Topline Data from Phase 2 ZEPHYR Trial Evaluating ML-007C-MA in Schizophrenia

July 27, 2026

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Agenda

Executive Summary and Unmet Medical Need	Chris Kroeger, M.D.	Co-Founder and Chief Executive Officer
Phase 2 ZEPHYR Design and Results	Erin Foff, M.D., Ph.D.	Chief Medical Officer
Future Development Considerations	Chris Kroeger, M.D.	Co-Founder and Chief Executive Officer
Closing Remarks	Chris Kroeger, M.D.	Co-Founder and Chief Executive Officer
Q&A Session	All	

ZEPHYR Met Its Primary Endpoint, Supporting Advancement into an Additional, Confirmatory Pivotal Study

ZEPHYR Schizophrenia Study

- **ZEPHYR met its primary endpoint and demonstrated a substantial treatment effect,** supported by concordant improvements across key secondary efficacy measures
- **Robust and clinically meaningful improvement in cognitive performance observed on a pre-specified secondary endpoint** supporting a potentially differentiated clinical profile
- **Favorable safety and tolerability profile observed**, with no serious or drug-related severe adverse events, low GI-related discontinuation, low rates of moderate GI side-effects, and no urinary retention, metabolic, hepatic, or movement-related signals
- **Designed for real-world use**, with no fasting requirement and a short, one-dose titration
- **Data support advancing to an additional pivotal trial to support registration**; planning and site identification underway ahead of EOP2 FDA interactions

GI = gastrointestinal; EOP2 = end-of-phase 2; FDA = Food and Drug Administration.

Unmet Need in Schizophrenia Remains High

Affects Over 20 Million People Globally, Including More Than 3 Million in the U.S.

ZEPHYR Schizophrenia Study

Patients Remain Underserved by Current SOC Antipsychotics…

2024: First New Mechanism Approved in Decades (Cobenfy)

…Yet Significant Treatment Gaps Still Remain After First Muscarinic Approval

~30%

show no meaningful response to treatment (1)

~40-50%

experience an inadequate response to standard of care (1)

~70%

discontinue oral therapies within 18 months, often due to burdensome side effects (e.g., EPS, weight gain) (2)

Cognitive benefit remains unproven

Existing evidence is derived from post hoc or exploratory pooled analyses across two studies

Many patients cannot reach or remain at target dose

Failure to achieve adequate therapeutic exposure may leave symptoms insufficiently controlled (3)

Tolerability burden is exacerbated in real world

Tolerability challenges observed in controlled trials amplified in practice, given dosing / fasting complexity (3)

SOC = standard of care; EPS = extrapyramidal symptoms.

(1) Siskind et al., Br J Psychiatry (2022); treatment-resistant≥2 treatments. Samara et al., Schizophrenia Bulletin (2019); response as measured within 4-6 weeks.

(2) Lieberman et al., NEJM (2005). CATIE trial; all-cause discontinuation.

(3) BMS. Real-world transition strategies with xanomeline/trospium. Poster, Psych Congress 2025.

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Developing a Differentiated Treatment, Designed to Translate into Real-World Use

ZEPHYR Schizophrenia Study

210/3 mg BID delivered statistically significant improvement across complementary measures of schizophrenia symptoms

- PANSS Total Score (mITT, primary endpoint): Effect Size of 0.37 (-4.5 pts versus placebo, p=0.015)
- PANSS Total Score (Completers): Effect Size of 0.50 (-6.0 pts vs. Placebo, p=0.002)
- Also demonstrated significant separation on key secondary endpoints, including CGI-S (ES=0.48) and positive symptoms (ES=0.39)

210/3 mg BID also delivered significant improvement on cognitive performance, a potentially differentiating component of the clinical profile

- Cognitive Composite Score in participants with baseline cognitive impairment (prespecified secondary endpoint): Effect Size of 0.51 (0.44 pts vs. Placebo, p=0.041), assessed via Cogstate battery
- No significant correlation observed (p=0.314), indicating the effect was not likely secondary to reduced psychotic symptoms

ML-007C-MA was generally well-tolerated, with a profile designed to translate into real-world use

- No serious or drug-related severe AEs: Moderate-or-worse TEAE burden was meaningfully lower for ML-007C-MA than reported in Cobenfy's pivotal trials
- Low discontinuation across active arms (19.9%)
- Infrequent BID dose reduction due to TEAEs (4.0%); low rates of discontinuation due to GI AEs (2%), moderate GI AEs, and anticholinergic GI AEs
- No metabolic, hepatic, or movement-related signal; no significant anticholinergic safety signals, including urinary retention
- No fasting requirement or complex titration, reducing barriers to adherence outside the controlled trial setting

BID = twice-daily; PANSS = Positive and Negative Syndrome Scale; mITT = Modified Intention-to-Treat; CGI-S = Clinical Global Impression of Severity; ES = effect size; GI = gastrointestinal; TEAE = treatment-emergent adverse event; AE = adverse event.
Note: Unless otherwise specified, p-values are nominal, two-sided. For the 210/3 mg dose, the PANSS total score and CGI-S results met the prespecified multiplicity-adjusted significance threshold.

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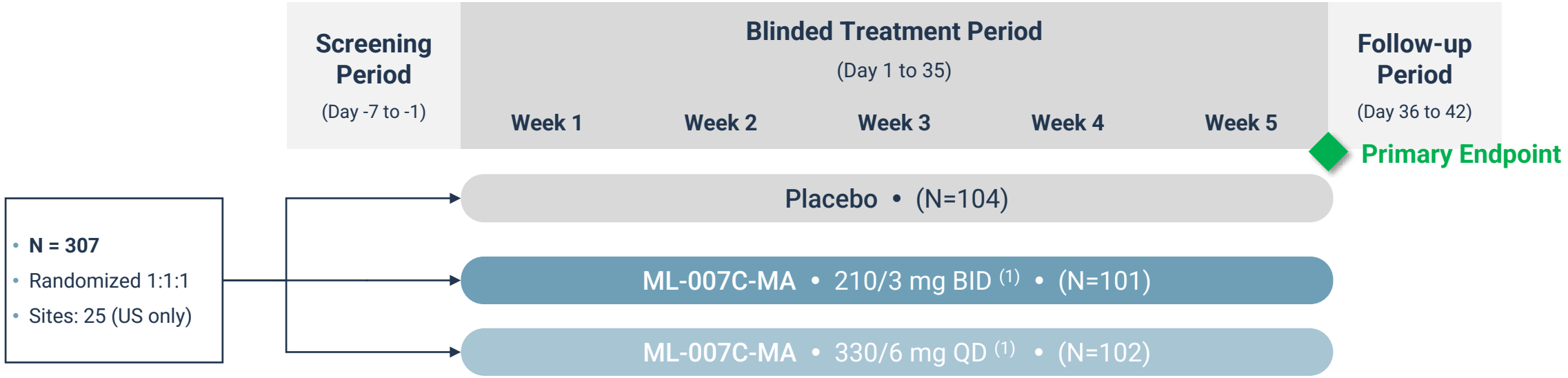
Phase 2 Design and Results

Erin Foff, M.D., Ph.D. | Chief Medical Officer

ZEPHYR Study Outline

Designed and Sized to Serve as a Registrational Study



Study Population	• 18 to 64 years of age with diagnosis of schizophrenia with MINI • PANSS 80-120 at screening and baseline • Score ≥4 for two or more positive symptom items • CGI-S score ≥4 • Untreated or recent wash-out of antipsychotics	**Primary Endpoint**	• CFB PANSS Total Score at Week 5
		Key Secondary Endpoints	• CFB CGI-S at Week 5 • CFB PANSS positive Marder factor at Week 5 • CFB PANSS negative Marder factor at Week 5
		Other Secondary (Prespecified)	• CFB Cognitive Composite Score at Week 5 in the cognitively impaired at baseline subgroup

CFB = Change from baseline; MINI = Mini-International Neuropsychiatric Interview; QD = once-daily.
(1) Single-dose titration; reduction of dose permitted once between Week 1 to 3 to 165/3 mg BID or 270/6 mg QD

Demographics & Baseline Characteristics

ZEPHYR Schizophrenia Study

	Placebo	210/3 mg BID	330/6 mg QD
Demographics(1)	N = 104	N = 99	N = 102
Mean Age, years	40	42	40
Male Sex at Birth, n (%)	80 (77%)	69 (70%)	77 (75%)
Race, n (%)			
Black or African American	81 (78%)	73 (74%)	80 (78%)
White	17 (16%)	22 (22%)	16 (16%)
Other	6 (6%)	4 (4%)	6 (6%)
Baseline Clinical Characteristics: Mean (Standard Deviation)	N = 104	N = 99	N = 102
PANSS Total Score	97 (7.9)	96 (7.3)	96 (7.5)
PANSS Marder Positive Factor Score	31 (3.7)	30 (3.6)	30 (3.7)
PANSS Marder Negative Factor Score	23 (4.4)	24 (4.4)	23 (4.0)
CGI-S Score	5 (0.6)	5 (0.6)	5 (0.6)

(1) N based on participants in safety set (all participants who were randomized and received at least 1 dose of study drug)

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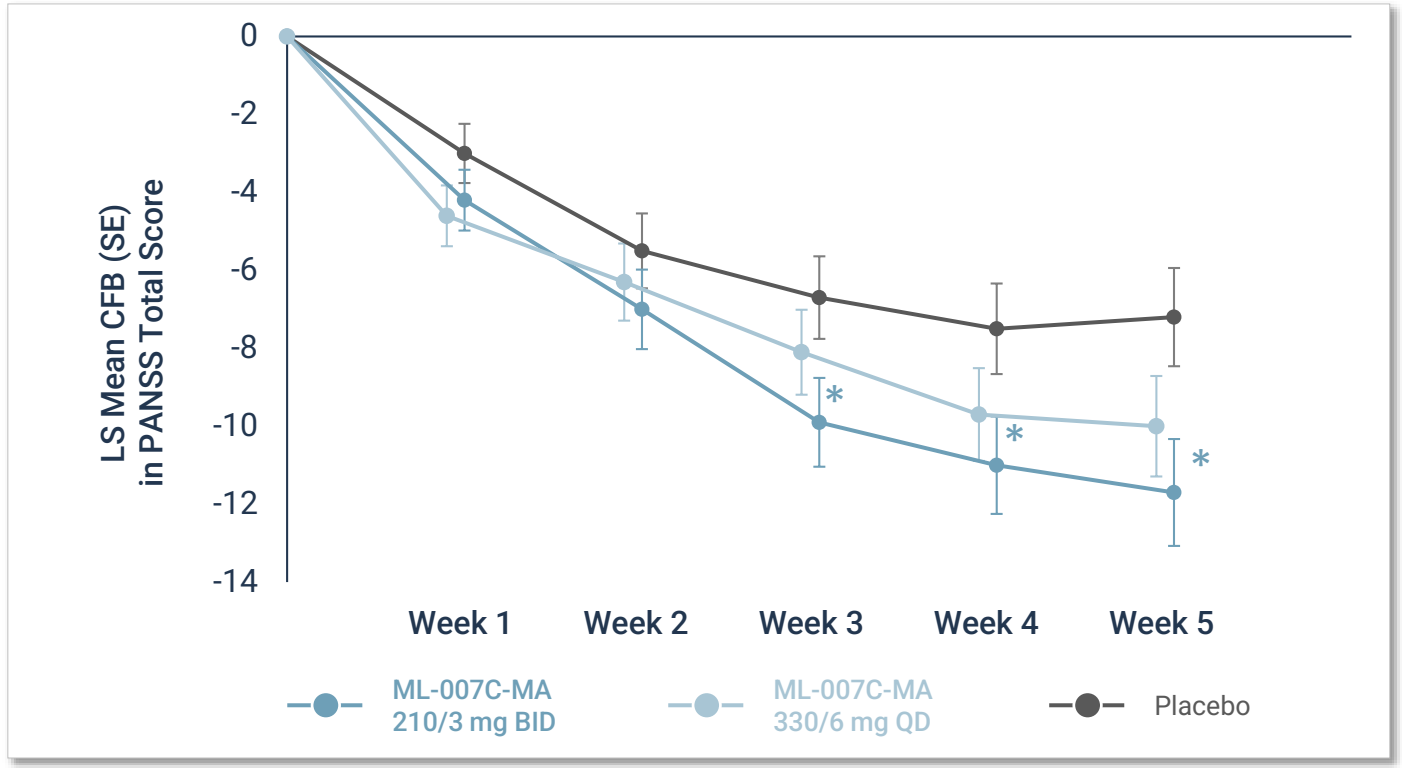
Primary Endpoint: PANSS Total Score

210/3 mg BID Met Primary Endpoint

ZEPHYR Schizophrenia Study

Change From Baseline in PANSS Total Score (LS Mean Difference)



	Placebo	210/3 mg BID	330/6 mg QD
N	N=103	N=93	N=98
LS Mean CFB	-7.2	-11.7	-10.0
LS Mean Diff vs. Placebo		-4.5	-2.8
P-value		**p=0.015**	p=0.110
Effect Size		**0.37**	0.23

- ZEPHYR met its primary endpoint: Demonstrated a statistically significant, clinically meaningful reduction in PANSS total score vs. placebo at Week 5
- 210/3 mg dose is also being evaluated for the treatment of ADP (VISTA[1] study ongoing)

**p<0.05*
LS = least squares; SE = standard error.
Note: Negative treatment deltas favor active treatment; effect size presented as an absolute value. Analysis based on the mITT population.
(1) NCT06887192: Evaluating ML-007C-MA for the treatment of hallucinations and delusions associated with Alzheimer's Disease Psychosis (ADP)

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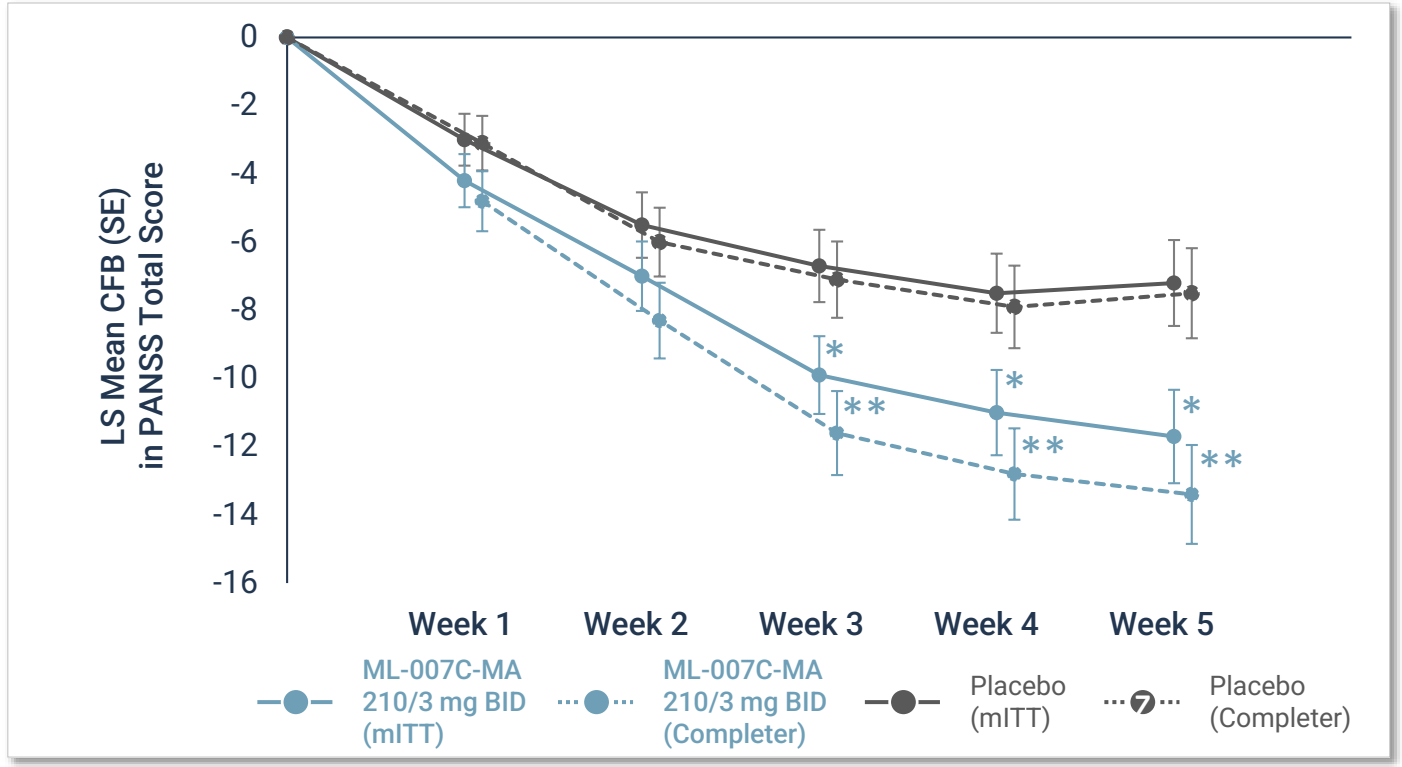
Primary Endpoint: PANSS Total Score

Robust Effect Demonstrated in Prespecified Completer Analysis

ZEPHYR Schizophrenia Study

Change From Baseline in PANSS Total Score (LS Mean Difference)



	Placebo (Completers)	210/3 mg BID (Completers)
N	N=88	N=73
LS Mean CFB	-7.5	-13.4
LS Mean Diff vs. Placebo		-6.0
P-value		**p=0.002**
Effect Size		**0.50**

- The completer analysis excludes modelled assumptions about missing data, relying solely on observed data from the full assessment period
- Bigger difference in completer analysis driven mostly by improvement in BID arm, not placebo

*p<0.05, **p<0.01
MMRM= Mixed model for repeated measures.
Note: Negative treatment deltas favor active treatment; effect size presented as an absolute value. Analysis based on the mITT population.

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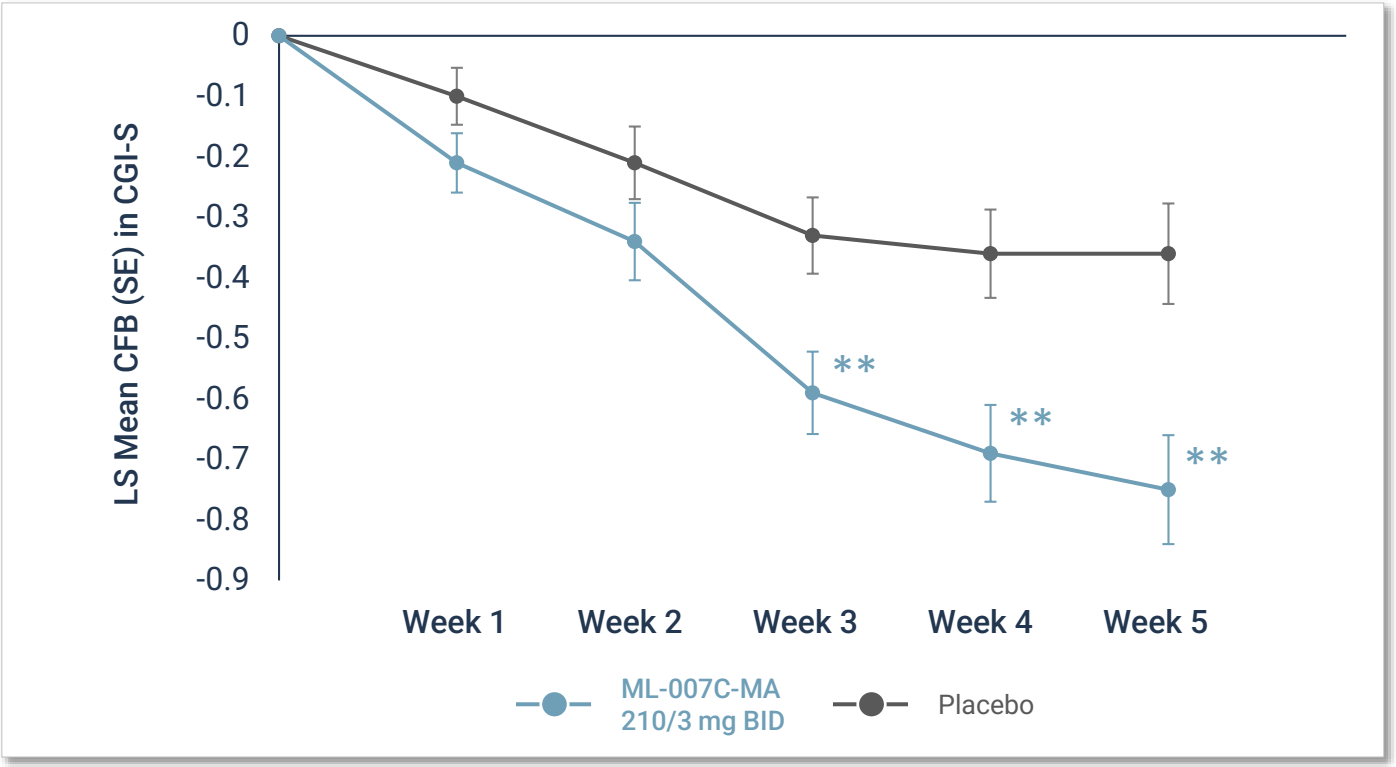
Key Secondary Endpoint: CGI-S

Significant Improvement Corroborates PANSS Improvement

ZEPHYR Schizophrenia Study

Change From Baseline in CGI-S (LS Mean Difference)



- Clinically meaningful and statistically significant improvement in CGI-S vs. placebo at Week 5
  - 0.38-point improvement
  - -0.75 active vs. -0.36 placebo
  - p=0.002(1)
  - ES = 0.48
- Numerical separation starting at Week 1, with statistical significance emerging by Week 3 and continuing over time

***p<0.01*
Note: Negative treatment deltas favor active treatment; effect size presented as an absolute value. Analysis based on the mITT population.
(1) Multiplicity-adjusted one-sided P value= 0.017

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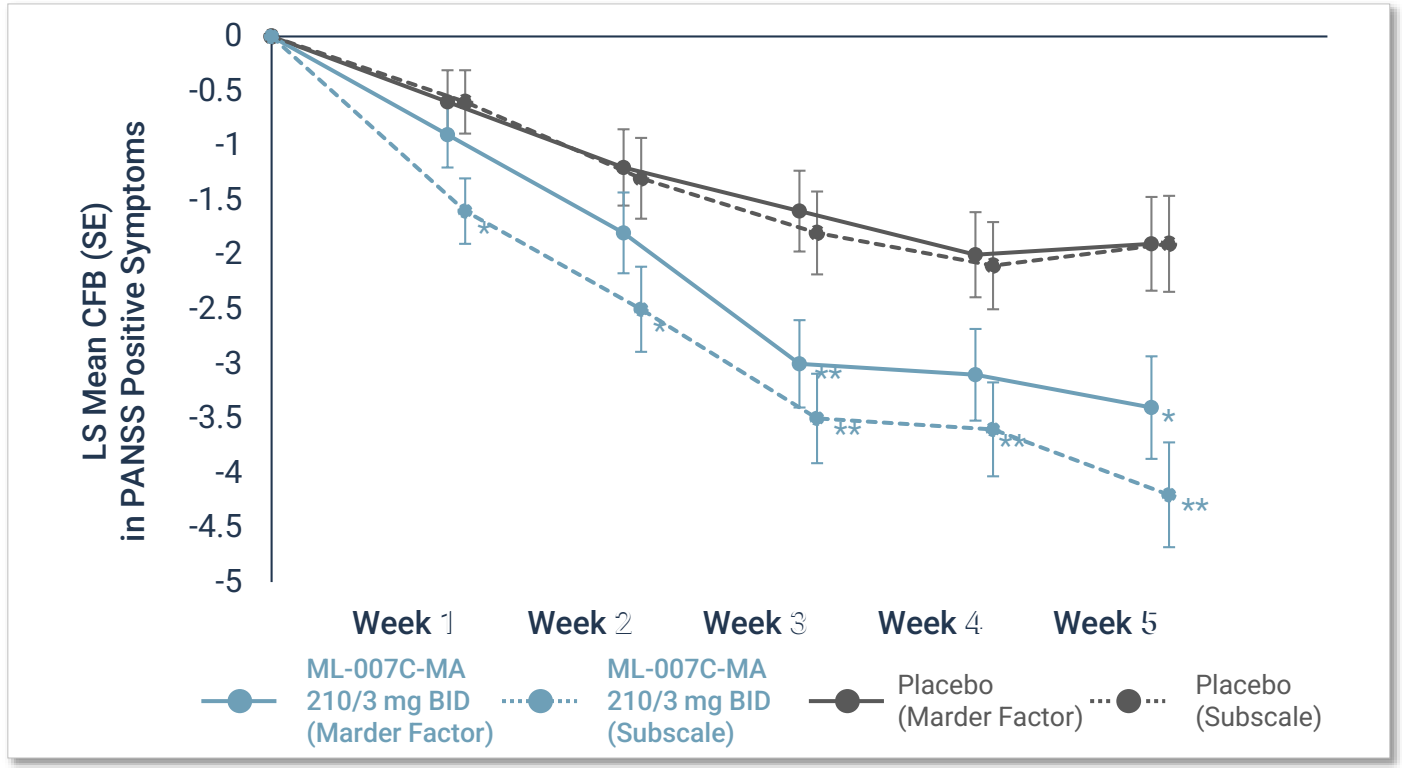
PANSS Positive Symptoms

Significant Improvement in PANSS Positive Marder Factor and Positive Subscale

ZEPHYR Schizophrenia Study

Change From Baseline in PANSS Positive Symptoms (LS Mean Difference)



	Placebo	PANSS + Marder	PANSS + Subscale
N	103	93	93
LS Mean CFB	-1.9/-1.9 (Marder/ Subscale)	-3.4	-4.2
LS Mean Diff vs. Placebo		-1.6	-2.3
P-value		**p=0.012**	**p=0.0003**
Effect Size		**0.39**	**0.56**

- Clinically meaningful and statistically significant improvement in PANSS positive symptoms vs. placebo at Week 5
- PANSS Positive Marder Factor was a key secondary- PANSS positive Subscale was prespecified

**p<0.05 , **p<0.01*
Note: Negative treatment deltas favor active treatment; effect size presented as an absolute value. Analysis based on the mITT population.

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Secondary Endpoint: Cognitive Composite

Robust and Clinically Meaningful Improvement on Cognitive Performance

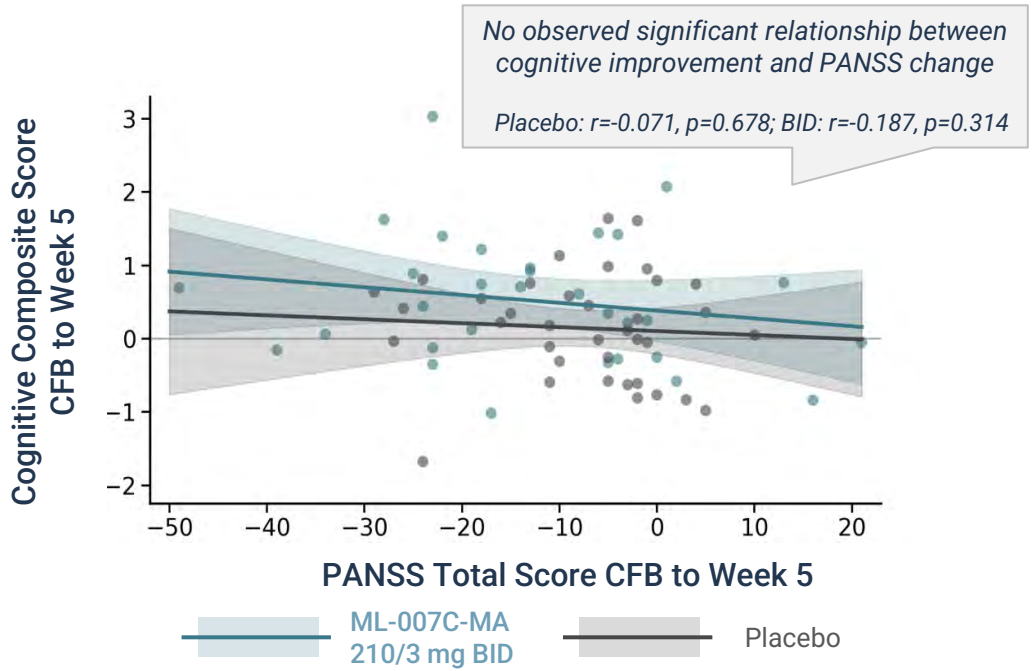
ZEPHYR Schizophrenia Study

Pre-specified Cognitive Composite Score Results

Cognitive Composite Score

	Placebo	210/3 mg BID
N with baseline impairment	N=37	N=31
LS Mean Change from Baseline	0.11	0.55
LS Mean Difference vs. Placebo		0.44
P-value		**p=0.041**
Effect Size		**0.51**

Dose used in VISTA



Note: Prespecified Cognitive Composite score derived from Cogstate Battery consisting of 6 individual tests

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Implications of Cognitive Signal Beyond ZEPHYR

ZEPHYR Schizophrenia Study

Supports Rationale for VISTA and Broader Development

Cognitive Impairment Remains an Unmet Need

- Cognitive impairment is estimated to affect >80% of patients with schizophrenia [1]
- Cognitive impairment is a major determinant of long-term functional outcomes, including employment, independent living and quality of life
- Despite decades of research, no therapies have been approved to treat cognitive impairment in schizophrenia
  - Highlights both the unmet need and the difficulty of demonstrating meaningful cognitive benefit
  - Sedation and dopamine blockade from many SOC antipsychotics may worsen cognition

The Signal Supports the Underlying Biology

- The cognitive benefit was observed on a prespecified secondary endpoint
- Change in the cognitive composite score was independent of changes in PANSS, suggesting it was not simply driven by better control of psychotic symptoms
- The finding is consistent with the established role of M1 receptor activation in learning and memory, strengthening confidence in the underlying mechanism

Why This Matters for VISTA [3] and Future Development

- A positive cognitive signal observed outside AD increases confidence that the biology translates across neuropsychiatric populations
- Off-label use of antipsychotics in ADP has been associated with accelerated cognitive decline (CATIE-AD), highlighting the need for new therapies [2]
- The 210/3 mg BID dose currently being evaluated in VISTA is the same dose that demonstrated cognitive benefit in ZEPHYR

(1) *Maroney, Ment Health Clin. 2022.*
(2) *Vigen et al., Am J Psychiatry. 2011.*
(3) *NCT06887192: Evaluating ML-007C-MA for the treatment of hallucinations and delusions associated with Alzheimer's Disease Psychosis (ADP).*

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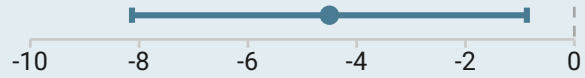
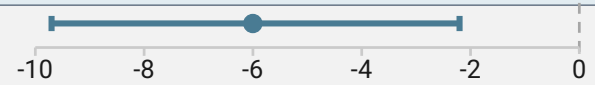
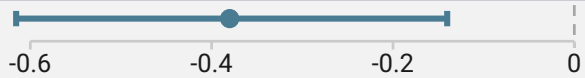
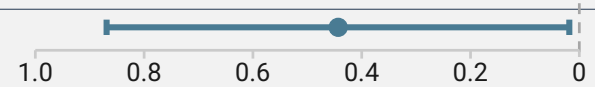
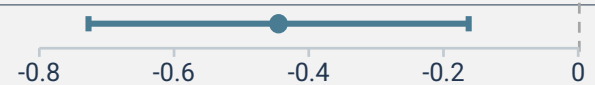
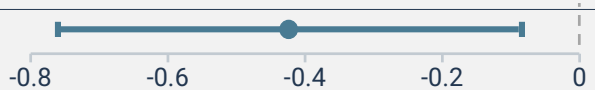
210/3 mg BID Demonstrated Effect Across Multiple Endpoints and Symptom Domains

ZEPHYR Schizophrenia Study

	N Active / PBO	LS Mean Difference [95% CI] ← *ML-007C-MA favored* *PBO favored* →	Effect Size	P-value
PANSS Total Score – mITT	93 / 103		**0.37**	**0.015**
PANSS Total Score - Completers	73 / 88		**0.50**	**0.002**
CGI-S	93 / 103		**0.48**	**0.002**
Cognitive Composite	31 / 37		**0.51**	**0.041**
PANSS Marder Positive Factor	93 / 103		**0.39**	**0.012**
PANSS Marder Negative Factor	93 / 103		0.18	0.244
CGI-C	93 / 103		**0.47**	**0.002**
PGI-C	93 / 103		**0.38**	**0.015**

Participants on active treatment were, compared to placebo:

- 2.4x more likely to achieve ≥30% response on the PANSS total score by Week 5 (p=0.021)
- 2.8x more likely to be ready for discharge out of the inpatient hospital setting by Week 5 (p=0.002)

CGI-C = Clinical Global Impression of Change; PGI-C = Patient Global Impression of Change.
Note: Graphed data represent the LS mean difference (ML-007C-MA 210/3 mg BID – placebo) and 95% confidence intervals

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ML-007C-MA Was Generally Well Tolerated

ZEPHYR Schizophrenia Study

Adverse Events Mostly Mild

- Adverse events, primarily cholinergic in nature, were mostly mild
- No serious or drug-related severe TEAEs occurred with either dose (1)
- The only severe TEAE (pneumonia) was assessed as unrelated to study drug

GI Events Rarely Led to Discontinuation with BID Dosing

- There were no instances of failure to reach target dose due to tolerability
- Dose reduction due to TEAE was infrequent (4 participants); TEAEs leading to dose reduction started in the first week, and most (75%) completed treatment following dose reduction
- Low rates of moderate GI side-effects
- Low rates of discontinuation (2 participants) due to gastrointestinal adverse events

No Signal Across Key Safety Domains

- No urinary retention signal observed: The active and placebo arms each had a single moderate urinary event (UTI)
- No metabolic, hepatic, or EPS signals observed: mean weight, glucose, lipid, liver enzyme, and movement-related parameters remained comparable to placebo
- Heart rate increases were mild and consistent with the fesoterodine label, with no evidence of significant blood pressure elevation

(1) Single serious adverse event occurred in placebo arm was worsening schizophrenia.

Most Adverse Events Were Mild

All Cause Discontinuation Was Low at 19.9% Across Active Treatment Arms

ZEPHYR Schizophrenia Study

Rates of TEAEs With BID Dosing

	Placebo N=104	210/3 mg BID N = 99
Discontinuations		
Due to TEAE	1.0%	7.1%
Due to GI TEAE	0	2.0%
Utilization of Lower Dose		
Dose Reduction Due to TEAE	1.9%	4.0%
Inability to Reach Target Dose	0	1% (1)
Any TEAE	48.1%	74.7%
Mild	36.5%	48.5%
Moderate	11.5%	25.3%
Severe TEAE	0	1.0% (2)
Serious TEAE	1.0%	0

GI TEAEs ≥2% in Active Arm and > Placebo

	Placebo N=104		210/3 mg BID N = 99	
	Mild	Moderate	Mild	Moderate
Nausea	6%	0	20%	9%
Vomiting	1%	2%	9%	4%
Dyspepsia (3)	0	1%	8%	1%
Constipation	3%	0	8%	1%
Abdominal pain (3)	3%	0	6%	3%
Diarrhea	1%	0	5%	0
GERD	2%	0	2%	0

All GI TEAEs were mild to moderate in severity

- Other TEAEs ≥5% include: headache, salivary hypersecretion, dizziness, hyperhidrosis, hot flushes, somnolence, chills, decreased appetite, tremor, and insomnia
- Single episode of unrelated hypertension; one episode of orthostatic hypotension observed in each of the placebo and BID dosing arms

AE = adverse event.

(1) One participant was withdrawn due to baseline (pre-dose) lab findings following titration dose but prior to first target dose.

(2) Assessed as unrelated to study drug (pneumonia).

(3) Dyspepsia includes dyspepsia and esophageal discomfort; abdominal pain includes abdominal discomfort, abdominal pain upper, abdominal pain, abdominal pain lower, abdominal distension, and abdominal tenderness

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Rates of TEAEs for Cobenfy in Pivotal Studies

All Cause Discontinuation Ranged From 25.4%-36.8% at 5 weeks [1]

	EMERGENT-2		EMERGENT-3	
	Placebo	Active	Placebo	Active
Discontinuations				
Due to TEAE	5.6% [2]	7.1% [2]	5.5% [3]	6.4% [3]
Due to GI TEAE	Not reported	3.2% [4]	Not reported	3.2% [4]
Utilization of Lower Dose				
Dose Reduction Due to TEAE[1]	0	5.6%	0.8%	0.8%
Inability to Reach Target Dose	1.6% [2]	17.5% [2]	9% [5]	21% [5]
Any TEAE	58.4%	75.4%	50.0%	70.4%
Mild [1]	27.2%	38.1%	25.8%	36.0%
Moderate [1]	24.8%	28.6%	20.3%	26.4%
Severe TEAE [1]	4.0%	7.1%	2.3%	8.0%
Serious TEAE	1.6% [2]	1.6% [2]	0	0.8% [6]

Moderate-or-worse TEAE burden was meaningfully lower for ML-007C-MA (26%) than reported in Cobenfy's pivotal trials (34-36%)

GI TEAEs ≥2% in Active Arm and > Placebo

	Cobenfy FDA Label	
EMERGENT-2/3 Pooled	Placebo (N=253)	Active (N=251)
Nausea	4%	19%
Dyspepsia [7]	5%	18%
Constipation	7%	17%
Vomiting	1%	15%
Abdominal Pain [7]	4%	8%
Diarrhea	2%	6%
GERD	<1%	5%

- **51%-78% did not complete 1 year of treatment in the open-label studies** [8]
- **Real-world non-persistence is ~80% by Month 13** [9]
- **Real-world Patient Experience (N=90)** [10]

>2-3x *the rates of nausea and vomiting*

>80% *did not reach the highest dose (125/30 mg)*

55% *received medication for GI events*

>50% *had no or only partial response to intervention*

(1) *Cobenfy FDA Summary Basis of Approval (SBA).*
(2) *EMERGENT-2 primary manuscript: Kaul et al., 2024. Pbo: appendicitis(n=1), schizophrenia (n=1). Active: suicidal ideation (n=2).*
(3) *EMERGENT-3 primary manuscript: Kaul et al., 2024.*
(4) *Pooled EMERGENT-2 and -3 rate. 8 participants discontinued in the Cobenfy arm per the SBA (Table 35) in the pooled EMERGENT-1,2,3 studies. Per Karuna 2023 10-K filing, only N=2 participants discontinued from the active arm of EMERGENT-1 (N=89), neither from the GI system organ class.*
(5) *Karuna 2023 10-K filing.*
(6) *EMERGENT-3 topline results, per Karuna Therapeutics press release (March 2023). Active: GERD (n=1).*
(7) *Dyspepsia includes dyspepsia and esophageal discomfort; abdominal pain includes abdominal discomfort, abdominal pain upper, abdominal pain, abdominal pain lower, and abdominal tenderness. EMERGENT-4 and EMERGENT-5 results, Kaul et al., 2026.*
(8) *Non-persistence: MapLight estimate, third-party Rx data.*
(9) *Retrospective analysis of real-world transition strategies for xanomeline and trospium chloride in adult patients with schizophrenia. Poster, Psych Congress 2025.*
(10)

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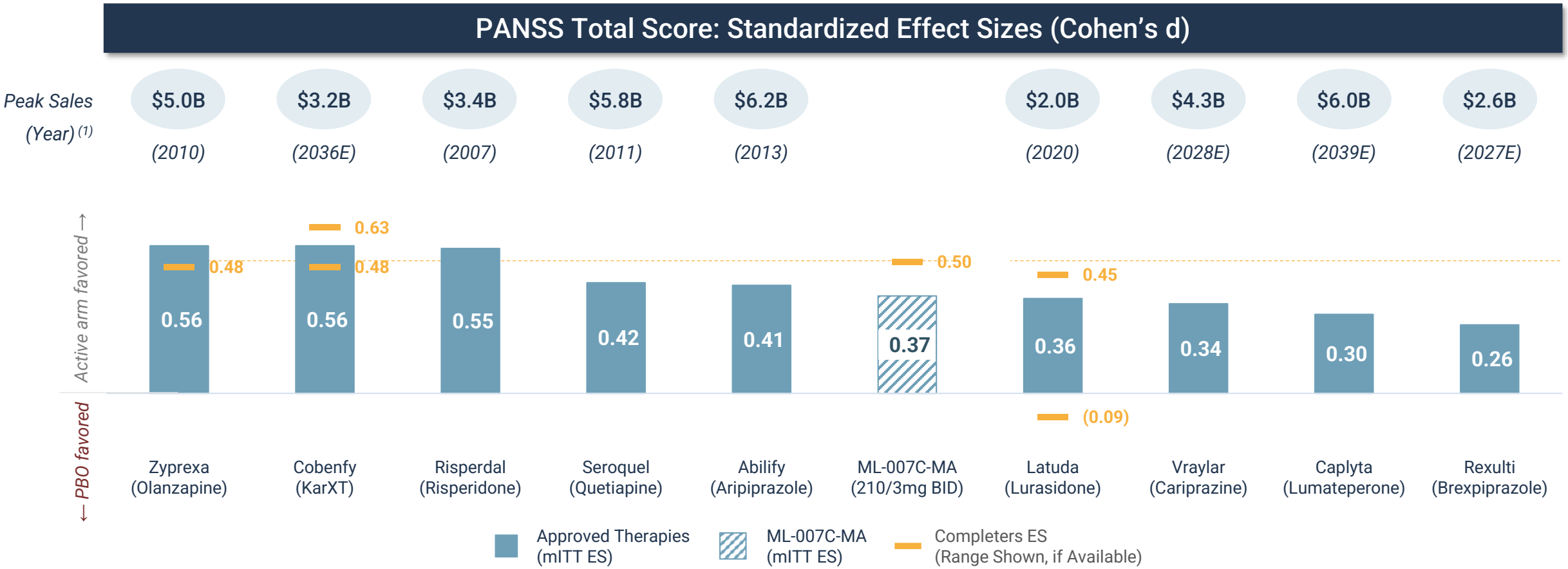
Future Development Considerations

Chris Kroeger, M.D. | Co-Founder and Chief Executive Officer

Significant Opportunity for New Therapies

210/3 mg BID Effect Size Falls Within the Range of Approved Antipsychotics

ZEPHYR Schizophrenia Study



Note: Assessments reflect management's current views based on publicly available information and internal analyses; comparisons are subject to uncertainty around interpretation. Differences exist among study designs, and caution should be exercised when comparing data across trials.

Sources: Approved antipsychotic effect sizes per Huhn et al., Lancet 2019; Correll et al., JAMA Psychiatry 2020; Cobenfy per Fabiano et al., 2025 meta-analysis. Completer analysis effect size for Cobenfy estimated based on data from Kaul et al., 2023 and Kaul et al., 2024; Zyprexa and Latuda based on data from Latuda's FDA Summary Basis of Approval Tables 37 and 52. Completer/observed-case values reflect trial-completer populations only, not intent-to-treat; ranges reflect variation across available analyses. ML-007C-MA completer analysis: N=73 (p=0.002).

(1) WW consensus peak sales (oral) as per Evaluate Pharma and Visible Alpha as of July 2026; Caplyta projections only available through 2030 (LOE 2039); all indications.

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ML-007C-MA Target Product Profile has Potential to be Differentiated Across Multiple Dimensions

ZEPHYR Schizophrenia Study

In development

	Program *Mechanism of Action*	ML-007C-MA (1) *M_1/M_4 Agonist + Peripheral Antagonist*	Cobenfy (2) *M_1/M_4 Agonist + Peripheral Antagonist*	Emraclidine (3) *M_4 PAM*	Direclidine (4) *M_4 Agonist*	SOC Antipsychotics *Primarily D_2-blockade*
	Efficacy in RCTs	210/3 mg BID hit primary endpoint		Not stat. sig. in Ph 2	U-shaped dose response	
	Cognitive Improvement	Prespecified secondary endpoint	Post-hoc/pooled analyses	No activity at M_1	No activity at M_1	Some may cause impairment
Factors expected to impact real world translation	Tolerability/Safety	Meaningfully lower rates of significant side effects	Moderate to severe TEAEs			Metabolic, movement, sedation
	No Fasting Requirement	Taken with food	Must be taken fasted			
	Simple Titration	One-dose titration	3-8 day, 2-step titration			Varies across APs
	Dosing Frequency	QD dose to be further explored	BID			Varies across APs

RCT = randomized controlled trials; PAM = positive allosteric modulator.
Note: Assessments reflect management's current views based on publicly available information and internal analyses; comparisons are qualitative and subject to uncertainty around interpretation. Differences exist among study designs, and caution should be exercised when comparing data across trials.
(1) Based on results from ZEPHYR-1 Phase 2 study, and product profile is subject to the completion of additional studies and review by the FDA
(2) Based on FDA prescribing information.
(3) Based on results from the Phase 2 EMPOWER-1 and EMPOWER-2 clinical trials, which failed to demonstrate a statistically significant improvement in PANSS total score.
(4) Based on results from the Phase 2 clinical trial, which showed statistically significant improvement only at the lowest dose of the four active drug arms evaluated.

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Phase 3 Program and Path to NDA Submission

Confirmatory Pivotal Trial Expected to Support Initial Approval

ZEPHYR Schizophrenia Study

ZEPHYR-1 (Study 211)

Complete

- Established primary efficacy signal and safety for 210/3 mg BID
- Result supports pivotal status, pending confirmation with the FDA

Engage with the FDA at EOP2 Meeting

ZEPHYR-2 (Study 311)(1)

Planned

- Similar design to Phase 2, evaluating 210/3 mg BID vs. placebo in U.S. sites
- Together with Study 211, intended to support initial NDA submission

ZEPHYR-3 (Study 312) (1)

Planned

- Additional pivotal trial evaluating 210/3 mg BID
- Potential to evaluate an alternate QD regimen (would pursue as sNDA)

VISTA (Study 221)

Ongoing — Topline results expected in 2H 2027

- Trial in ADP patients evaluating 210/3 mg BID (potentially registrational)
- On track, supported by ZEPHYR's prespecified cognitive signal

Evaluating potential in additional indications, including for the treatment of mild-moderate Alzheimer's disease

(1) Subject to FDA feedback at EOP2 Meeting.

Closing Remarks

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Closing Remarks

ZEPHYR Schizophrenia Study

Statistically Significant Across Complementary Measures

- Met the primary endpoint on PANSS Total Score (ES=0.37), with a stronger effect in completers in which there are no modelled assumptions of missing data (ES=0.50)
- Achieved significance on CGI-S and PANSS Positive Marder Factor

Potentially Differentiating Cognitive Signal

- Prespecified Cognitive Composite Score improved significantly (ES=0.51)
- Cognitive signal independent of antipsychotic effect; not a byproduct of reduced psychotic symptoms

Tolerability Built for Real-World Use

- No serious or drug-related severe adverse events; 99% of patients reached the target dose; low rates of moderate GI side-effects
- No fasting requirement or complex titration, unlike other agents in the class, potentially increasing adherence and persistence

Data support advancement of 210/3 mg BID into a confirmatory pivotal trial and continued investment in indication expansion, leveraging the observed cognitive signal; next steps will be guided by the planned EOP2 meeting

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Advancing a Broad and Diversified Pipeline

Program	Circuit	Indications	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
ML-007C-MA M_1/M_4 agonist co-formulated with PAC	Direct and Indirect Pathways	Schizophrenia			ZEPHYR		**Engage with FDA at EOP2 meeting**
		Alzheimer's Disease Psychosis			Fast Track VISTA		Topline results in 2H 2027
ML-004 5-$HT_{1B/1D}$ agonist	Dorsal Raphe to Nucleus Accumbens	Autism Spectrum Disorder Sociability/Irritability			IRIS		**Engage with FDA at EOP2 meeting**
ML-009 GPR52 PAM	Indirect Pathway	Hyperactivity/Impulsivity					Complete IND-enabling studies in 2027
ML-055 Next-Gen M_1/M_4 agonist	Direct and Indirect Pathways	Neuropsychiatric Disorders					Nominate preclinical candidate in 2026
ML-021 M_4 antagonist	Direct Pathway	Parkinson's Disease					Finalize preclinical candidate in 2027

Potential in other indications being explored

Leveraging our versatile circuit-based discovery platform for ongoing pipeline expansion

GPR = G-protein-coupled receptor. PAC = peripherally acting anti-cholinergic. PAM = positive allosteric modulator.

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Q&A