HELUS PHARMA

APPROACH Phase 3 Topline Study Results

November 16, 2026

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Opening Remarks

Michael Halstead
Chief Executive Officer, Helus Pharma

Positive APPROACH Phase 3 Topline Results

Rapid, Robust, and Durable Effect

- Both primary and key secondary endpoints were statistically significant and clinically meaningful
- 7.6-point MADRS improvement over placebo at Week 6 (primary endpoint) and 7.0-point MADRS improvement over placebo at Week 12 (key secondary endpoint)
- Improvement in MADRS was statistically significant starting as early as Day 2
- Response and remission rates were statistically significant starting as early as Day 2
- Improvements in CGI-S and CGI-I were statistically significant at all time points measured

Favorable Safety and Tolerability Profile

- Generally well tolerated
- Most adverse events were mild to moderate in severity, transient, and primarily limited to the day of dosing
- No new safety signals were identified

MADRS: Montgomery-Åsberg Depression Rating Scale, CGI-S: CGI-S: Clinical Global Impression-Severity

Major Depressive Disorder is a Highly Prevalent Condition with Unmet Needs

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A Highly Prevalent Condition

~22 Million U.S. Adults[1]

+ More than 300 million people affected by depressive disorders worldwide[2]

~2 out of 3 of patients do not remit on first-line therapy[3]

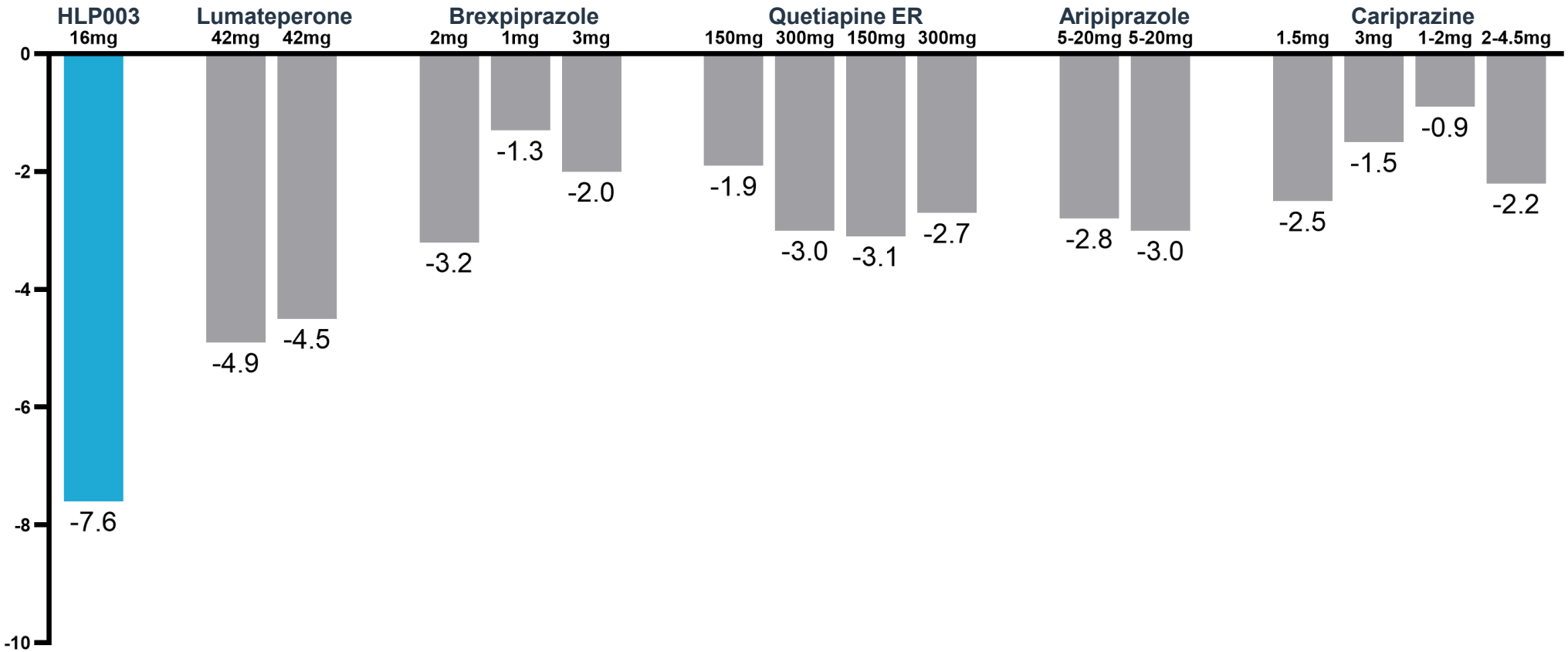


Adjunctive therapy is a common add on treatment approach for patients who only partially improve on initial antidepressant therapy[4]

1. Key substance use and mental health indicators in the United States: Results from the 2023 National Survey on Drug Use and Health. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Link 2. World Health Organization Depressive disorder (depression), Accessed 10/14/2026. Link 3. Pigott HE, et al., BMJ Open. 2023;13(7):e063095. 4. Department of Veterans Affairs (VA) & Department of Defense (DoD). VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder (MDD), Version 4.0, 2022.

HLP003 Has the Potential to Set a New Benchmark in Adjunctive Treatment of MDD

ATYPICAL ANTIPSYCHOTIC MADRS CHANGE vs. PLACEBO AT PRIMARY ENDPOINT[1-7]



1. The information presented in this slide is derived from APPROACH Topline Results and FDA approved package inserts which includes from multiple clinical trials, each conducted under distinct protocols and settings. As such, these data may not be directly comparable due to the lack of a head-to-head comparison. Differences in trial design, patient demographics, and other variables may account for variations in the observed outcomes. Study results for each drug are intended to be representative, however, multiple trials of the approved treatments have been conducted with varying results, including results that may have demonstrated a larger or smaller treatment effect than those presented. 2. Data on file. 3. CAPLYTA® (lumateperone) capsules PI. Revised 4/2026. 4. REXULTI® (brexpiprazole) tablets PI. Revised 4/2026. 5. SEROQUEL XR® (quetiapine) extended-release tablets PI. Revised 1/2025. 6. ABILIFY® (aripiprazole) Tablets PI. Revised 1/2025. 7. VRAYLAR® (cariprazine) capsules PI. Revised 12/2025. Third party trademarks used herein are trademarks of their respective owners.
MADRS: Montgomery-Åsberg Depression Rating Scale

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Phase 3 Topline Study Results for HLP003 as an Adjunctive Treatment for Major Depressive Disorder

Amir Inamdar MBBS, DNB (Psych), FFPM
Chief Medical Officer, Helus Pharma

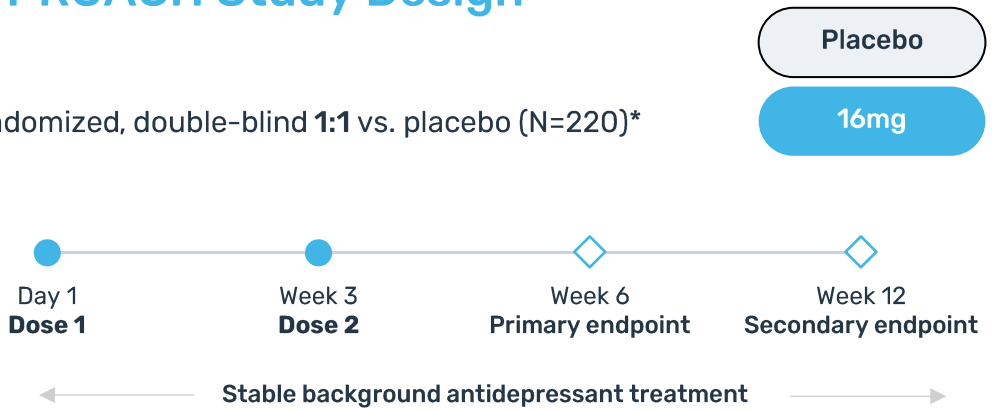
APPROACH Study Design

A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Trial to Evaluate the Efficacy & Safety of HLP003 as Adjunctive Treatment in MDD[1]

HLP003-002

APPROACH Study Design

Randomized, double-blind **1:1** vs. placebo (N=220)*



Efficacy Measures

Primary endpoint: MADRS change from baseline vs. placebo at Week 6
Key Secondary endpoint: MADRS change from baseline vs. placebo at Week 12

ENTRY CRITERIA

Key Inclusion Criteria:

- Adult participants with a DSM-5 diagnosis of MDD (using MINI and confirmed with SAFER), who are otherwise healthy
- MADRS score ≥24 and CGI-S ≥4 at Screening and Baseline
- Participant has to be on a stable, label-specified dose of a single antidepressant medication in the month prior to Screening and had an inadequate response (less than 50% improvement).

Key Exclusion Criteria:

- Any psychiatric disorder that is the primary focus of treatment, other than MDD
- History or current diagnosis of treatment-resistant depression, psychosis, bipolar disorder, personality disorder or substance abuse disorder
- Clinically significant risk of suicidality
- Any exposure to psychedelics, including microdosing, in the last 12 months and maximum of 10 lifetime uses

*planned

1. Forward-looking statements are subject to risks and assumptions. See "Cautionary Statement" on page 2 of this presentation.

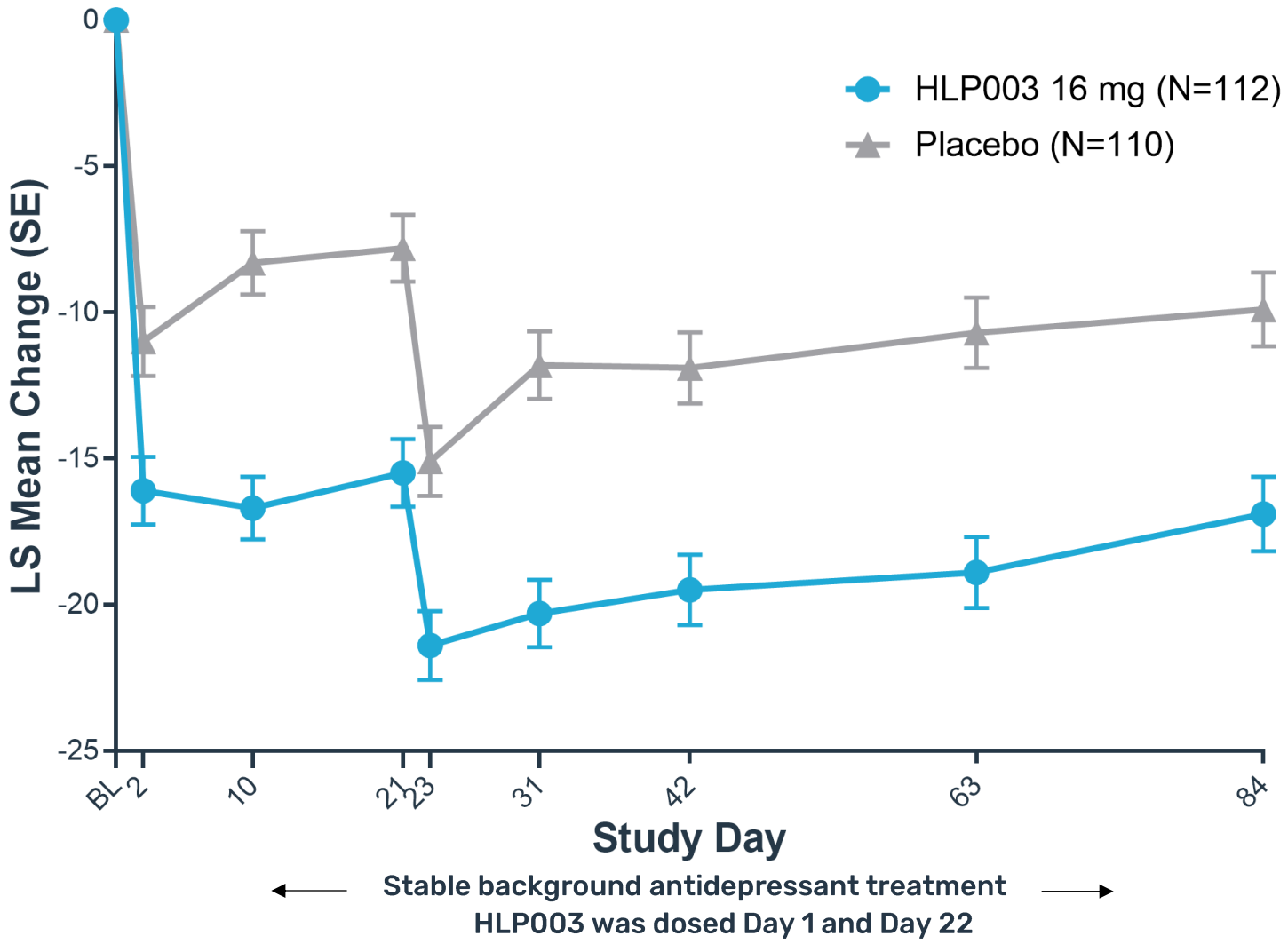
CGI-S: Clinical Global Impression-Severity, DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; MADRS: Montgomery-Åsberg Depression Rating Scale,MINI: Mini-International neuropsychiatric interview, SAFER: Massachusetts General Hospital - Clinical Trials Network and Institute

Demographics and Baseline Characteristics

Characteristic	HLP003 16 mg (N = 112)	Placebo (N = 110)	Total (N = 222)
Age (years)			
Mean (SD)	47.3 (13.75)	43.9 (13.41)	45.6 (13.66)
Sex			
Female	65.2%	65.5%	65.3%
Male	34.8%	34.5%	34.7%
Race			
White	78.6%	70.9%	74.8%
Black or African American	12.5%	13.6%	13.1%
Asian	3.6%	10.9%	7.2%
Prior Psychedelic Use			
Yes	21.4%	21.8%	21.6%
Baseline severity			
MADRS total score, mean (SD)	32.7 (5.49)	33.8 (5.33)	33.2 (5.42)
CGI-S score, mean (SD)	4.4 (0.53)	4.4 (0.52)	4.4 (0.52)

CGI-S: Clinical Global Impression-Severity, MADRS: Montgomery-Åsberg Depression Rating Scale, SD: standard deviation

Rapid, Robust and Clinically Meaningful Improvement



Primary Endpoint

LS Mean Difference at Week 6
-7.6 points, p <0.0001
Effect Size = 0.653

Key Secondary Endpoint

LS Mean Difference at Week 12
-7.0 points, p <0.0001
Effect Size = 0.581

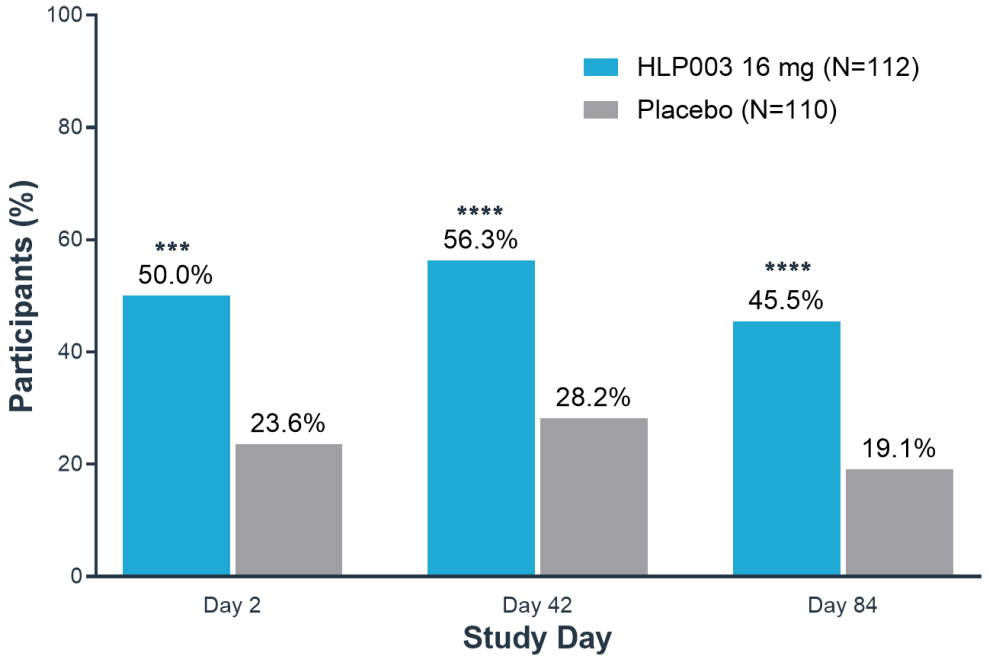
Rapid onset

LS Mean Difference at Day 2
-5.0 points, p=0.0013
Effect Size = 0.438

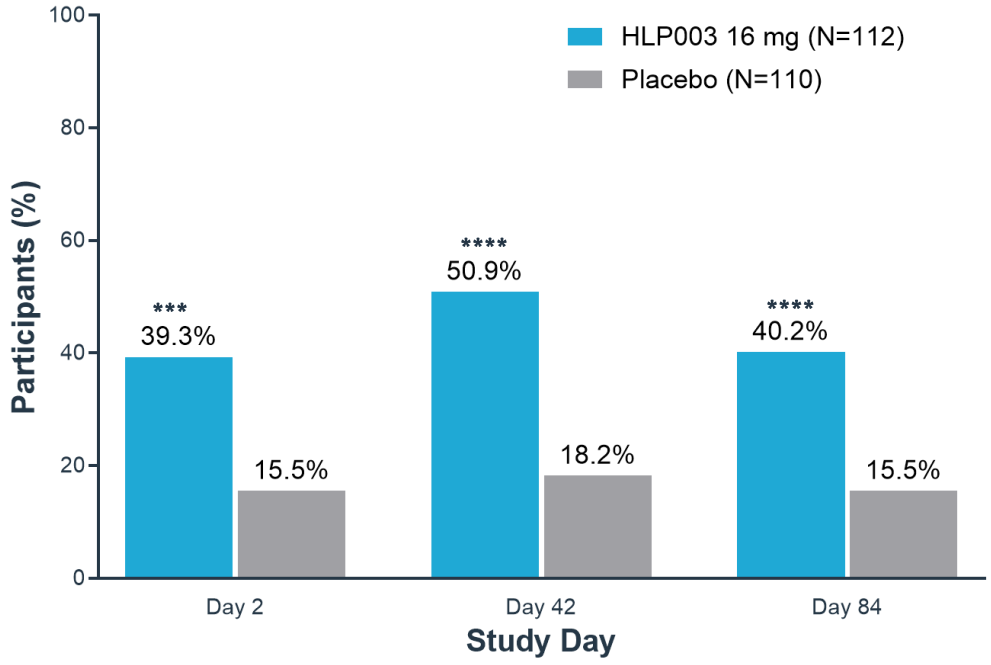
Primary endpoint: LS-means difference in change from baseline in MADRS total score between HLP003 and placebo at 6 week. Key Secondary: LS means difference in change from baseline in MADRS total score between HLP003 and placebo at 12 weeks.
Mean baseline MADRS score: HLP003: 32.7, placebo: 33.8. SE: standard error

Robust, Durable Response and Remission

Response ≥50% MADRS Reduction

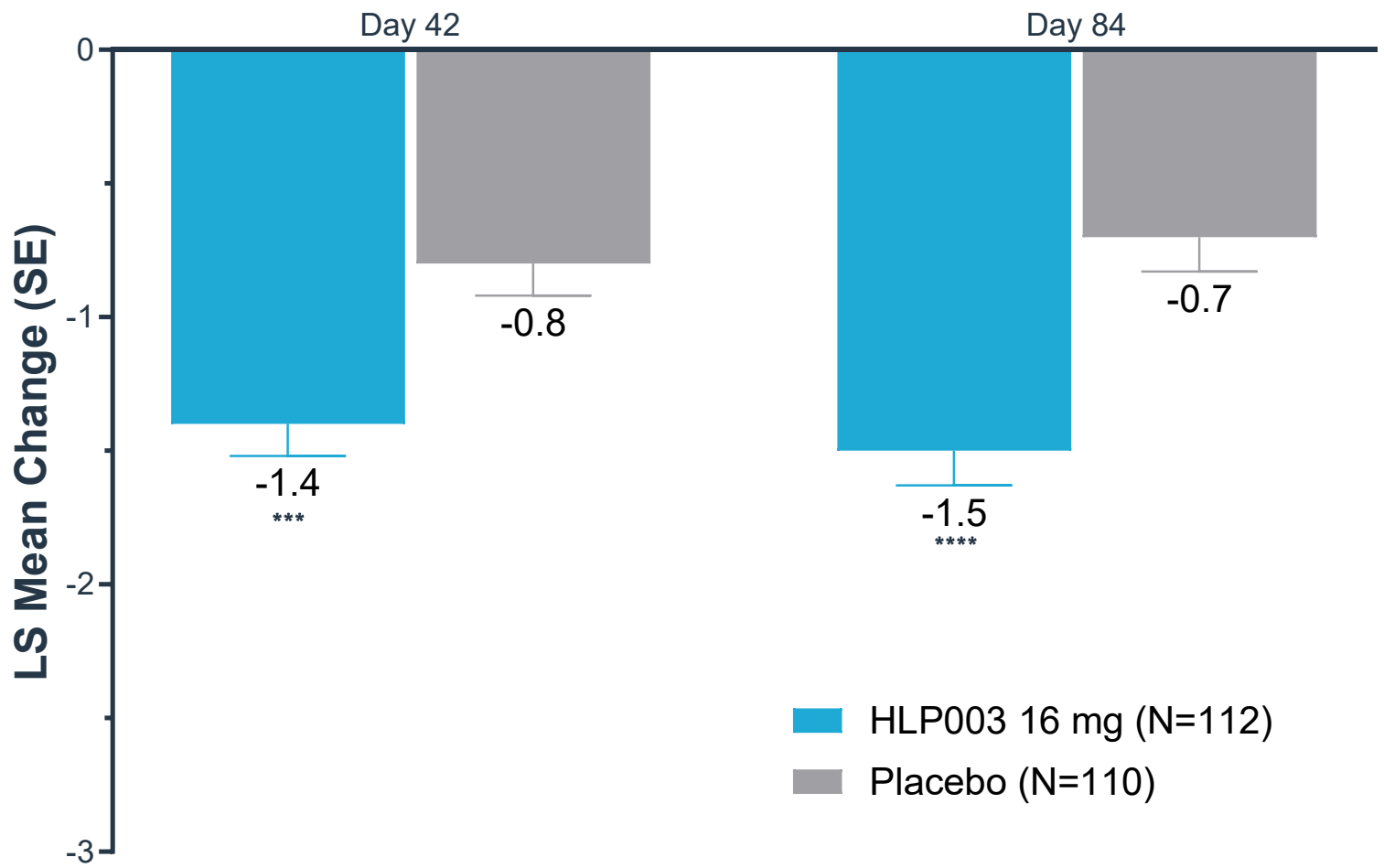


Remission ≤10 MADRS Score



***p<0.001; ****p<0.0001

Statistically Significant Reduction of Clinical Global Impression of Severity (CGI-S)



***p<0.001; ****p<0.0001
SE: standard error

HLP003 Was Generally Well Tolerated

Adverse Events reported in ≥ 10% of participants		
Preferred Term	**HLP003 16 mg (N=112)**	**Placebo (N=110)**
Perceptual disturbance	48 (42.9%)	13 (11.8%)
Nausea	45 (40.2%)	14 (12.7%)
Headache	39 (34.8%)	26 (23.6%)
Hallucination, visual	37 (33.0%)	7 (6.4%)
Time perception altered	26 (23.2%)	5 (4.5%)
Crying	25 (22.3%)	6 (5.5%)
Fatigue	22 (19.6%)	14 (12.7%)
Dizziness	20 (17.9%)	13 (11.8%)
Somnolence	19 (17.0%)	20 (18.2%)
Anxiety	17 (15.2%)	6 (5.5%)
Inappropriate affect	16 (14.3%)	1 (0.9%)
Euphoric mood	14 (12.5%)	2 (1.8%)
Blood pressure increased	13 (11.6%)	4 (3.6%)
Feeling abnormal	12 (10.7%)	5 (4.5%)
Feeling cold	12 (10.7%)	7 (6.4%)
Feeling of relaxation	9 (8.0%)	12 (10.9%)

Most adverse events were mild to moderate in intensity

Most treatment emergent adverse events occurred and resolved on dosing day

Treatment-related SAEs reported for HLP003

- Depression (n=2)
- Suicide attempt (n=1)

SAE: serious adverse event

Overall Conclusions

Rapid and Robust Efficacy with Durable Response through Week 12

- Rapid onset of effect on MADRS starting as early as Day 2: 5.0 points, p=0.0013
- MADRS improvement over placebo at Week 6: 7.6 points, p<0.0001
- MADRS improvement over placebo at Week 12: 7.0 points, p<0.0001
- Robust response, remission rates and CGI score starting as early as Day 2 and maintained at all time points

Favorable Safety and Tolerability profile

- Most AEs were mild-to-moderate in severity
- Most TEAEs occurred and resolved on dosing day
- No new safety signals were identified

AEs: Adverse Events, LS: least squares, MADRS: Montgomery-Åsberg Depression Rating Scale, TEAEs: Treatment emergent AEs

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Closing Remarks

Michael Halstead
Chief Executive Officer, Helus Pharma

EMBRACE Study Topline Results Anticipated Q4 2027[1]

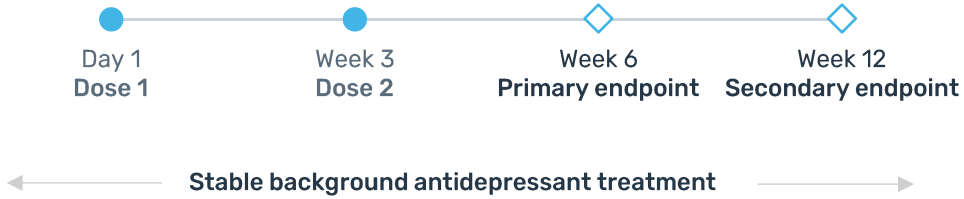
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HLP003-002

APPROACH

Randomized, double-blind **1:1** vs. placebo (N=220)*

- Placebo
- 16 mg



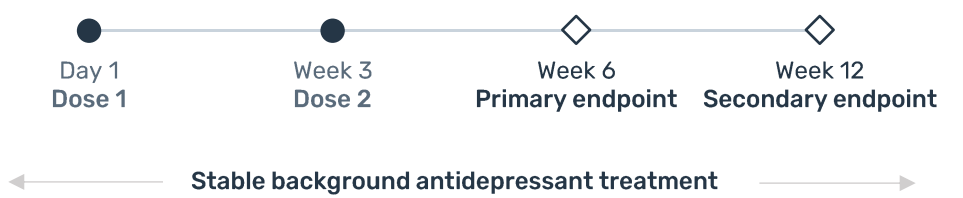
POSITIVE RESULTS

HLP003-003

EMBRACE

Randomized, double-blind **1:1:1** vs. placebo (N=330)*

- Placebo
- 8 mg
- 16 mg



Data Anticipated Q4 2027

Week 6 Primary Endpoint
MADRS change from baseline vs. placebo

Week 12 Secondary Endpoint
MADRS change from baseline vs. placebo

HLP003-004

EXTEND – Long-term extension study

Assesses durability of effect and time / frequency of re-dosing for participants on a stable dose of antidepressant therapy who did not respond in APPROACH or EMBRACE, or who relapsed during the extension

*planned

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