

# HLP004

Helus Pharma Announces Positive Phase 2 Data For Its Novel Serotonergic Agonist in Generalized Anxiety Disorder (GAD)

Helping Minds Heal

**March 2026**

Nasdaq: HELP  
Cboe CA: HELP

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The Company conducts research and development and is focused on developing and commercializing psychedelic-inspired regulated medicines. The Canadian, United States and Ireland federal governments regulate drugs. Psilocybin is currently a Schedule III drug under the Controlled Drugs and Substances Act (Canada), a Schedule I drug under the Controlled Substances Act (United States) and a Schedule I controlled substance in Ireland under the Misuse of Drugs Act, 1977, 1984 and 2015, the Misuse of Drugs Regulations 2017 and the Criminal Justice (Psychoactive Substances) Act 2010. Health Canada, the Food and Drug Administration in the United States and such similar regulatory authorities in Ireland have not approved psilocybin as a drug for any indication. The Company does not deal with psychedelic substances except indirectly within laboratory and clinical trial settings conducted within approved regulatory frameworks in order to identify and develop potential treatments for medical conditions and, further, does not have any direct or indirect involvement with illegal selling, production or distribution of any substances in jurisdictions in which it operates. No product will be commercialized prior to applicable legal or regulatory approval. For these reasons, the Company may be (a) subject to heightened scrutiny by regulators, stock exchanges, clearing agencies and other authorities, (b) susceptible to regulatory changes or other changes in law, and (c) subject to risks related to drug development, among other things. There are a number of risks associated with the business of the Company. The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated claims regarding psilocin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of psilocin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds can diagnose, treat, cure or prevent any disease or condition. Rigorous scientific research and clinical trials are needed. If the Company cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.

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# Leading the Development of Novel Serotonergic Agonists (NSAs)<sup>1,2</sup>

- 1** **Two proprietary clinical programs, HLP003 and HLP004, targeting major depressive disorder ("MDD") and generalized anxiety disorder ("GAD") with positive Phase 2 safety and efficacy results**
- 2** Lead program HLP003 has been granted **U.S. Food and Drug Administration Breakthrough Therapy Designation and is in Phase 3 studies for the adjunctive treatment of MDD**
- 3** **Differentiated pipeline with potential for expansion into additional mental health indications with high unmet need affecting >200M people in the U.S.<sup>3</sup>**
- 4** **Strong Intellectual Property Portfolio** with over 350 filed patents of which 100 are already granted

Notes:

- 1) Novel serotonergic agonists (NSAs): synthetic molecules designed to activate serotonin pathways that are believed to drive neuroplasticity.
- 2) Forward looking statements are subject to risks and assumptions. See "Cautionary Statement" on page 1 of this presentation. There is no assurance that timelines will be met. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to Helus. Such statements are informed by, among other things, regulatory guidelines for developing a drug with timeline safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and Helus's development efforts to date.
- 3) Addressable market is estimated based on U.S. census population of 337,049,203 as of September 8, 2024 and on U.S. prevalence of indications including depression, anxiety disorders/PTSD, bipolar disorder, substance use/addiction disorders, eating disorders, cluster headaches/migraine, and chronic pain management.

# Executing on Our Innovative Pipeline to Enable a Paradigm Shift in Mental Health

	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Key Milestones <sup>1,2</sup>
<b>HLP003</b> Deuterated Novel Serotonergic Agonist (NSA) (Oral)	Adjunctive treatment of MDD	Phase 3 study dosing underway Granted FDA Breakthrough Therapy Designation				<b>Q4 2026:</b> Phase 3 APPROACH Topline Data
<b>HLP004</b> Deuterated NSA (Intramuscular)	GAD	Phase 2 signal-finding study complete				✓ <b>Q1 2026:</b> Phase 2 Topline Data
<b>HLP005</b> Phenethylamines and Tryptamines	Central Nervous System (CNS) Disorders	Preclinical studies				

Notes:

- 1) Forward-looking statements are subject to risks and assumptions. See "Cautionary Statement" on page 1 of this presentation.
- 2) Subject to receipt of all necessary regulatory approvals from all applicable governmental authorities, including, as applicable, the academic and scientific organizations with which Helus is working. There are multiple risk factors regarding the ability to successfully commercially scale a chemically synthesized process to obtain psilocin and other analogues. There is no assurance that timelines will be met. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to Helus. Such statements are informed by, among other things, regulatory guidelines for developing a drug with timeline safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and Helus's development efforts to date.

# HLP004's Emerging Best-in-Class Profile

## Positive Phase 1 and Phase 2 Results in Moderate-to-Severe Generalized Anxiety Disorder

### Rapid, Robust Treatment Effect

Clinically meaningful 10-point HAM-A reduction at 6 weeks ( $p < 0.0001$ ) with effects seen as early as **Day 2**

### Effects in Real World Clinical Setting

Effects seen as an **adjunct on top of SOC** in moderate-to-severe GAD

### Superior Durability, Response & Remission

Durable effects from single cycle **through at least 6 months** with **~70% responders** and **~40% in remission**

### Favorable Safety Profile

**Transient** mild-to-moderate AEs; **no drug-related SAEs or suicidality**

### Scalable Within Practice Paradigm

**Ready for discharge by 3 hours<sup>1</sup>**, acute effects lasting **~90 minutes** well within existing interventional psychiatry infrastructure

### Franchise Durability

**Composition of Matter IP through to 2041** with 90+ issued patents

Note:

1) In Phase 1 study at 30 mg dose

# Comprehensive Studies Characterizing Dimethyltryptamine (DMT) Pharmacological Properties

Study	Key Findings
Phase 1/2a study with IV DMT in moderate to severe MDD (no SSRIs) <sup>1</sup>	Rapid and durable antidepressant and anxiolytic effects after single administration
Phase 1 IV/IM study <sup>1</sup>	Characterized safe and well-tolerated IM route
Phase 1 SSRI DDI study <sup>1</sup>	Non-deuterated DMT safe and well-tolerated when co-administered with SSRIs with potential additive effects
Phase 1 Study of IV HLP004 and IV DMT	Deuteration extends the duration of effects of DMT
Phase 1 IM/IV dNSA study <sup>2,3</sup>	Established relationship between IV and IM doses and provided safety and pharmacodynamic data
HLP004-002: Phase 2 IM Signal finding in GAD patients	IM administration of HLP004 provides rapid, robust and sustained relief from symptoms of GAD
HLP004-001: Phase 1 IM Dose ranging study	HLP004 IM provides higher exposure, slower clearance, and a prolonged systemic duration, while preserving rapid onset compared to DMT (within 15 minutes) and has dose-dependant pharmacokinetics

**Run in Parallel**

Notes:

- 1) Completed with SPL026, a non-deuterated IV DMT
- 2) dNSA = deuterated novel serotonergic agonists
- 3) Study completed with related dNSA, SPL028

# HLP004 Was Designed To Improve Upon IV DMT To Deliver Rapid & Durable Symptom Relief Via Single Treatment Cycle

## Limitations of IV DMT

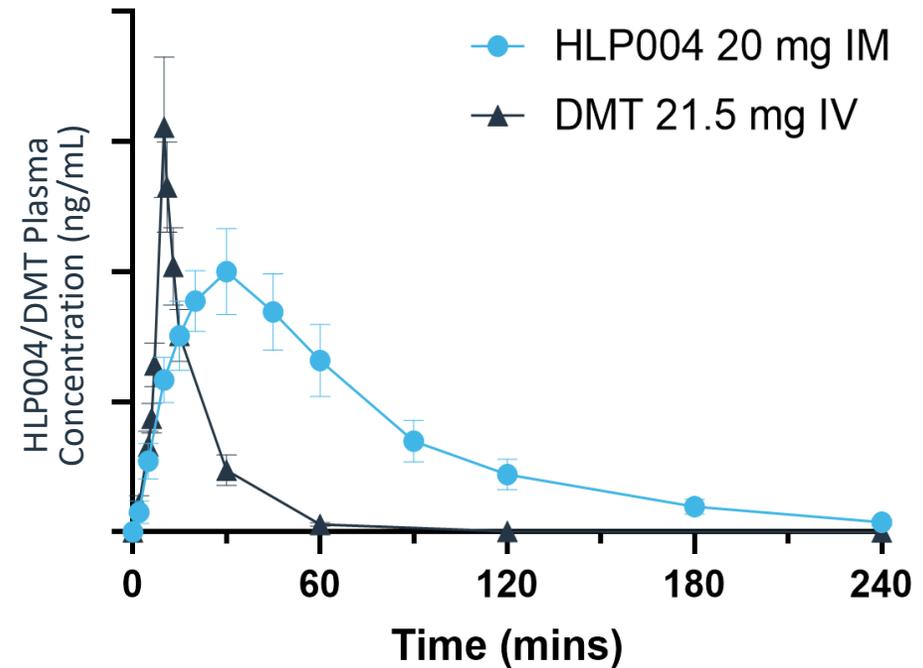
- **Unfavorable pharmacokinetics:** rapid peak, rapid elimination resulting in short-lived, intensive <30 min experience
- **Not scalable:** requires carefully controlled infusions

## HLP004 IM D-DMT

- ✓ **Favorable pharmacokinetics:** rapid peak but lasts 60-90 min; favorable experience, shorter than psilocybin and LSD
- ✓ **Greater scalability:** can be easily administered in clinical setting

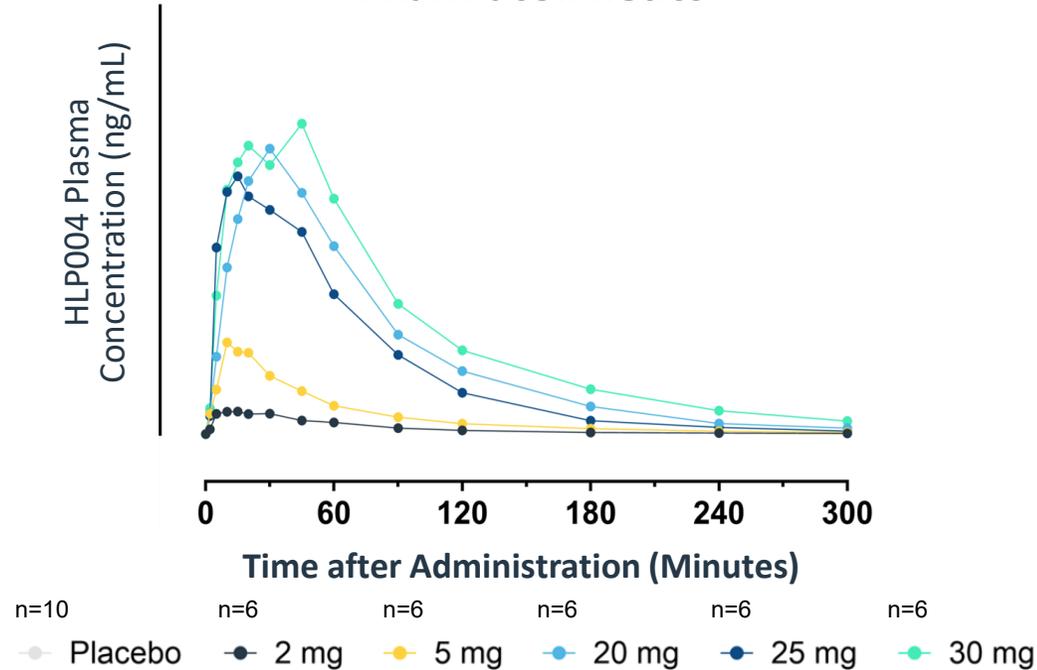
## HLP004

### Improved Pharmacokinetic Properties vs. IV DMT



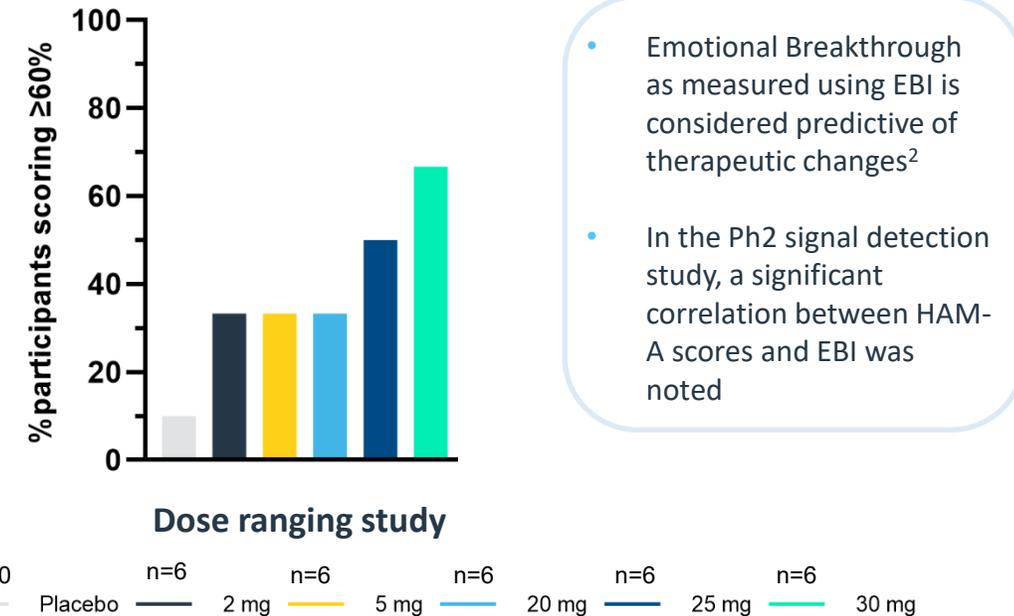
# Linear, Predictable and Reproducible Pharmacokinetics and Pharmacodynamics

## Pharmacokinetics



- **Rapid absorption and onset of response** within 15 min of IM administration
- **Dose-proportional increases in plasma concentrations**
- **Rapid elimination and short duration acute effects** with half-life of 60 minutes across all doses

## Emotional Breakthrough Inventory (EBI)<sup>1</sup>



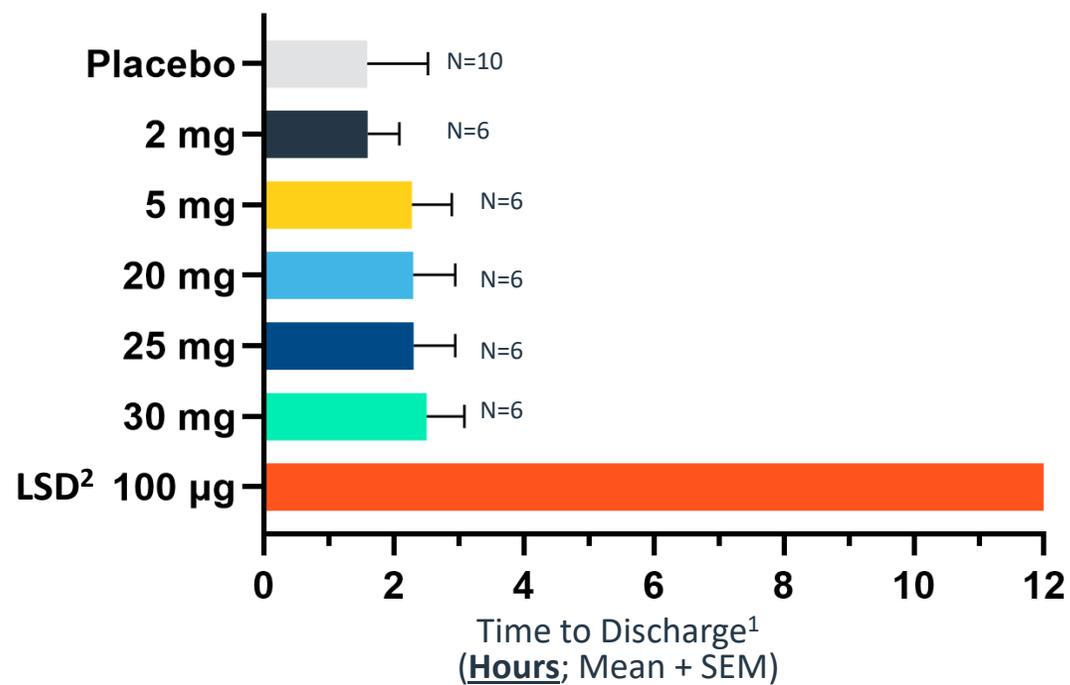
- Emotional Breakthrough as measured using EBI is considered predictive of therapeutic changes<sup>2</sup>
- In the Ph2 signal detection study, a significant correlation between HAM-A scores and EBI was noted

- **Robust pharmacodynamic effects consistent with therapeutic effect** as demonstrated by EBI in both 20 mg and 2 mg
- **In the dose-ranging study, the proportion of participants scoring ≥60% on EBI were similar for the 2 mg and 20 mg groups and lower for the placebo group**

### Notes:

- 1) The Emotional Breakthrough Inventory (EBI) is a validated, 6-item self-report questionnaire designed to measure the intensity of emotional release and therapeutic breakthroughs during a psychedelic experience.
- 2) Roseman L *et al.* Emotional breakthrough and psychedelics: Validation of the Emotional Breakthrough Inventory. *J Psychopharmacol.* 2019;33(9):1076-1087.

# Intramuscular Administration Permits Rapid Discharge Within 3 Hours



**Acute effects last 90 minutes only<sup>3</sup>**

**Ready for discharge within 3 hours<sup>4</sup>**  
 allowing for access into existing Spravato  
 treatment paradigm

Notes:

- 1) Time to first 'Yes', as assessed using the Clinical Global Assessment of Discharge Readiness (CGADR), starting at 60 minutes. Popova, et al. Am J Psychiatry 2019.176:428. Daly, et al. Supplement to JAMA Psychiatry. 2019.76:893.
- 2) Robison, et al. JAMA, 2025. 334(15):1358-1372. For the 100 µg dose group, 97.5% resolution of acute affects within 12 hours.
- 3) Not statistically different from placebo after 90 mins.
- 4) For 30 mg dose.

# Phase 2 Topline Data

**HLP004 in Generalized Anxiety Disorder**

# High Patient Burden and Persistent Treatment Gaps in GAD Create a Clear Opportunity for Innovation

## Significant Unmet Need in GAD

>300M

persons worldwide with anxiety disorders<sup>1</sup>

>20M

persons with GAD in the US<sup>2</sup>

77%

of GAD patients in the US are moderate-to-severe<sup>3</sup>

~\$95B

annual costs of anxiety disorders in the US<sup>4</sup>

Most common

anxiety disorder within primary care<sup>5</sup>

>45%

patients in interventional psychiatric practices suffer from GAD<sup>6</sup>

## Current Treatments Continue to Fail GAD Patients

- 2/3 of GAD patients experience no relief with initial SoC treatment<sup>7</sup>
- 57% of patients with anxiety do not adhere to SoC due to side effects<sup>8</sup>
- Average time to discontinuation is <90 days<sup>9</sup> due to efficacy / safety
- Last approval was in 2007 (Cymbalta<sup>10</sup>); no approved adjunctive treatment to date

### Notes:

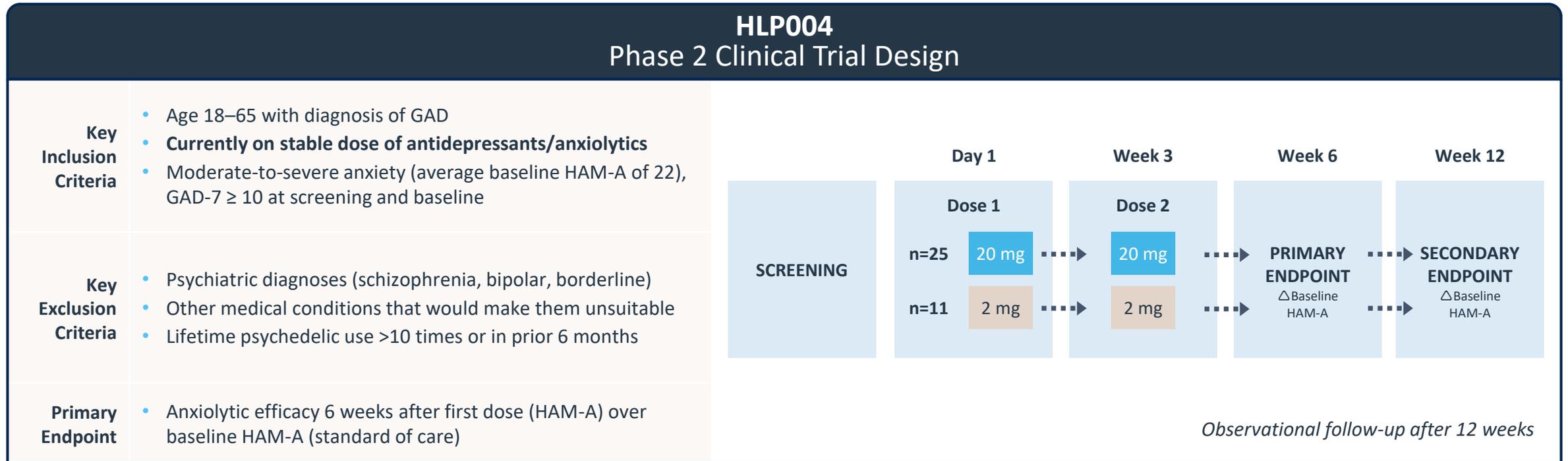
- 1) Yang, X., et al. Epidemiol Psychiatr Sci. 2021. 30:e36.
- 2) Ringeisen, H., et al. RTI International, 2023.
- 3) Kessler, R.C., et al. Arch Gen Psychiatry, 2005. 62(6):617-27.

- 4) Little, et. al. Medical Economics. 2023. <https://www.medicaleconomics.com/view/not-screening-for-anxiety-costs-and-solutions>.
- 5) Ansara, E.D. Ment Health Clin, 2020. 10(6):326-334.
- 6) Helus, Proprietary quantitative HCP market research (n=60). 2024.

- 7) Little, A. Am Fam Physician, 2009. 80(2):167-72.
- 8) Stein, M.B., et al. Psychiatr Serv, 2006. 57(5):673-80.
- 9) Louie D, et al. Treatment Patterns for Newly Diagnosed Generalized Anxiety Disorder (GAD): Insights from Real -World Evidence. Presentation at ACNP 2026.
- 10) CYMBALTA is a registered trademark of Eli Lilly and Company.

# HLP004 Phase 2 Signal Detection Study in GAD

Double-blinded Phase 2 study of HLP004 as an adjunctive treatment on top of SOC for patients suffering with GAD



- **Designed as a signal detection study to assess within subject changes in two active dose levels**
  - Not powered to show separation between doses
- **Designed to mimic real-world treatment paradigm**

# Baseline Characteristics Demonstrate Real World Treatment Paradigm

Characteristic	20 mg (n=25)	2 mg (n=11)	Overall (n=36)
Age (years); Mean (SD)	34.6 (9.92)	42.4 (12.14)	37.0 (11.08)
Female (n; %)	23 (92.0)	7 (63.6)	30 (83.3)
White (n; %)	14 (56.0)	6 (54.5)	20 (55.6)
BMI (kg/m <sup>2</sup> ); mean (SD)	28.6 (6.06)	26.2 (5.02)	27.9 (5.80)
Past psychedelic used (n; %)	2 (8.0)	2 (18.2)	4 (11.1)
HAM-A <sup>1</sup> at Baseline; Mean (SD)	22.0 (5.42)	21.0 (5.74)	21.7 (5.46)

## Key Takeaways

- Moderate-to-severe patients (average HAM-A lower than monotherapy trials), consistent with subjects on concomitant SoC
- Inadequately responding patients are a harder to treat population
- **Known to be a challenging population to show an effect in adjunct – no approved adjunctive in GAD on top of SOC**

### Notes:

Some values subject to affect of rounding.

1) Hamilton Anxiety Rating Scale (HAM-A) has total score range of 0-56, where ≤17 indicates mild severity, 18-24 moderate and 25-30 severe.

# Generally Well-Tolerated, Adverse Events were Transient, with No Drug Related Serious Adverse Events Recorded

SOC Psychiatric Disorders AEs > 10% across all participants	20 mg N (%)	2 mg N (%)	Total N (%)
Hallucination, visual	11 (44.0)	1 (9.1)	12 (33.3)
Time perception altered	4 (16.0)	1 (9.1)	5 (13.9)
Anxiety	3 (12.0)	1 (9.1)	4 (11.1)
Confusional state	4 (16.0)	0	4 (11.1)
Depersonalization / derealization disorder	3 (12.0)	1 (9.1)	4 (11.1)
Emotional disorder	4 (16.0)	0	4 (11.1)

All AEs were mild/moderate

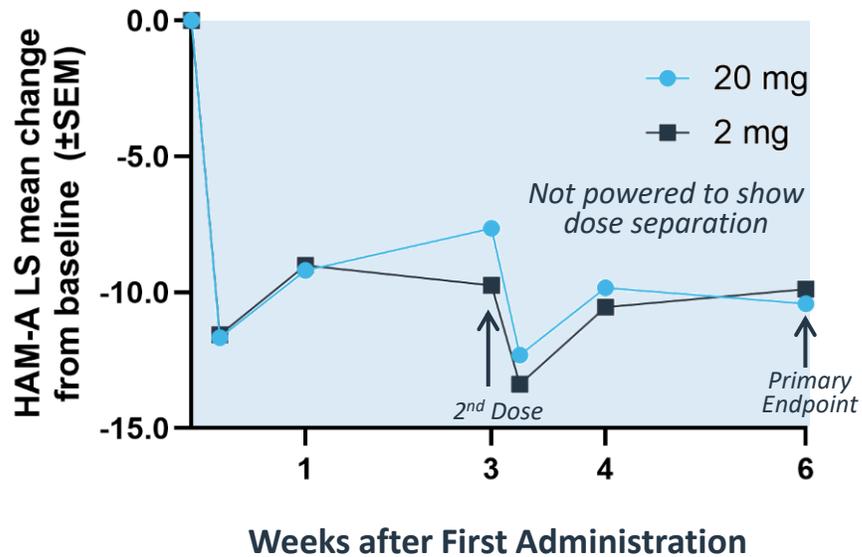
No severe or serious AEs

No suicidality-related safety signal

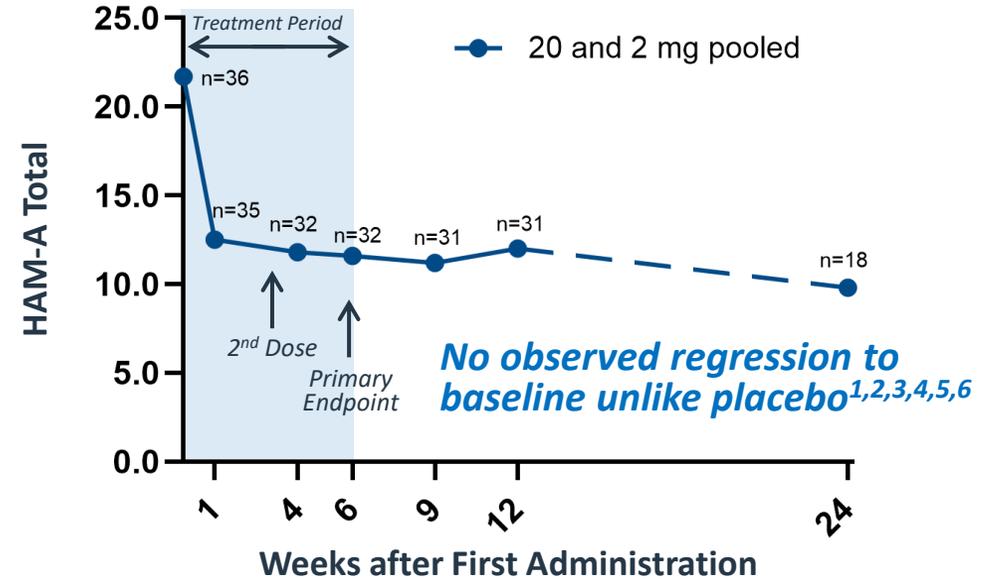
- No discontinuations due to AEs
- All related AEs resolved without sequelae
- No AEs required emergent intervention
- All AEs largely confined to the day of dosing

# HLP004 Demonstrated Rapid and Profound Effects over SoC, with Effects Sustained Through at Least 6 Months

**Anxiety Symptom Improvement Meets Primary Endpoint at 6 Weeks**



**Durable Anxiety Symptom Improvement Through 6 Months**



- Rapid, within-subject improvements from Day 2
- Primary endpoint achieved over SoC, ~10-point HAM-A improvement (p<0.0001)
- Not powered to show dose separation
- Durable improvements for 6 months
- Placebo effects regress to baseline after stopping treatment in GAD<sup>1,2,3,4,5,6</sup>
- Sustained improvements following second dose

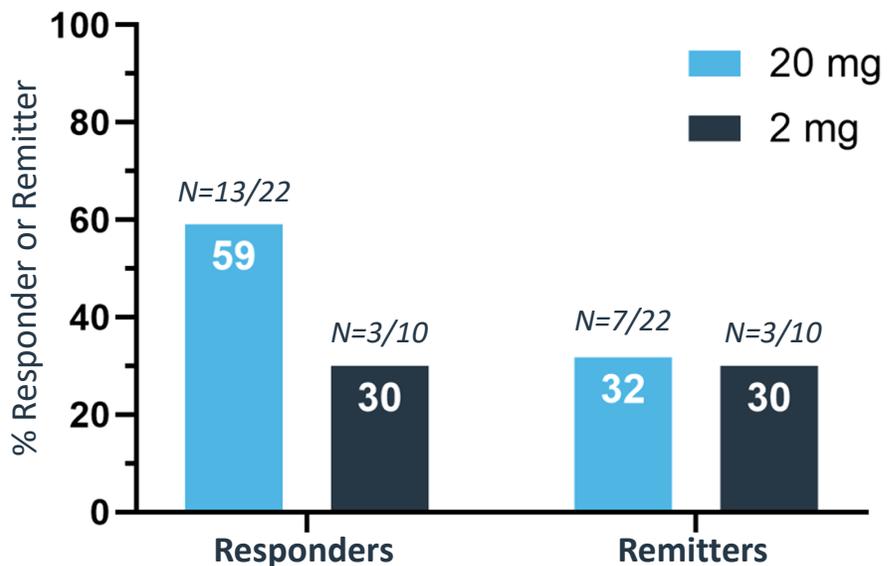
Notes:

1) Gueorguieva, et al. Lancet Psychiatry, 2017. 4(3):230-237.  
 2) Rutherford, et al. Depress Anxiety, 2015. 32(12):944-57.  
 3) Berwian, I.M., et al. Psychol Med, 2017. 47(3):426-437.  
 4) Jones, B.D.M., et al. JAMA Network Open, 2021. 4(9):e2125531-e2125531.

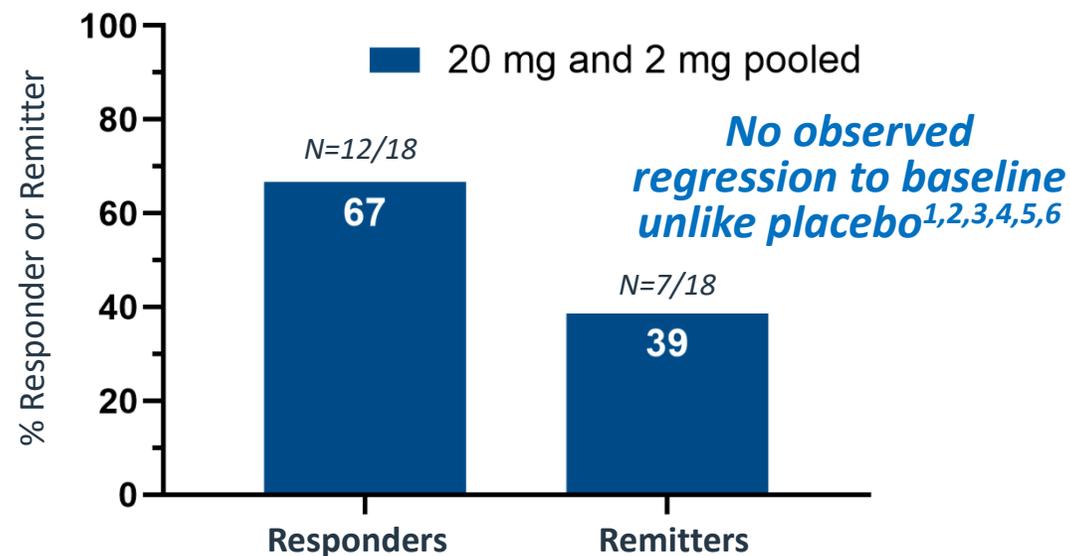
5) Davidson, et al. Eur Neuropsychopharmacol, 2008. 18(9):p. 673-81.  
 6) Quitkin, et al. Arch Gen Psychiatry, 1984. 41:p. 782-786.

# Single HLP004 Treatment Cycle Resulted in ~70% Responders and ~40% Remitters at 6 months

Responders and Remitters at 6 Weeks



Responders and Remitters at 6 Months



- Up to ~60% responders and ~1/3<sup>rd</sup> remitters at 6 weeks

- ~70% responders and ~40% remitters at 6 months
- Sustained improvements at 1 year
  - 5 participants; 4 of which were remitters
  - Average HAM-A is 4.0

Notes:

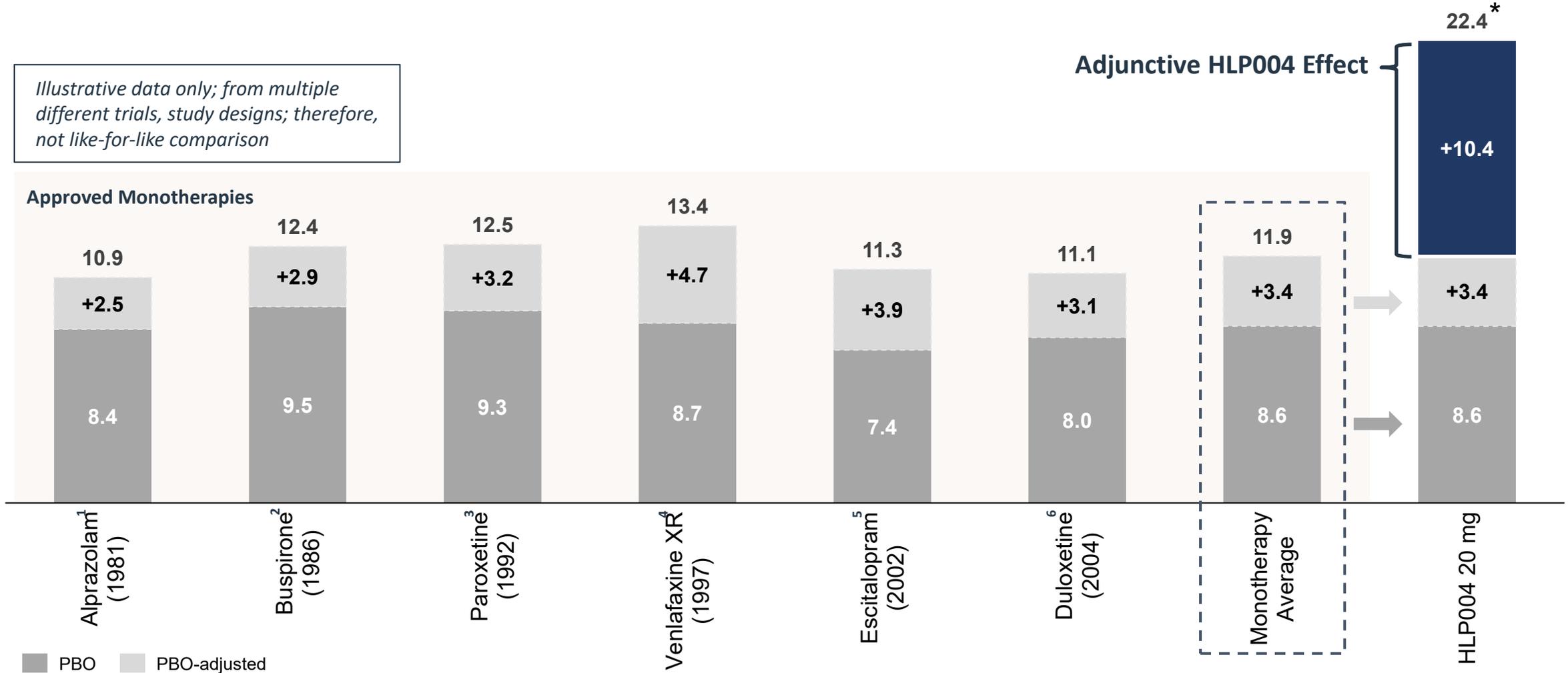
1) Gueorguieva, et al. Lancet Psychiatry, 2017. 4(3):230-237.  
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 3) Berwian, I.M., et al. Psychol Med, 2017. 47(3):426-437.  
 4) Jones, B.D.M., et al. JAMA Network Open, 2021. 4(9):e2125531-e2125531.

5) Davidson, et al. Eur Neuropsychopharmacol, 2008. 18(9):p. 673-81.  
 6) Quitkin, et al. Arch Gen Psychiatry, 1984. 41:p. 782-786.

# Impact of HLP004 in Real World Clinical Setting

## Illustrative Benefit of Adjunctive Treatment in GAD

Illustrative data only; from multiple different trials, study designs; therefore, not like-for-like comparison



Notes:

Some values subject to affect of rounding.

- 1) Rickels 2005.
- 2) Sramek 1996.
- 3) Rickels 2003.
- 4) Gelenberg, 2007.
- 5) Davidson 2004.
- 6) Allgulander 2008.

\*Absolute HAM-A response calculated using 10.42 response of HLP004 in adjunctive setting and monotherapy average of 11.93

# HLP004's Emerging Best-in-Class Profile As a Short Acting Treatment for Psychiatric Conditions

	Acute Subjective Effects	Ready to Discharge	Fits Spravato's Commercial Model	Single Treatment Cycle	Durability with Single Treatment Cycle	Patient Population in Trial	AEs	Intellectual Property
<b>HLP004</b> <i>(D-DMT; GAD)</i>	~90 Minutes	100% within 3 hours <sup>1</sup>	Yes	2 doses	At least 6 months+	Real-world adjunctive	Transient	CoM 2041
<b>SOC</b>	Minimal	-	-	Chronic	Daily Dosing Required	Monotherapy	Sexual Dysfunction, Weight Gain, Insomnia	Generic

*Favorable to HLP004*

**Notes:**

To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable.

1) For 30 mg dose.

# Leading the Development of Novel Serotonergic Agonists (NSAs)<sup>1,2,3</sup>

1

Following HLP004's positive Phase 2, Helus now has **two late-stage programs** in large psychiatry markets of MDD and GAD with near-term valuation catalysts

2

Proprietary novel entities supported by **robust intellectual property portfolio** with over 350 filed patents of which 100 are already granted

3

Trials to date have yielded **compelling results**

4

Both late-stage compounds have demonstrated amongst the **longest durability** to date in the sector

5

Differentiated pipeline with potential for **expansion into additional mental health indications with high unmet need** affecting >200M people in the U.S.<sup>3</sup>

6

Ongoing execution on clinical data, Nasdaq uplisting, rebranding and strengthened management team

## Notes:

1) Novel serotonergic agonists (NSAs): synthetic molecules designed to activate serotonin pathways that are believed to drive neuroplasticity.

2) Forward looking statements are subject to risks and assumptions. There is no assurance that timelines will be met. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to Helus. Such statements are informed by, among other things, regulatory guidelines for developing a drug with timeline safety studies, PoC studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and Helus's development efforts to date.

3) Addressable market is estimated based on U.S. census population of 337,049,203 as of September 8, 2024 and on U.S. prevalence of indications including depression, anxiety disorders/PTSD, bipolar disorder, substance use/addiction disorders, eating disorders, cluster headaches/migraine, and chronic pain management.

**Thank You**

