.

If you are unsure whether you have ADH1, speak with your doctor to see if you may be eligible for genetic testing.

We are very grateful to the study participants and their families, our advocacy partners, and the staff at the study sites for their contributions to the CALIBRATE Study. We truly appreciate your courage and support.

Sincerely,

The Calcilytix Therapeutics Team

References:

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2. Dershem R, et al. Familial Hypocalciuric Hypercalcemia Type 1 and Autosomal-Dominant Hypocalcemia Type 1: Prevalence in a Large Healthcare Population. *Am J Hum Genet.* 2020;106(6):734 – 747.
3. Mannstadt M. Next-Generation Sequencing for Detection of Underlying Genetic Causes of Nonsurgical Hypoparathyroidism: Preliminary Results from a Sponsored Testing Program. Poster presented at Endocrine Society's Annual Meeting, 2023; Chicago, IL.