

bridgebio

hope through
rigorous science

CALIBRATE Phase 3 Topline Results of Encaleret in ADHD1

October 29, 2025

Encaleret is an investigational drug. Its safety and efficacy have not been fully evaluated by any regulatory authority.



Alexis and Jackson
Living with ADHD1



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Chief Executive Officer, BridgeBio

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Chief Operating Officer, BridgeBio Cardiorenal

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Chief Medical Officer, Calcilytix Therapeutics, a BridgeBio Company

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VP, Clinical Development, Calcilytix Therapeutics, a BridgeBio Company

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Matt Outten, M.B.A.
Chief Commercial Officer, BridgeBio

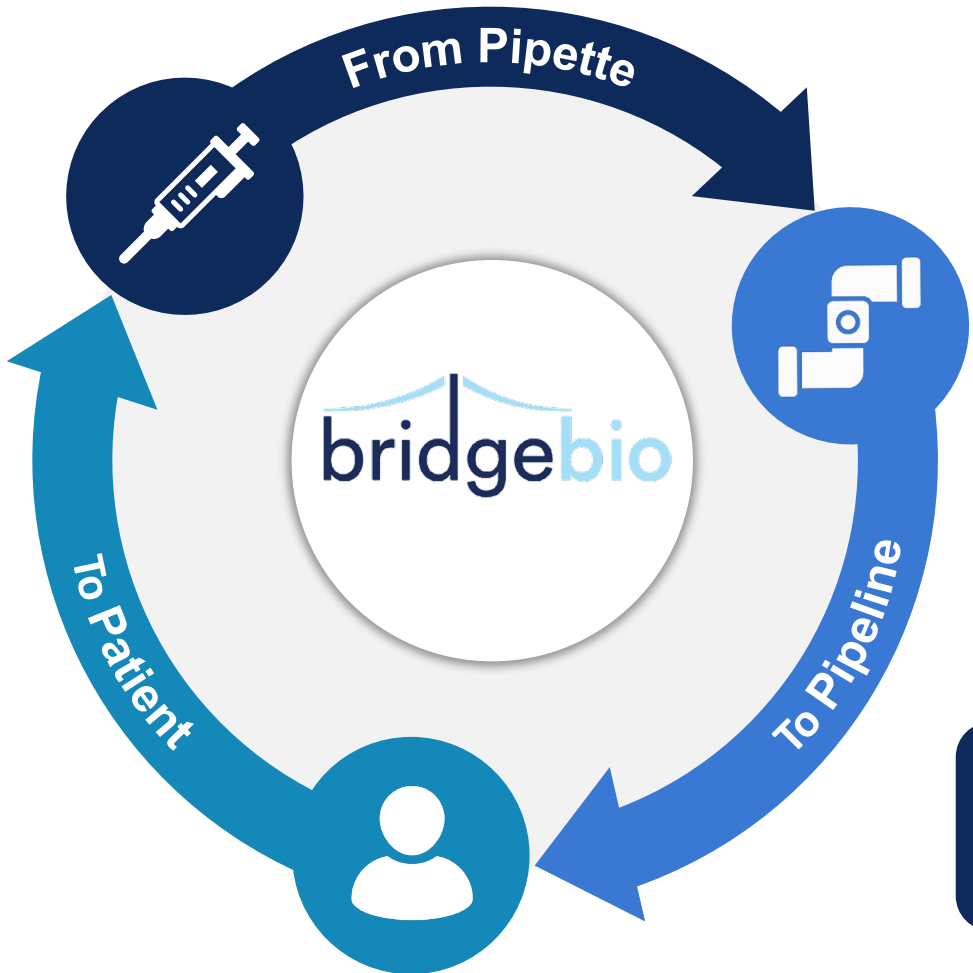


CALIBRATE

encaleret for Autosomal Dominant Hypocalcemia Type 1 (ADH1)

A sincere THANK YOU to the patients, families, advocates, investigators, clinical research staff, referring providers, and collaborating research partners

We have built a sustainable, high velocity engine to deliver medicines



Attruby™
(acoramidis) 356 mg tablet

*Obtained
Approval for 3
Medicines*

Nulibry®
(fosdenopterin)
for injection

TRUSELTIQ™
(infigratinib) capsules

> 2,000
patients in
trials

> 30 trials
> 30 countries
> 500 sites

3 fully
enrolled
pivotal trials

+ 2 Positive
Phase 3 Results

> 70
papers
published

> 35
academic
partnerships

19
INDs created

< \$10M and
< 3 yrs to
IND

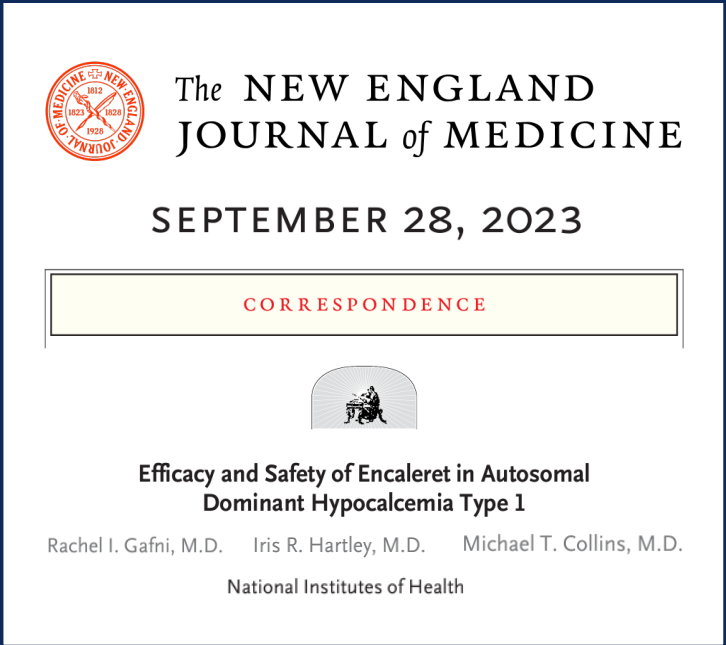
Encaleret is an exemplar of BridgeBio’s model of partnering with leading academics to translate beautiful science to patient impact

“Connect the dots”
therapeutic hypothesis



National Institutes
of Health

Meaningful clinical data¹



Genetic disease represents
the just the tip of the iceberg



¹Gafni RI et al., NEJM, 2023. ²Powers et al., J. Bone Miner. Res., 2013. ³Clarke et al., J. Clin. Endocrinol. Metab., 2016. ⁴Underbjerg et al., J. Bone Miner. Res., 2013.

ADH1 Overview

Ananth Sridhar
Chief Operating Officer,
BridgeBio Cardioresnal



CALIBRATE achieved & exceeded all criteria set forth as an upside target, with a 76% responder rate following 24 weeks of encaleret treatment

Upside Target Clinical Profile

- ✓ Statistically significant primary analysis result compared to conventional therapy
- ✓ At Week 24, $\geq 50\%$ of study participants achieve target serum and urine Ca on encaleret
- ✓ Majority of participants randomized to encaleret able to remain independent from conventional therapy¹
- ✓ At Week 24, mean iPTH within normal range on encaleret
- ✓ Comparable safety and tolerability profile to conventional therapy

Outcome Observed

Primary endpoint met ($p < 0.0001$) demonstrating superiority to conventional therapy

76% (34 out of 45) achieved target serum and urine Ca on encaleret vs. 4% on conventional therapy

Among encaleret responders at Week 24, none required conventional therapy during Period 3¹

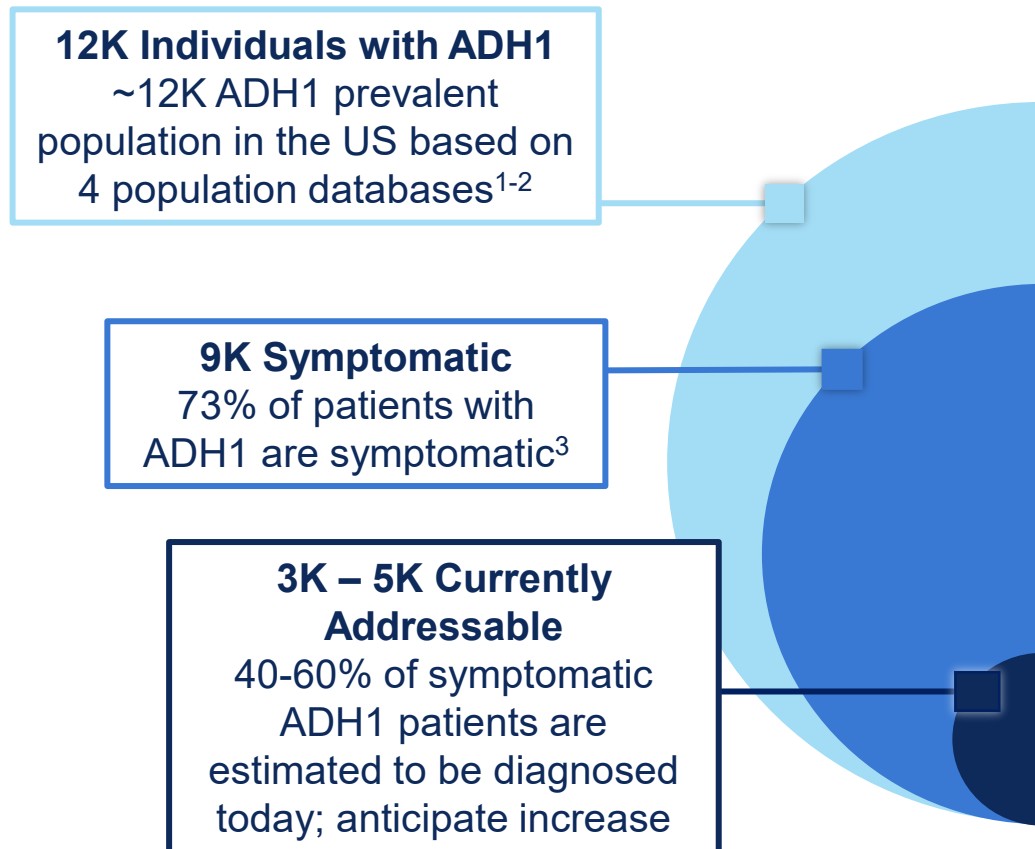
>90% of participants administered encaleret achieved iPTH above the lower limit of the reference range

Encaleret was well-tolerated; no discontinuations related to study drug

¹Requirement for conventional therapy defined as oral calcium >600 mg/day and/or active vitamin D during Period 3.

Ca = Calcium; iPTH = Intact Parathyroid Hormone. Encaleret is an investigational drug. Its safety and efficacy have not been fully evaluated by any regulatory authority.

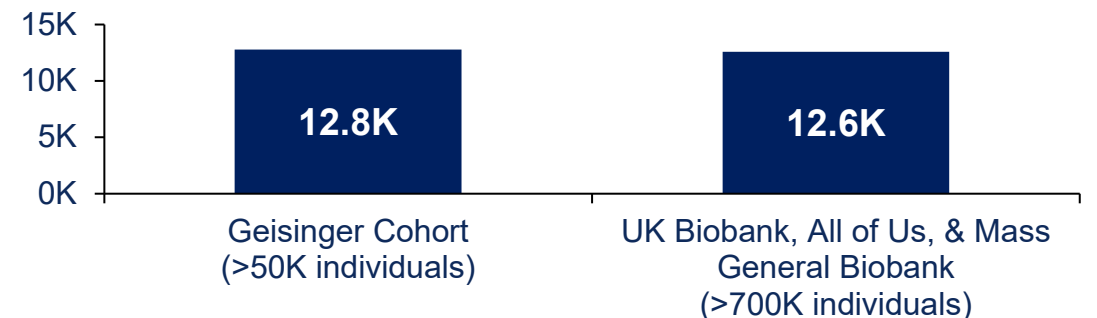
There are no therapies currently indicated to treat ADH1, a serious and rare genetic condition



An analogous ADH1 market is XLH

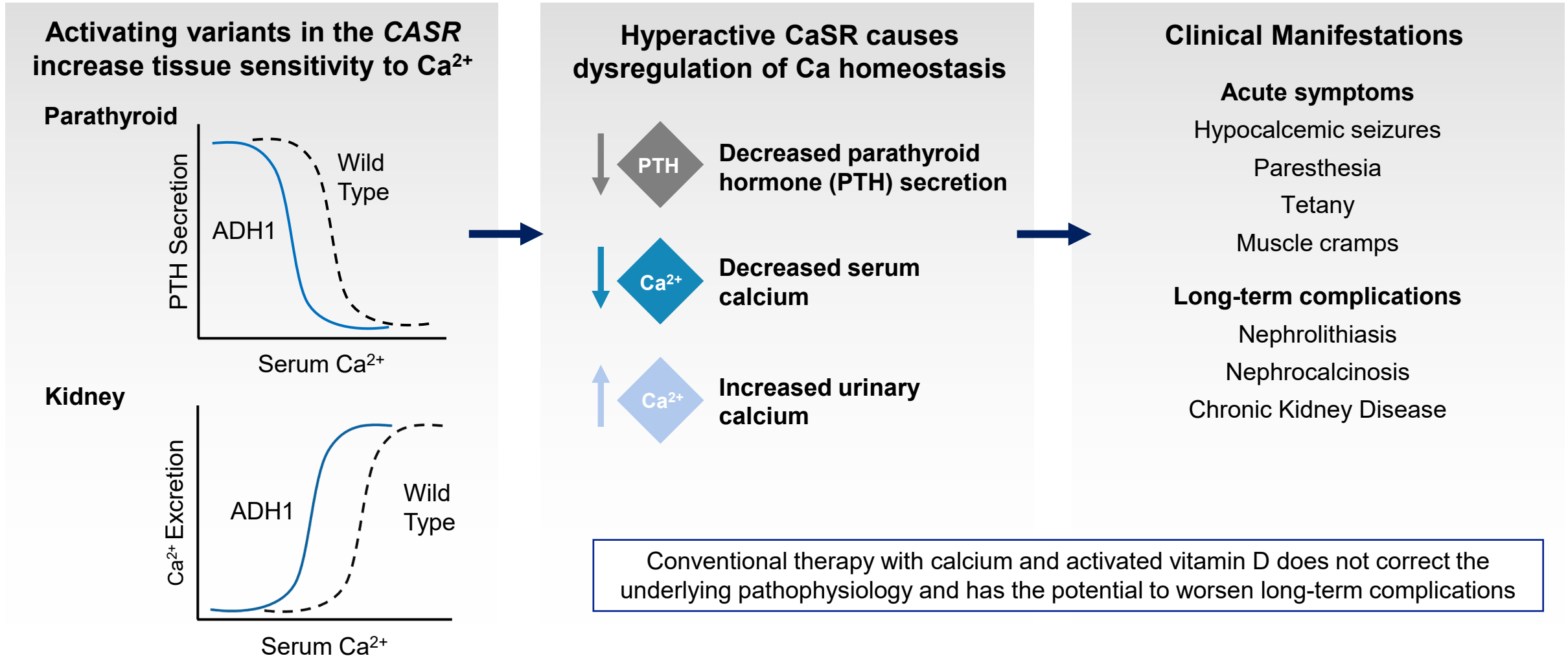
	XLH	ADH1
Prevalence (US)	12K ⁵	12K
Disease burden	Hypophosphatemia	Acute - hypocalcemia Chronic - hypercalciuria
Standard of care	Vitamin D, daily phosphate	Vitamin D, daily calcium
Registrational endpoint	Serum phosphate	Serum and urine calcium
Projected peak year sales	\$2B+ ⁶	\$1B+

ADH1 variant frequency estimates in literature¹⁻²



¹Dershem, et al. Amer Jour of Hum Genetics, 2020. ² Chang, et al. Am J Hum Genet., 2025. ³Roszko, et al. JBMR. 2022. ⁵Dahir, et al. Jour Endo Soc., 2020. ⁶Evaluate Pharma. XLH = x-linked hypophosphatemia.

Activating variants in the *CASR* cause ADH1



Encaleret is an investigational, potential first-in-class therapy that targets the underlying disease mechanism of ADH1

Design Principles



Only investigational treatment directly targeting ADH1 at its source

Potential to restore physiologic mineral homeostasis that is disrupted by CaSR oversensitivity



Address common symptomatology

Designed to normalize PTH, serum Ca, and urine Ca levels, potentially correcting the root cause of neuromuscular and renal consequences



Convenient oral dosing

First potential targeted treatment for ADH1 in a convenient form for patients and providers

CALIBRATE

Phase 3

Topline Results

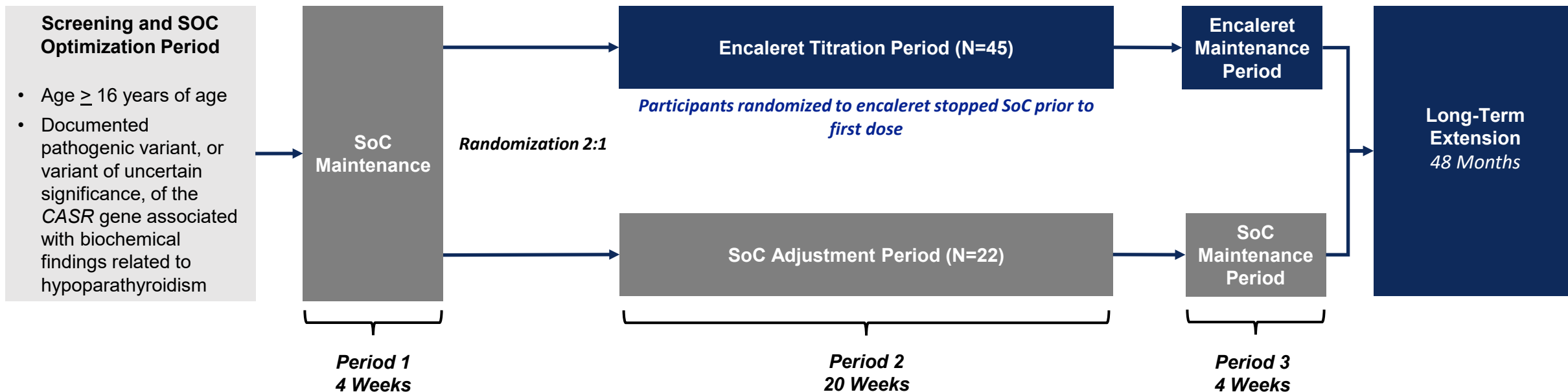
Scott Adler, M.D.

Chief Medical Officer

Calcilytix Therapeutics, a
BridgeBio Company



Encalaret phase 3 registrational study design



Primary Composite Endpoint:

- Proportion of participants achieving:
 - Corrected Ca¹ within the target range of 8.3-10.7 mg/dL
- AND**
- 24-hour urine Ca within the reference range (<300 mg/day for men & <250 mg/day for women)

Key Secondary Endpoint:

- Proportion of participants achieving iPTH above the lower limit of the reference range

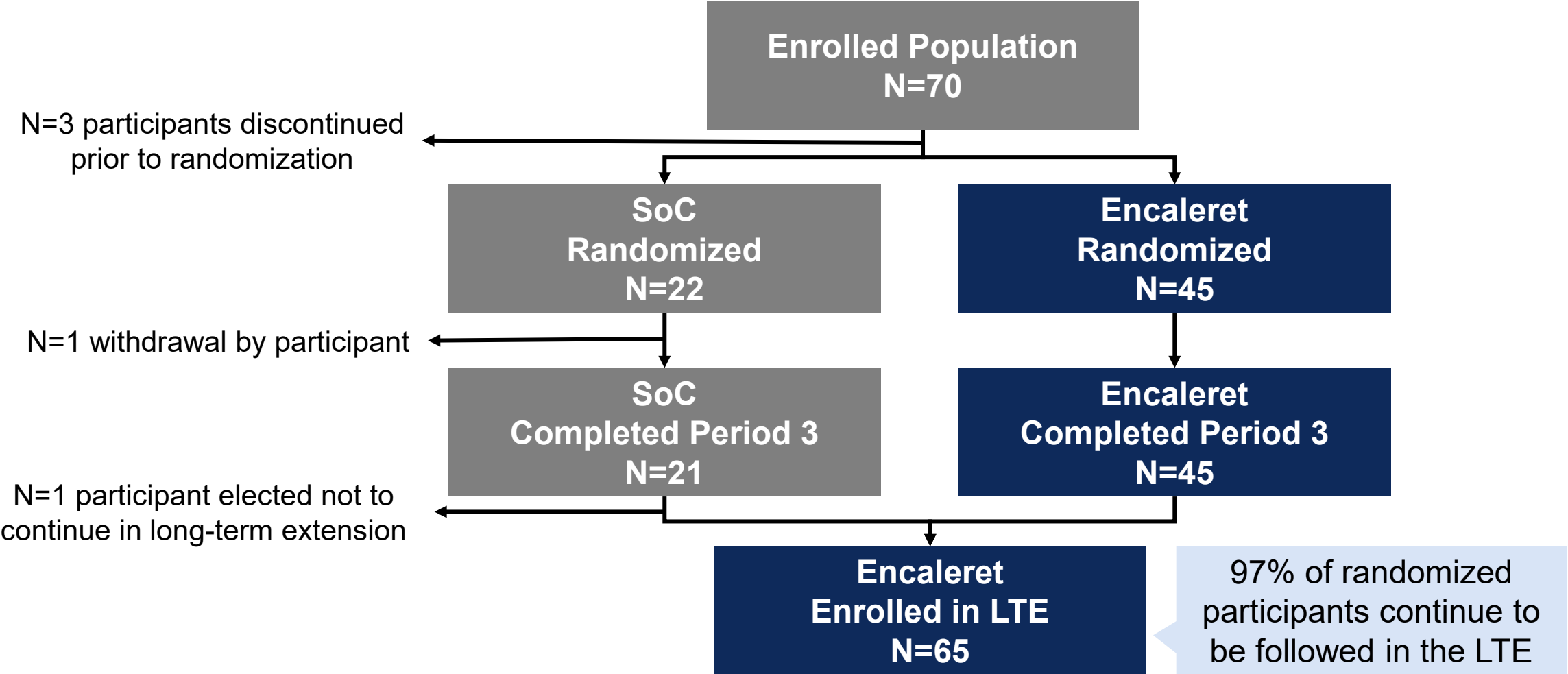
Select Secondary Endpoints:

- 1,25-(OH)₂ Vitamin D, magnesium, and phosphate
- Bone turnover markers
- Renal ultrasound and renal function

¹Albumin-corrected calcium.

SoC = standard of care; a combination of oral activated Vitamin D and/or calcium supplements. CASR = calcium-sensing receptor gene. iPTH = intact parathyroid hormone.

Study Participant Disposition



Efficacy population defined as all randomized participants. LTE = Long-Term Extension.

Baseline demographic characteristics

Characteristic	SoC (N=22)	Encaleret (N=45)	All Participants (N=67)
Demographics			
Age, yr, mean (range)	37 (16-63)	44 (16-76)	42 (16-76)
Female, n (%)	11 (50%)	24 (53%)	35 (52%)
Race, n (%) ¹			
White	20 (91%)	38 (84%)	58 (87%)
Asian	2 (9%)	5 (11%)	7 (10%)
Other	1 (5%)	2 (4%)	3 (4%)

¹Percentages for race do not add up to 100% because when multiple races are recorded, a participant is included in all recorded categories.

Baseline clinical characteristics

Characteristic	SoC (N=22)	Encaleret (N=45)	All Participants (N=67)
Baseline Characteristics			
Serum Calcium ¹ , mg/dL, mean (SD)	7.9 (0.7)	8.4 (0.8)	8.2 (0.8)
24hr Urine Calcium, mg/day, mean (SD)	331 (195)	397 (178)	376 (185)
Intact PTH, ng/L, mean (SD)	6.0 (4.5)	6.8 (7.8)	6.6 (6.8)
Phosphate, mg/dL, mean (SD)	5.0 (1.0)	4.8 (0.7)	4.9 (0.8)
Magnesium, mg/dL, mean (SD)	1.7 (0.1)	1.8 (0.2)	1.8 (0.2)
Nephrocalcinosis/Nephrolithiasis ² , n(%)	17 (81%)	35 (80%)	52 (80%)

Participants with 46 unique variants of the *CASR* were enrolled

¹Albumin-corrected serum calcium. ²Renal ultrasound performed at baseline in N=65 participants. Percentages are based on the number of participants with renal ultrasound available.

76% of participants randomized to encaleret met the primary endpoint achieving serum calcium¹ and 24-hour urine calcium in the target ranges

Primary Analysis – Within Group	Week 4 SoC (N=45)	Week 24 Encaleret (N=45)	p-value⁴
Number of Participants Meeting The Primary Endpoint (Responder status) ^{2,3}	2	34	
Proportion, %	4%	76%	
Difference in Proportion of Responders (95% CI)	71% (58%, 84%)		<0.0001

Key Secondary Analysis – Between Group at Week 24 (Encaleret vs. SoC) responder status confirmed a statistically significant result (p<0.0001)⁵

¹ Albumin-corrected serum calcium. ²The primary endpoint assessed responder status of participants who achieved both corrected calcium and 24-hour urine calcium in the target range at the completion of the maintenance periods. ³Participants randomized to receive encaleret who required doses of elemental calcium >600 mg/day for >7 days during Period 3 were evaluated as non-responders. ⁴Analyzed by McNemar's test. ⁵Analyzed by Barnard's unconditional exact test.
CI = Confidence Interval.

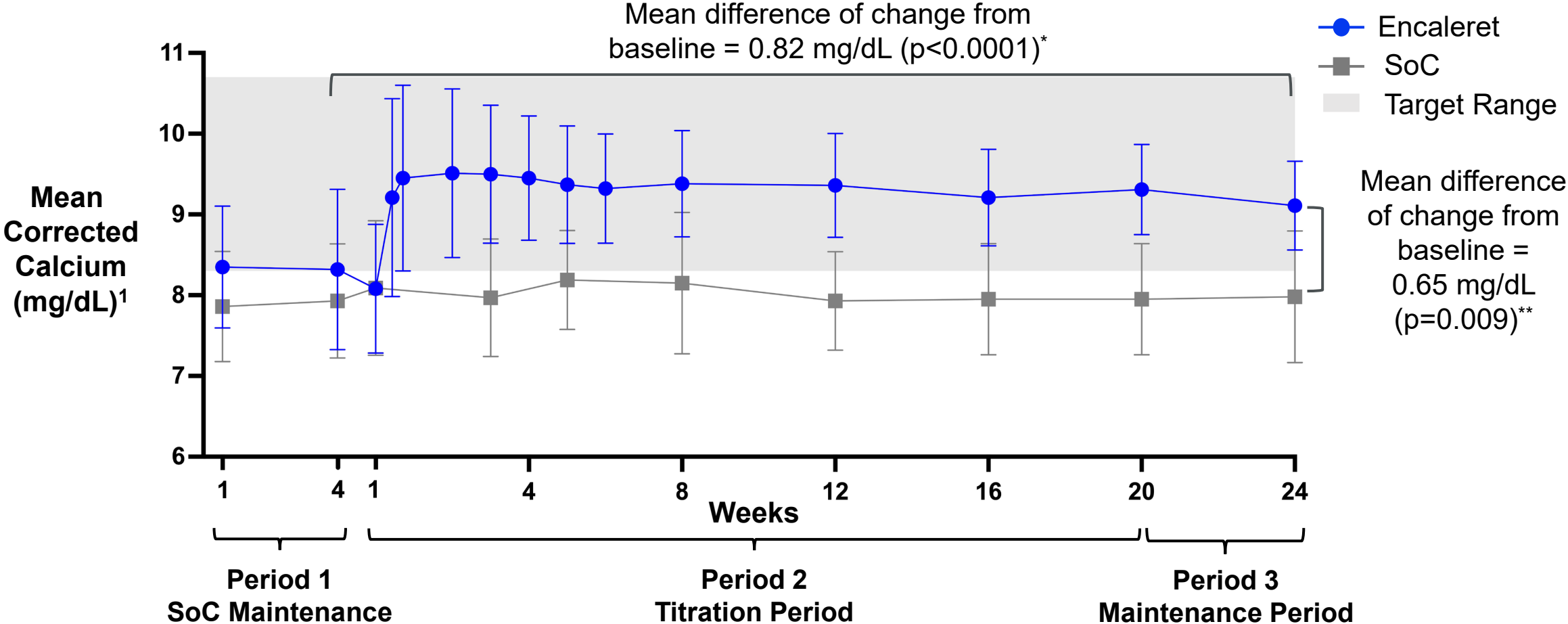
91% of participants randomized to encaleret achieved intact PTH above the lower limit of the reference range

Key Secondary Analysis – Within Group	Week 4 SoC (N=45)	Week 24 Encaleret (N=45)	p-value ¹
Number of Participants With <u>iPTH</u> ≥ LL Reference Range	3	41	
Proportion, %	7%	91%	
Difference in Proportion of Responders (95% CI)	84% (74%, 95%)		<0.0001

Key Secondary Analysis – Between Group at Week 24 (SoC vs. Encaleret) responder status of iPTH above the lower limit of the reference range confirmed a statistically significant result (p<0.0001)²

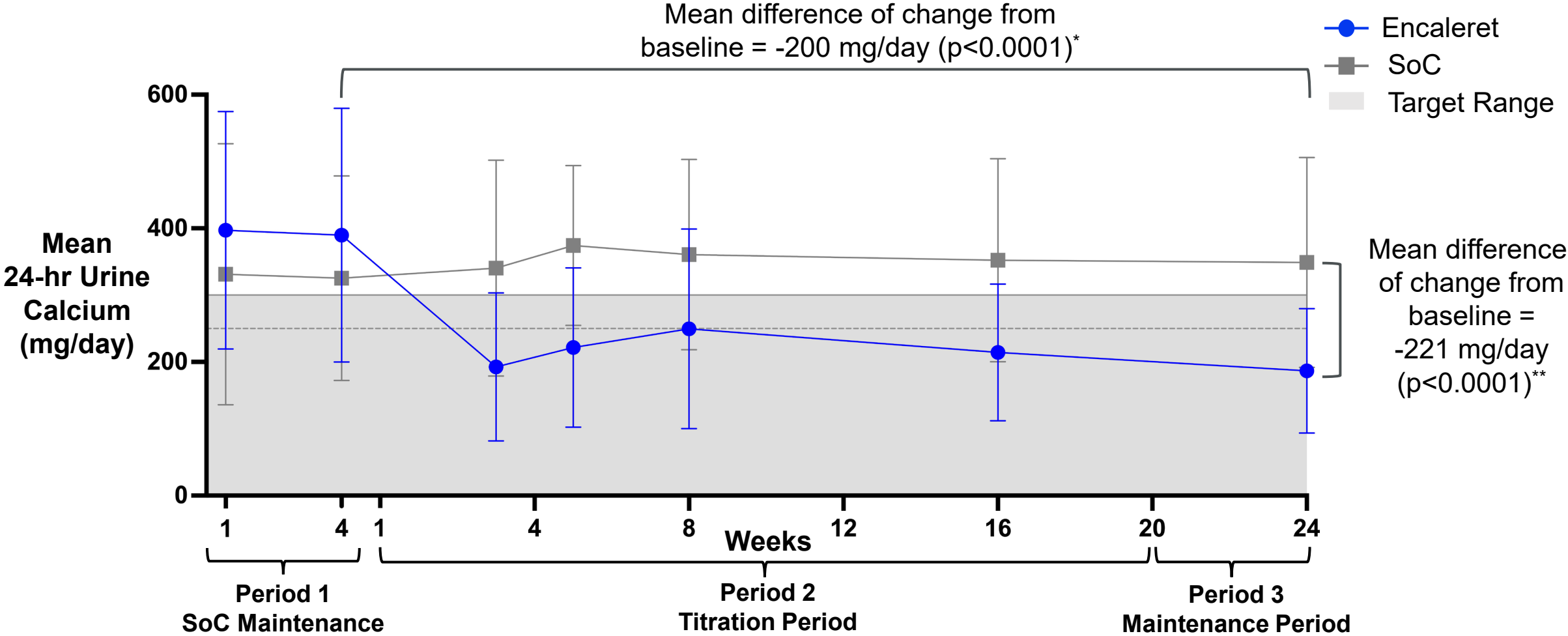
¹Analyzed by McNemar's test. ²Analyzed by Barnard's unconditional exact test.
CI = Confidence Interval. LL = Lower Limit

Encaleret demonstrated a rapid and sustained increase in serum calcium¹ into the normal range over 24 weeks



¹Albumin-corrected serum calcium. Data reported as mean±SD. Corrected calcium target range: 8.3-10.7 mg/dL.
 *Within patient comparison of change from baseline of Week 4 vs Week 24. **Between group comparison of change from baseline of Period 3 Week 24.

Encaleret demonstrated a robust effect on urine calcium reduction into the normal range over 24 weeks



Data reported as mean±SD. Solid line for urine calcium reflects the upper limit for men and dashed line reflects upper limit for women.
 *Within patient comparison of change from baseline of Week 4 vs Week 24. **Between group comparison of change from baseline of Period 3 Week 24.

Encaleret was well-tolerated with no TEAEs resulting in encaleret or study discontinuation

	Period 1	Periods 2 and 3	
	SoC N=67	SoC N=22	Encaleret N=45
Participants experiencing any Serious TEAE	2 (3%)	3 (14%)	4 (9%)
Serious Related TEAE	1 (2%)	0 (0%)	1 (2%)
Participants experiencing any TEAE	30 (45%)	14 (64%)	40 (89%)
Mild	23 (34%)	6 (27%)	21 (47%)
Moderate	4 (6%)	6 (27%)	16 (36%)
Severe	3 (5%)	2 (9%)	3 (7%)
Related TEAE	4 (6%)	0 (0%)	16 (36%)
TEAE of Hypocalcemia	4 (6%)	3 (14%)	3 (7%)
TEAE of Hypercalcemia	3 (5%)	0 (0%)	10 (22%)
TEAE Leading to Study Discontinuation	0 (0%)	0 (0%)	0 (0%)

For each category, participants are included only once, even if they experienced multiple events in that category. Relatedness assessed on the basis of the investigational product being administered in the respective study period reported.

TEAE = Treatment-Emergent Adverse Event

Encaleret was found to restore physiologic mineral homeostasis through its action on the CaSR

- 76% of participants randomized to encaleret achieved serum and urine calcium in the target range compared to the same individuals on conventional therapy (difference 71%, $p < 0.0001$)^{1,2}
 - Among encaleret responders at Week 24, none required conventional therapy during Period 3³
- Clinically meaningful restoration of intact PTH in participants administered encaleret compared to the same individuals on conventional therapy (difference 84%, $p < 0.0001$)¹
- Clinically meaningful increase in corrected serum calcium ($p < 0.0001$) and decrease in 24-hour urine calcium excretion ($p < 0.0001$) at Week 24
- Similar changes for the above parameters were also demonstrated between treatment arms
- Encaleret was well tolerated, with no discontinuations related to study drug

¹Analyzed by McNemar's test. ²Participants randomized to receive encaleret who required doses of elemental calcium >600 mg/day for >7 days during Period 3 were evaluated as non-responders. ³Requirement for conventional therapy defined as oral calcium >600 mg/day and/or active vitamin D during Period 3. Encaleret is an investigational drug. Its safety and efficacy have not been fully evaluated by any regulatory authority.

Program Next Steps

Mary Scott Roberts, M.D.
VP, Clinical Development
Calcilytix Therapeutics, a
BridgeBio Company



NDA submission planned in the first half of 2026 with two additional registrational studies planned for initiation next year

Advance encaleret towards registration in ADH1



Submit New Drug Application to FDA
1H 2026



Submit Marketing Authorization Application to EMA
2H 2026

Generate clinical evidence for encaleret in additional patient populations



Initiate Phase 2/3 study in Pediatric ADH1
1Q 2026



Initiate Phase 3 study in chronic hypoparathyroidism
2026



CALIBRATE results planned for presentation at relevant medical conference in 1H 2026

Launch Readiness

•—————•
Matt Outten, M.B.A.
Chief Commercial Officer
BridgeBio



Leveraging our proven commercial infrastructure to successfully launch encaleret

Built on the foundation of Attruby's® global commercial success and tailored to the unique ADH1 market opportunity






Established commercial infrastructure
Commercial operational teams already in place

Proven launch playbook
Enabling faster and more efficient mobilization

Targeted resource deployment
Relying on precision engagement, KOL partnerships, and patient identification initiatives

How we will win

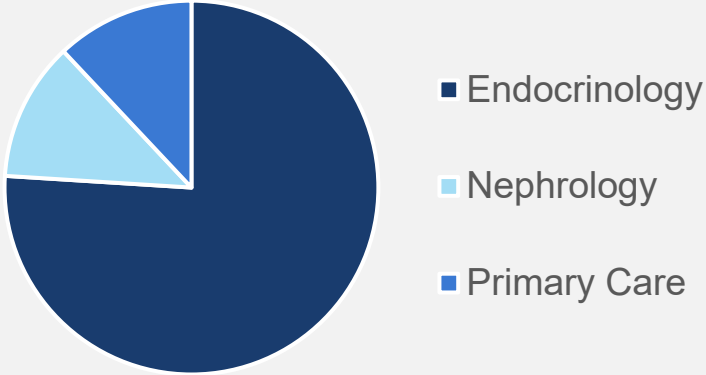
Redefining standard of care in ADH1

	Strategic area	Objective
	Capitalize on potential first-in-class profile	Position encaleret as the new standard of care due to transformative clinical outcomes
	Disease awareness	Drive recognition of ADH1 as a genetically distinct condition
	Speed time to treatment	Build urgency for early diagnosis and therapy initiation
	Maximize adherence	Support patients through titration and long-term maintenance
	Enable broad and global access	Secure payer support and remove barriers to care globally

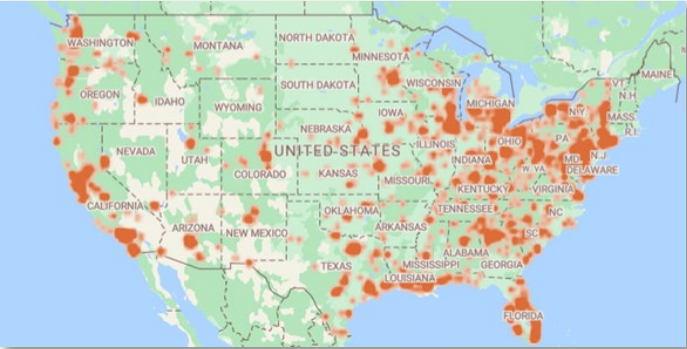
Data-driven commercial precision to accelerate ADH1 diagnosis and treatment

State of Market

ADH1 patients predominantly managed by endocrinologists



Concentration of HCPs Managing Patients



Concentrated prescriber base enabling targeted engagement

How we will capitalize on this first-in-category opportunity



Leverage existing data to prioritize and activate top endocrinologists and nephrologists



Employ AI/ML analytics to identify undiagnosed patients and managing HCPs



Attract patients to diagnosis opportunities via familial screening and digital targeting

Source: BBIO data on file; Symphony Health claims; Definitive Healthcare.

A proven market access strategy built for a successful planned encalaret launch in ADH1

Market Access strategy designed to support logistics for patients and providers and payer coverage

	Strategic area	Objective
	Rapid and seamless titration	Infrastructure in place to ensure dose adjustments can be immediately informed by lab values
	Streamlined access	Systems and payer strategies designed to remove delays from prior authorizations
	Comprehensive coverage	Payer engagement and education underway to secure access
	High-touch patient and HCP support	Experienced team and established tools to guide treatment initiation and adherence

Capitalizing on BridgeBio's proven commercial platform to accelerate launch readiness with focused build at the customer engagement level



Q&A Session