

LB Pharmaceuticals Inc

Developing Novel Therapies for Neuropsychiatric Disorders

September 2025



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Investment Highlights

Advancing a Phase 3 ready asset in schizophrenia (SCZ) with differentiated clinical profile

Phase 2 SCZ trial demonstrated statistically significant benefit versus placebo at all doses studied

Positive FDA feedback offering potential for SCZ approval with one successful Phase 3 trial

Strong scientific and clinical rationale for planned Phase 2 clinical trial in bipolar depression (BPD)

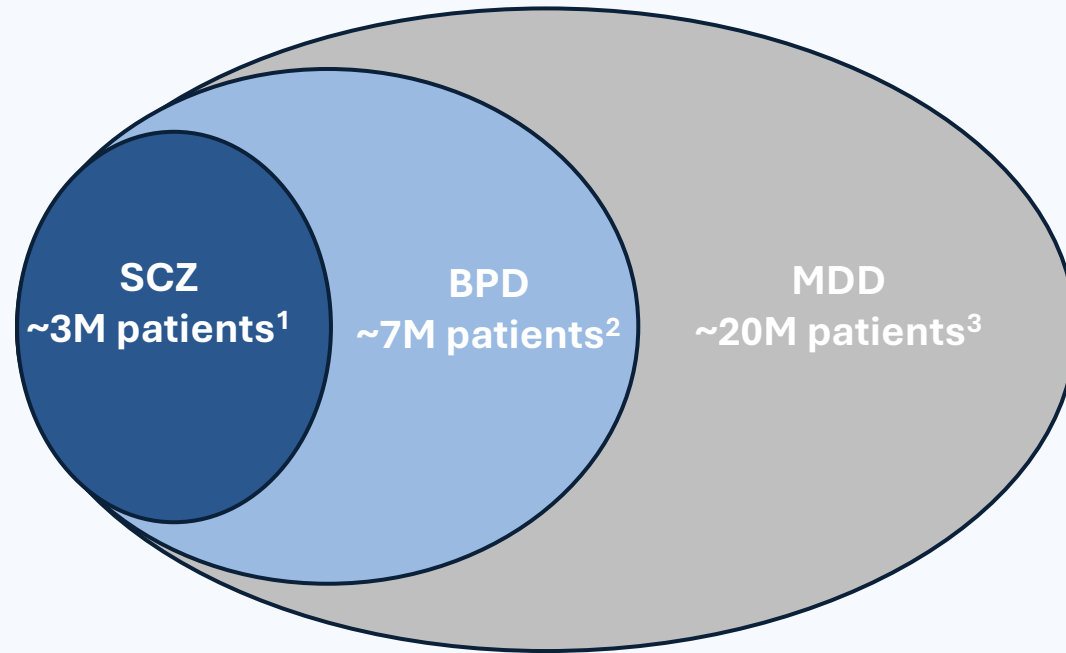
Future indication expansion opportunities including major depression (MDD)

Composition of matter IP with protection expected to 2041¹

Multibillion-dollar sales potential for LB-102 as treatment for SCZ, BPD and MDD²

¹ Includes estimated Hatch-Waxman extension, composition of matter IP expires 2037; LB-102 patent portfolio includes: 7 U.S. issued, 11 foreign issued, 7 U.S. pending, and 19 foreign pending patents; ² Proprietary company data

Development of APs Typically Starts in SCZ and with a Suitable Mechanism Expands to BPD and MDD



- Development path validated by Vraylar and Caplyta
 - 2024 Vraylar sales exceeded \$3 billion
 - 2025 Intra-Cellular acquired for \$14.6 billion
- LB-102's mechanism, Phase 2 SCZ data and the legacy of amisulpride all support development of LB-102 in:
 - Schizophrenia
 - Bipolar depression
 - Major depression

¹ <https://www.hopkinsmedicine.org/health/wellness-and-prevention/mental-health-disorder-statistics#:~:text=Approximately%201%25%20of%20Americans%20are,late%20teens%20or%20early%2020s.> ;

² <https://www.nimh.nih.gov/health/statistics/bipolar-disorder>; ³ [https://www.nimh.nih.gov/health/statistics/major-depression#:~:text=disorders%2C%20or%20medication,-Prevalence%20of%20Major%20Depressive%20Episode%20Among%20Adults,more\)%20races%20\(13.9%25\)](https://www.nimh.nih.gov/health/statistics/major-depression#:~:text=disorders%2C%20or%20medication,-Prevalence%20of%20Major%20Depressive%20Episode%20Among%20Adults,more)%20races%20(13.9%25))

Significant Milestones and Runway Expected Through 1Q 2028^{LB PHARMACEUTICALS}

		Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
LB-102 (Oral)	Acute Schizophrenia					- Phase 3 initiation 1Q 2026 - Topline data expected 2H 2027 - Pre-NDA meeting expected 1Q 2028
	Bipolar I Depression					- Phase 2 trial initiation 1Q 2026 - Topline data expected 1Q 2028
LB-102 (LAI)	LAI Formulation					Formulation development in 2026

LAI = Long acting injectable

World-Class Leadership Backed by Premier KOLs and Investors



Heather Turner
Chief Executive Officer
Director



Gad Soffer
Chief Business Officer



Anna Eramo, MD
Chief Medical Officer



Richard Silva
SVP Technical Operations



Marc Panoff
SVP Finance



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Christoph Correll, MD	Zucker School of Medicine, Charite – University Medicine, Berlin, Germany

LB-102 is a Derivative of Amisulpride, a Well Regarded and Widely Used AP in Europe

Drug	Effect size (Overall change in symptoms)
Clozaril/Clozapine ¹	0.89
Solian/Amisulpride ¹	0.73
Zyprexa/Olanzapine ¹	0.56
Cobenfy/KarXT ²	0.56
Risperdal/Risperidone ¹	0.55
Invega/Paliperidone ¹	0.49
Abilify/Aripiprazole ¹	0.41
Latuda/Lurasidone ¹	0.36
Vraylar/Cariprazine ¹	0.34
Rexulti/Brexpiprazole ¹	0.26

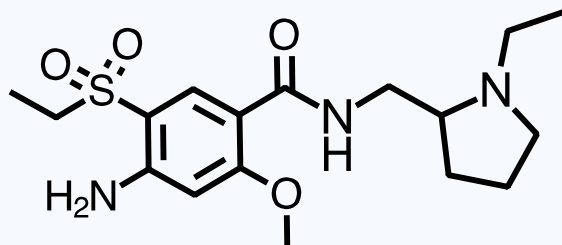
- 2 million+ monthly Rx / yr in EU³
- Approvals in SCZ, negative symptoms of SCZ and dysthymia, a form of depression⁴
- Not approved in U.S. because the requirements of FDA were incompatible with patent coverage
- Extensive use in mood disorders
- Second highest effect size among approved APs
- One of the lowest all-cause discontinuation rates
- Favorable safety and tolerability profile⁵

¹The Lancet. 2019;394(10209):939–949; ²European Neuropsychopharmacology. 2025;92;62-73; ³Proprietary Company data from Austria, Germany, Italy, Romania, Belgium, Greece, Luxembourg, Slovakia, Czech Republic, Hungary, Poland, Spain, France, Ireland, Portugal, Switzerland, Rx / year = prescriptions per year; ⁴Solian label; ⁵Lancet, 2008, 371, 1085-1097

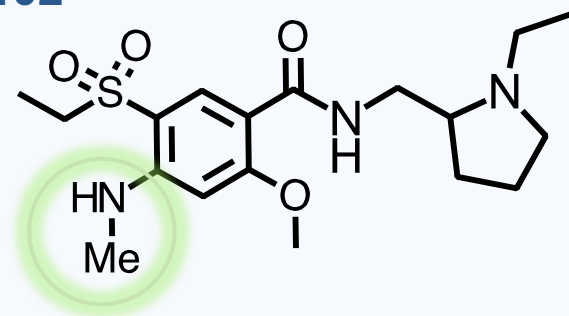
We Developed LB-102 to Address the Limitations of Amisulpride

LB-102 is a Derivative of Amisulpride (Ami); Represents a New Chemical Class for Treatment of Neuropsychiatric Disorders in U.S.

Amisulpride



LB-102

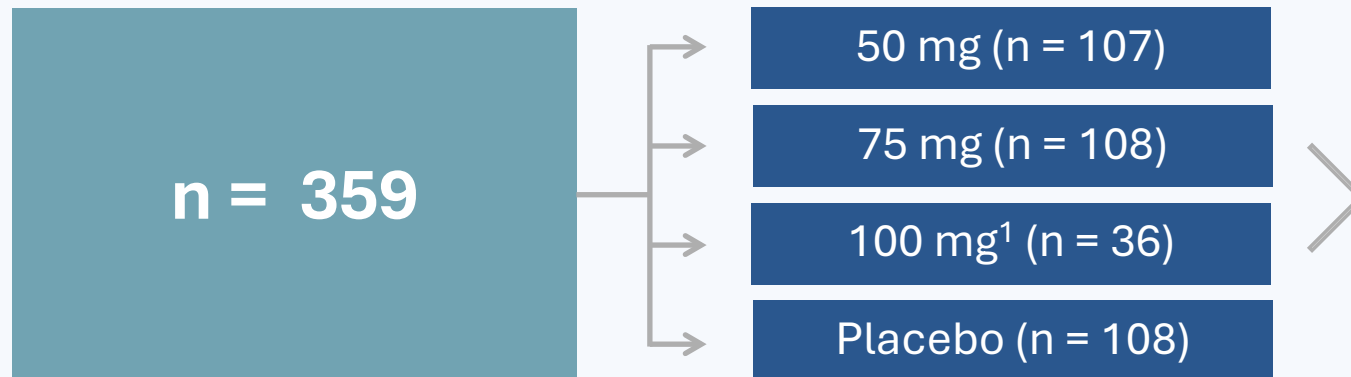


- Phase 1 data suggest that methylation improves blood-brain-barrier permeability and potency
 - 50 mg LB-102 $\approx$ 400 mg amisulpride¹
- Phase 2 data validates improved potency and QD dosing profile with potential for better tolerability
- LB-102 retains binding profile of amisulpride:
 - Strong and selective antagonism of D2, D3, 5-HT7
 - Few off-target effects^{2,3}

Phase 2 SCZ Clinical Trial was Designed to be Registrational

4-week, in-patient, double-blinded, placebo-controlled, oral once daily dose in acute schizophrenia patients

- 359 patients at 25 U.S. clinical trial sites
- 50 mg, 75 mg, 100 mg¹, and placebo (Pbo)
- Designed trial to be potentially pivotal by including a large sample size, robust statistical analyses, and other attributes



Primary endpoint: Change from baseline in Positive and Negative Syndrome Scale (PANSS) at 28 days

Secondary endpoints: CGI-S, PANSS positive and negative subscales, Marder factor

Exploratory endpoints: cognition

Safety and tolerability

¹ Exploratory dose

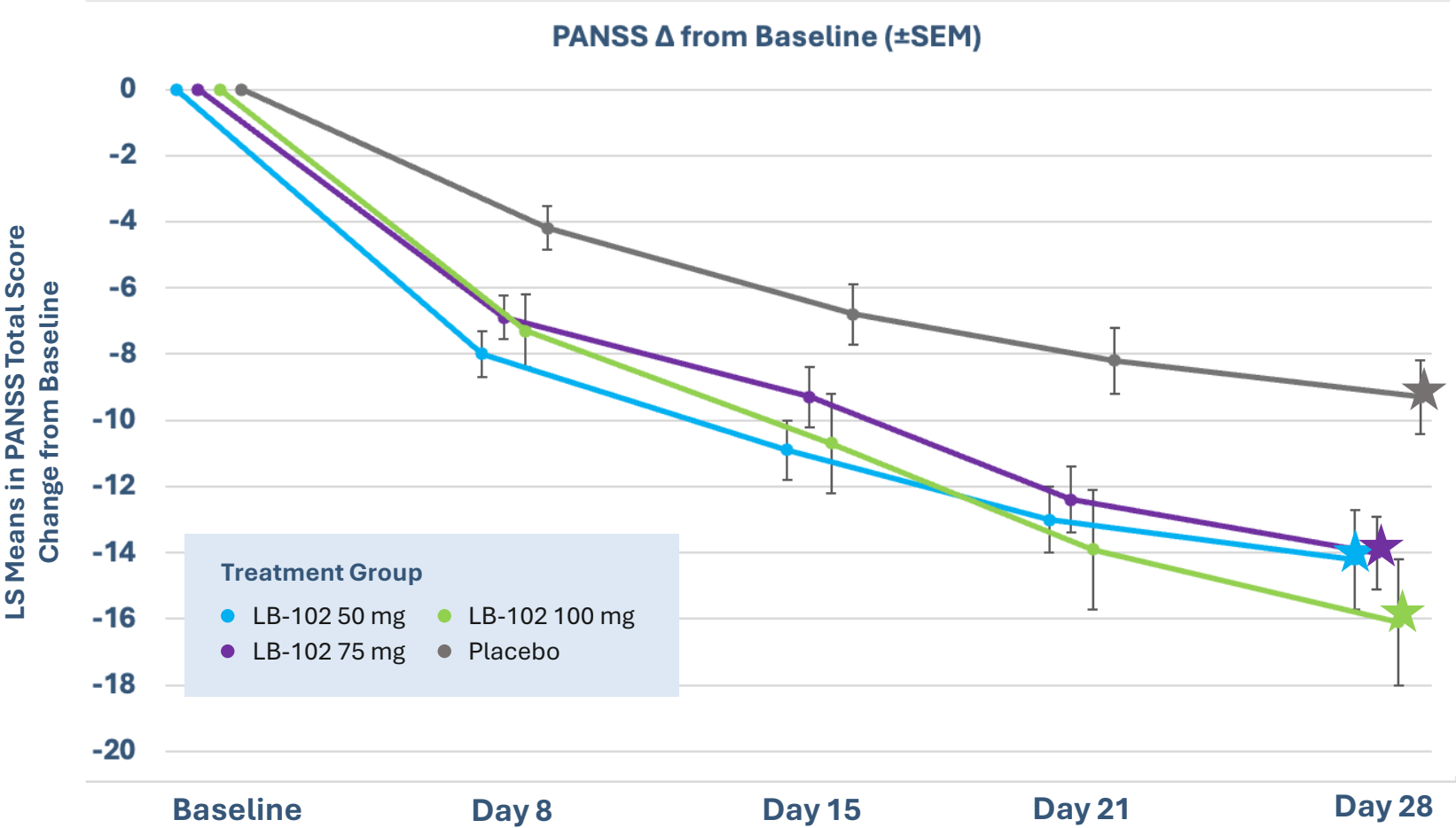
End-of-Phase 2 (EOP2) Feedback from FDA Highlighted the Potential for a Streamlined Path to Approval of LB-102 in SCZ

- FDA noted, in writing, that our Phase 2 SCZ trial appeared to have many of the characteristics of an adequate and well-controlled trial
- Based on this feedback, our Phase 2 trial may serve as one of two trials required to support approval¹

**We believe there is a viable path to approval in SCZ
with a single 6-week Phase 3 trial¹**

¹ Adequacy of our Phase 2 trial to support registration will be a matter of review by the FDA at the time of new drug application (NDA) submission and will depend on the totality of the data included in our submission, including the results of our planned Phase 3 trial. FDA noted preference for a 6-week phase three trial. Registration in SCZ would require the planned Phase 3 trial to meet its primary endpoint as well as compilation of the requisite safety data set and completion of a defined set of clinical and non-clinical NDA-enabling studies. There is no guarantee that our Phase 2 trial may serve as one of the two pivotal trials required for FDA approval, and in such case, we may be required to conduct an additional pivotal trial in acute schizophrenia.

Statistically Superior Clinical Activity to Placebo at All Three Doses



Effect Size vs. Placebo	
Dose	Effect Size
50 mg vs. Pbo	0.61
75 mg vs. Pbo	0.41
100 mg vs. Pbo	0.83

PANSS Δ vs. Placebo	50 mg	75 mg	100 mg	Pbo
	★	★	★	★
	-14.3 (-5.0 vs. Pbo) (p=0.0009)	-14.0 (-4.7 vs. Pbo) (p=0.0022)	-16.1 (-6.8 vs. Pbo) (p=0.0017)	-9.3

LS Mean = least squared mean; SEM = standard error of the mean, PANSS Δ is defined as change in PANSS from baseline to day 28; Effect size is calculated by taking the difference in average observed PANSS change among completers between two groups (an active treatment arm and placebo) and dividing it by a single measure of variability that combines both groups' observed pooled standard deviation. P refers to "p-value," the conventional method for determining the statistical significance of a result, which represents the probability that random chance caused the result (e.g., a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant.

Robust Cognition Data, Unmet Need Spans SCZ and Mood Disorders

Global Composite Effect in Cognition¹
(LB-102 Phase 2 Trial Results)

	Dose	Effect Size vs Pbo	p	n
LB-102 (Phase 2)	50 mg	0.26	0.0476	84
	75 mg	0.41	0.0027	74
	100 mg	0.66	0.0018	20

Global composite effect on cognition represents composite of five tests covering psychomotor function, memory, attention, working memory and executive function

- Dose dependent significant treatment effect size versus Pbo
- High rate of satisfactory completion of cognitive tests
- Broad patient population without enriching for severe cognitive impairment at baseline
- Substantial unmet need spans SCZ, BPD and MDD²

¹ Cognition was evaluated as an exploratory endpoint in our Phase 2 clinical trial utilizing the CogState Computerized Schizophrenia Battery of Tests, a well validated measure of cognitive ability in subjects with schizophrenia. Effect size versus placebo was calculated in a post hoc analysis after excluding certain outliers that did not meet the test performance pass quality control metric; ²Horan et al., 2025 Schizophrenia Bulletin, 51 (2) , 262–273

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Generally Favorable Adverse Event (AE) Profile in Phase 2

AEs Reported in Greater Than or Equal to 5% of Patients¹ ***Number of subjects (% of treatment group)***

Adverse Events	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Insomnia	27 (25.2%)	23 (21.3%)	14 (38.9%)	24 (22.2%)
Headache	12 (11.2%)	9 (8.3%)	2 (5.6%)	10 (9.3%)
Anxiety	10 (9.3%)	9 (8.3%)	4 (11.1%)	9 (8.3%)
Agitation	11 (10.3%)	6 (5.6%)	4 (11.1%)	10 (9.3%)
Weight increase	13 (12.1%)	8 (7.4%)	3 (8.3%)	4 (3.7%)
Hyperprolactinemia	11 (10.2%)	8 (7.5%)	6 (16.6%)	0
Blood creatine phosphokinase increased	4 (3.7%)	1 (0.9%)	2 (5.6%)	3 (2.8%)
Alanine aminotransferase increased	3 (2.8%)	1 (0.9%)	2 (5.6%)	1 (0.9%)
Somnolence	1 (0.9%)	4 (3.7%)	2 (5.6%)	0
Constipation	4 (3.7%)	1 (0.9%)	2 (5.6%)	0

Most AEs were mild or moderate in severity

AEs leading to discontinuation were reported at the following rates: 50 mg (1.9%), 75 mg (2.8%), 100 mg (8.3%), Pbo (1.9%)

Serious Adverse Events (SAE) occurred at the following rates: 50 mg (less than 1%), 75 mg (less than 1%), 100 mg (2.8%), Pbo (1.9%)

¹ Comorbid conditions at study entry influenced the reporting of TEAEs in our trial. Because TEAEs were defined as any adverse event that began on or after the first dose of trial medication, or any pre-existing condition that reappeared during the treatment period and up to 14 days following the last dose, the rates of certain AEs, such as insomnia, appear elevated in both placebo and LB-102 patients.

Weight gain reflects any increase without a threshold. We observed ~1.6 kg placebo adjusted weight gain. There were no concerning metabolic signals

Differentiated and Potentially Class Leading Safety Profile: Low EPS and QTc Prolongation with Negligible Sedation

EPS

<i>Number of subjects (% of treatment group)</i>				
Preferred Term	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Dystonia	0	3 (2.8%)	1 (2.8%)	1 (0.9%)
Akathisia	1 (0.9%)	2 (1.9%)	0	1 (0.9%)
Extrapyramidal disorder	0	1 (0.9%)	1 (2.8%)	2 (1.9%)
Total EPS	1 (1.0%)	6 (5.6%)	2 (5.6%)	4 (3.7%)

Related to prolactin increase

<i>Number of subjects (% of treatment group)</i>				
Preferred Term	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Galactorrhea	2 (1.9%)	1 (0.9%)	0	0
Breast enlargement	0	0	1 (2.8%)	0
Erectile dysfunction	0	0	1 (2.8%)	0
Total related to Prolactin	2 (1.9%)	1 (0.9%)	2 (5.6%)	0

Sedation

<i>Number of subjects (% of treatment group)</i>				
Preferred Term	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Sedation	0	1 (0.9%)	0	0

QTcF Prolongation

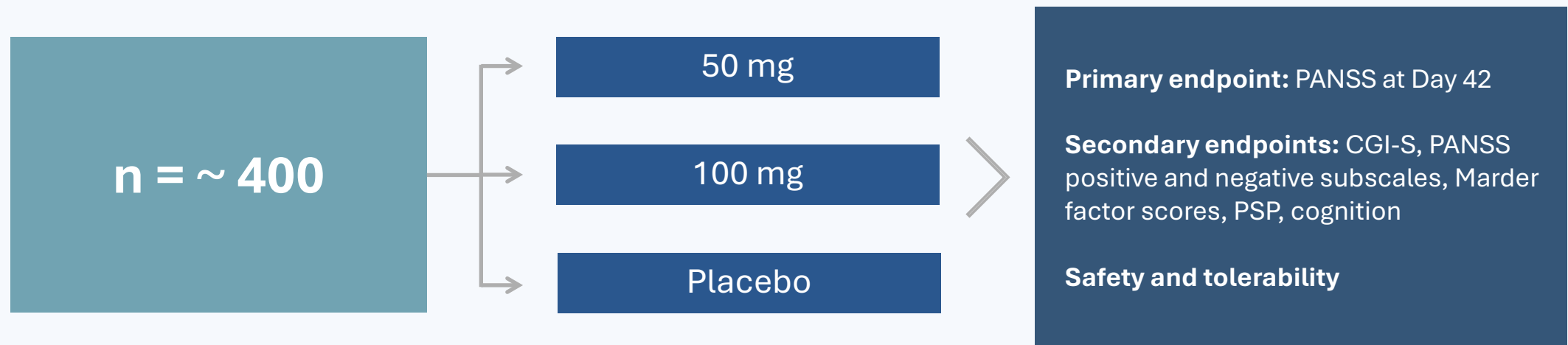
<i>QTcF Δ from Baseline at Day 28 (ms)</i>				
	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Baseline	393.4	394.7	390.0	393.4
Day 28	4.9	4.3	5.4	1.7

Stopping criteria not met at any dose

Planned Phase 3 SCZ Clinical Trial Design Aligned with FDA

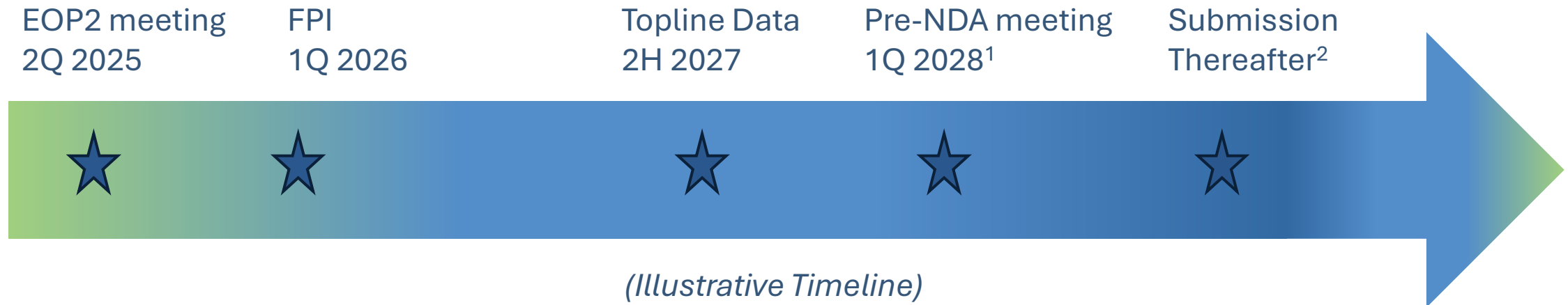
6-week in-patient, double-blinded, placebo-controlled, oral once daily dose in acute schizophrenia

- ~ 400 patients, U.S. only, ~ 25 sites
- Expect to initiate in 1Q 2026 with topline readout anticipated in 2H 2027
- 50 mg, 100 mg, and placebo (randomized: 1:1:1)
- Concurrent open label study to accrue safety population as well as additional cognition and negative symptoms data in stabilized patients (n = ~ 900 patients)



Phase 3 SCZ Trial Initiation Expected in 1Q 2026

- Trial design finalized with FDA input from positive End-of-Phase 2 interaction
- Operationally ready: clinical trial material (CTM) on track, contract research organization (CRO) selected



¹ Subject to positive topline data readout; ² Subject to positive feedback from FDA

LB-102 has Potential to be the Branded AP of Choice in SCZ

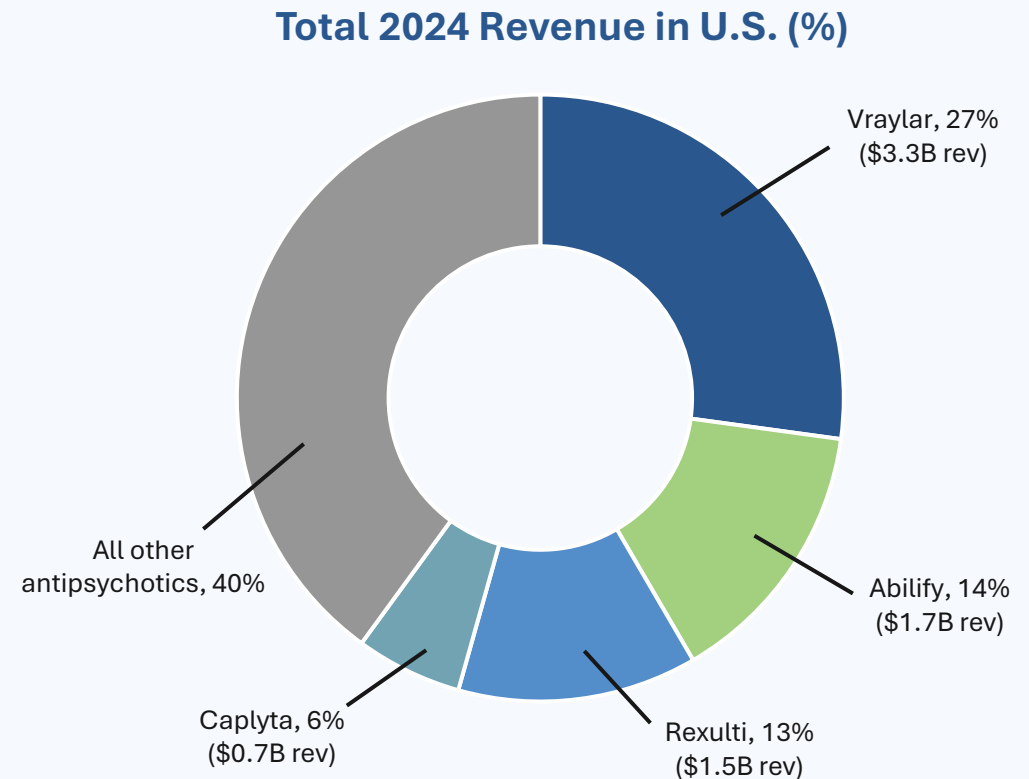
- Compelling evidence of clinical activity in 4-week trial
 - Clinically meaningful PANSS reduction across all three tested dose levels
 - Strong effect size with treatment effect of 0.83 at 100 mg
 - Significant effect on negative symptoms at 50 mg dose
- Potentially class leading safety profile including low EPS, QTc prolongation, negligible sedation
- Robust, significant, dose dependent treatment effect on cognition
- 6-week Phase 3 trial has potential to further improve PANSS reduction
- Additional negative symptoms and cognition data from open label trial available at launch
- New chemical class in the U.S. to expand treatment options
- Potential for first-in-class benzamide LAI and global opportunity

Potential for LB-102 to have competitive efficacy, improved safety, low EPS and sedation, with a positive effect on cognition and negative symptoms

Branded APs Achieve Significant Revenue Driven by Sales in SCZ, BPD and MDD

Indication	# of U.S. Patients
Schizophrenia	~ 3 million
Bipolar Depression	~ 7 million ¹
Major Depressive Disorder	~ 20 million ²

2024 Branded AP Sales in U.S.: ~\$12B Four Branded APs Account for ~60% of Sales



¹ <https://www.nimh.nih.gov/health/statistics/bipolar-disorder>; ² <https://www.nimh.nih.gov/health/statistics/major-depression>; 2024 sales data from EvaluatePharma

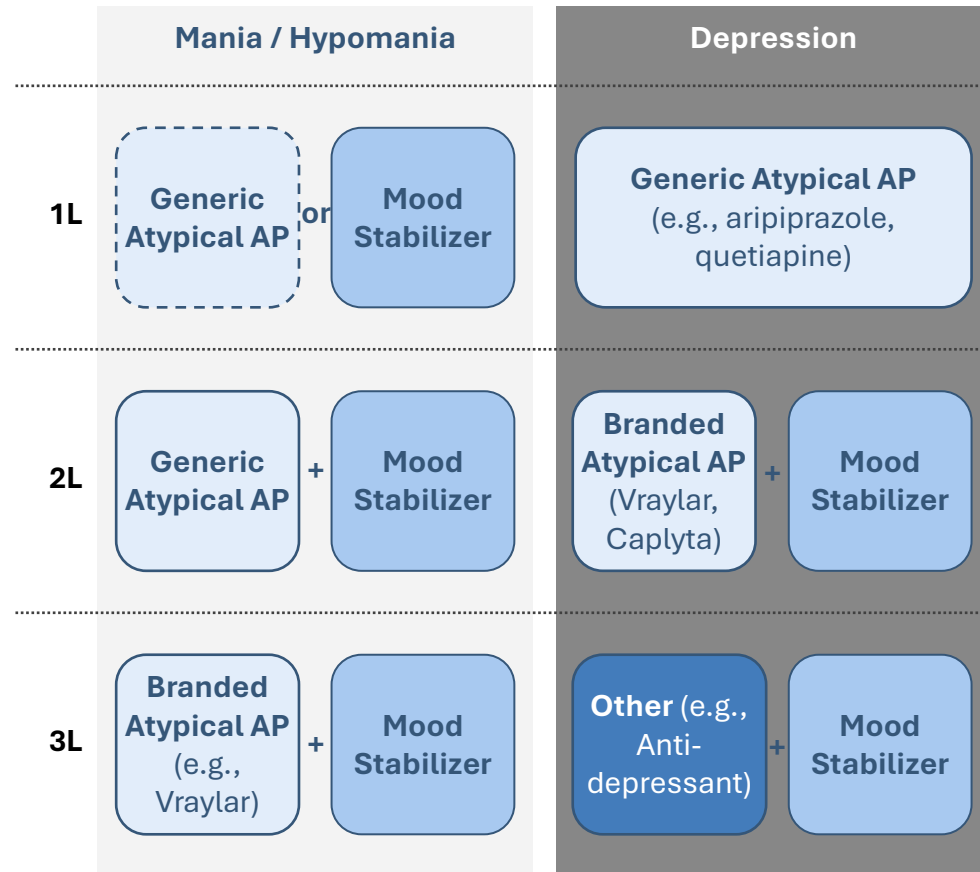
BPD Offers an Attractive Initial Opportunity in Mood Disorders

- Large global revenue opportunity, ~ 40 million patients worldwide¹
- Strong scientific and clinical rationale from SCZ Phase 2 data and Ami experience
- Following SCZ with BPD streamlines cost and timeline
- Few branded agents expected at launch²
- Additional opportunity for LAI
- Success supports expansion into MDD

Differentiated Profile with Potentially Competitive Efficacy, Negligible Sedation or GI Effects and Potential to Improve Cognition

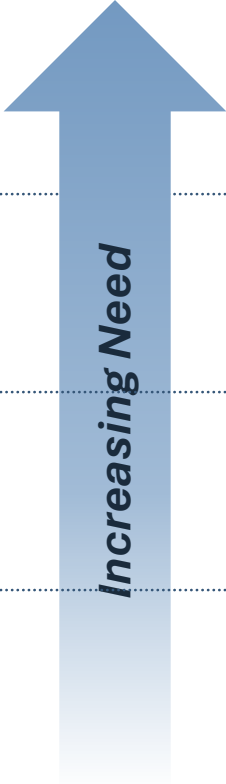
¹ LB-102 <https://www.who.int/news-room/fact-sheets/detail/bipolar-disorder>; ² At that time of potential LB-102 approval in BPD, Caplyta may be the sole branded agent since Vraylar is expected to go off patent in 2029

Atypical Antipsychotics Are a Mainstay of Treatment for BPD



- APs are favored in patients with bipolar depression with or without mood stabilizers
- Nearly all drugs approved as monotherapy in bipolar depression received their initial approval in SCZ
- Key advantage of APs is ability to treat depression without triggering mania
- Antidepressants are effective in treating depression, but are used in later lines given risk of causing mania

Substantial Unmet Need Remains in the Treatment of BPD

Unmet Need		Description
Fewer AEs	 Increasing Need	Especially sedation, EPS, which impact function, and weight gain
Better Efficacy		Cognitive impairment, anhedonia significantly affect functionality Especially important in BPD patients with higher baseline function
Compliance		Poor compliance, often due to AEs, increases risk of relapse
Novel MOA		Drugs with new mechanisms would be welcomed

Switching treatments is common with ~61% of BPD patients having switched at least once due to inadequate clinical response and side effects

MOA = mechanism of action; Qualitative Interviews conducted Sept/Oct 2024. Source: Physician Interviews (N=30), Physician Follow-Up Interviews (N=5), Physician Survey (N=168 Schizophrenia, N=100 Bipolar Depression), ClearView Analysis; LB Pharma bipolar depression Advisory Board

Leading Therapeutics Approved for BPD Highlight Unmet Need

Metric	Caplyta (Branded)	Vraylar (Branded)	Seroquel (Generic)
MADRS	4.6 point Δ vs Pbo	2 - 4 point Δ vs Pbo	4 - 6.5 point Δ vs Pbo
Cognition / Anhedonia	No data	No data	No data
Somnolence / Sedation	13% vs 3% Pbo	6-7% vs 4% Pbo	~57% vs ~15% Pbo
EPS (including akathisia)	~1.3% vs 1.1% Pbo	10-16% vs 4% Pbo	7% vs 2% Pbo
Nausea / Vomiting / Dry mouth	17% vs 4% Pbo	7% vs 3% Pbo	49% vs 17% Pbo
Average Weight gain vs Pbo	-0.3 kg vs Pbo	~0.5-0.8kg vs Pbo	$\geq 7\%$ increase: 8% vs 2% Pbo

Potential for LB-102 to have competitive efficacy, improved safety, low EPS and sedation, and a positive effect on cognition / anhedonia

There is a Strong Scientific and Clinical Rationale for LB-102 in BPD

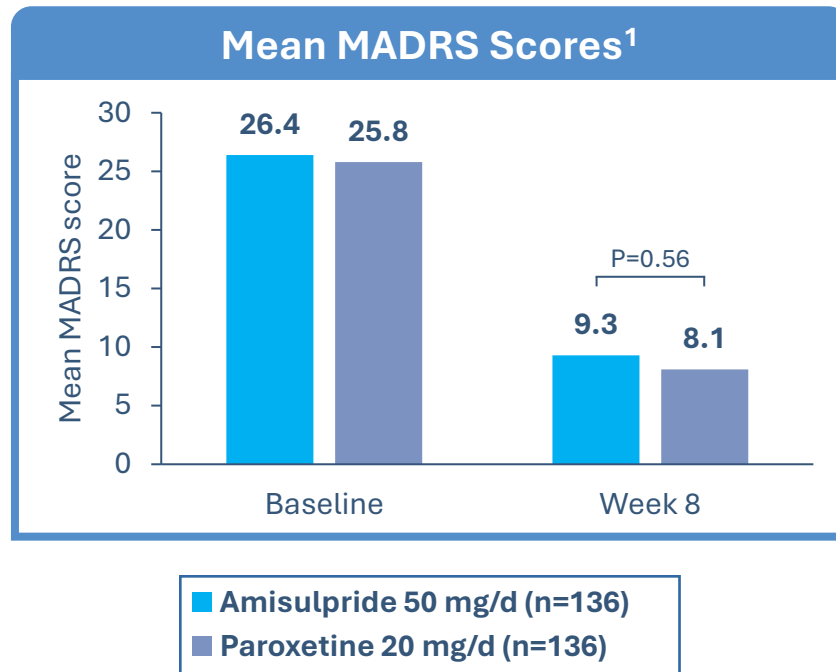
- LB-102's strong antagonism of D2, D3, and 5HT7 makes it well suited for mood disorders
- LB-102 Phase 2 trial in SCZ demonstrated antipsychotic activity and differentiation potential (e.g., tolerability, cognition)
- Ami is approved for dysthymia in Europe and is demonstrated to be as effective as certain approved agents for MDD ^{2,3}
- Efficacy in MDD translates to BPD
- Non-racemic Ami showed antidepressant activity in two third-party, Pbo-controlled BPD trial
- There is wide use of amisulpride in bipolar disorder (approximately 3.4% of Ami Rx / yr in Europe)¹
- Planned LB-102 Phase 2 in BPD will employ a fixed-flexible dose trial design

¹ Proprietary IQVIA Data from Austria, Germany, Italy, Romania, Belgium, Greece, Luxembourg, Slovakia, Czech Republic, Hungary, Poland, Spain, France, Ireland, Portugal, Switzerland; ² Cassano GB, et al. Int Clin Psychopharmacol. 2002;17(1):27-32.;

³ Amore M, et al. Int Clin Psychopharmacol. 2001;16(6):317-324

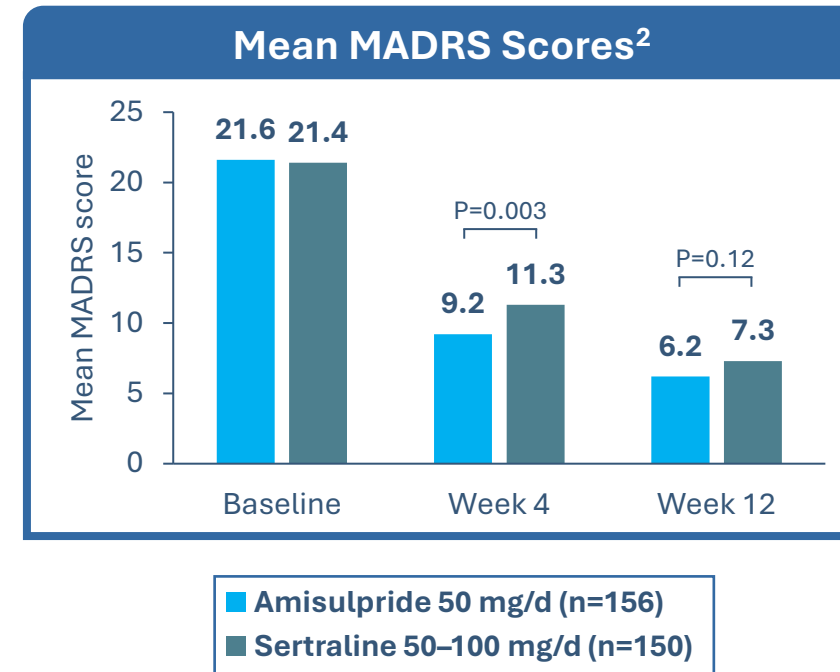
Amisulpride Was Observed to Be Equivalent to or Better Than the Most Effective Antidepressants Approved in Major Depression

Amisulpride vs Paxil
(head-to-head study)



~ 16.5 point reduction in MADRS from Baseline

Amisulpride vs Zoloft
(head-to-head study)

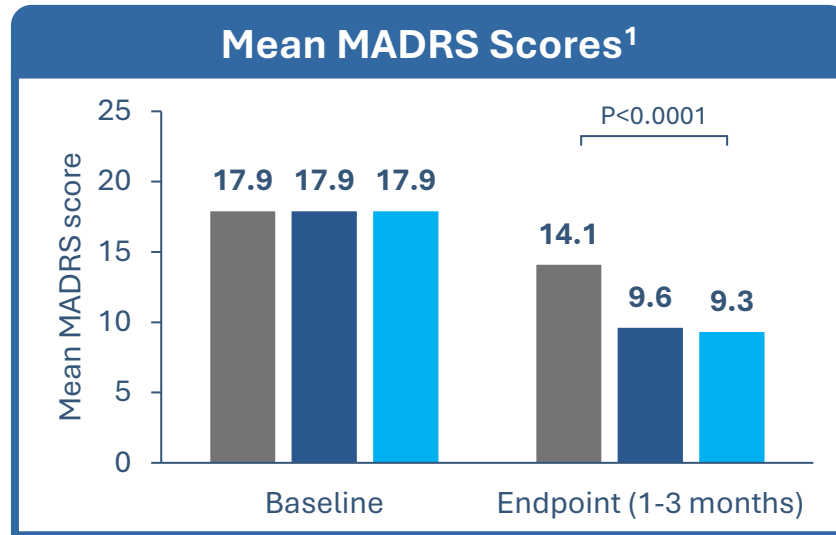


~ 12-15 point reduction in MADRS from Baseline

¹Cassano GB, et al. Int Clin Psychopharmacol. 2002;17(1):27-32.; ²Amore M, et al. Int Clin Psychopharmacol. 2001;16(6):317-324; Zoloft and Paxil approved for MDD; MADRS = Montgomery-Åsberg Depression Rating Scale

Amisulpride has also Demonstrated Statistically Significant Benefit versus Placebo in Depression

Amisulpride vs Placebo



~ 4.8-point MADRS Δ versus Pbo

Consistent with magnitude of benefit of approved agents

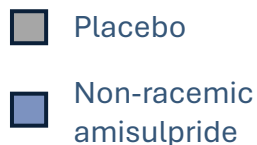
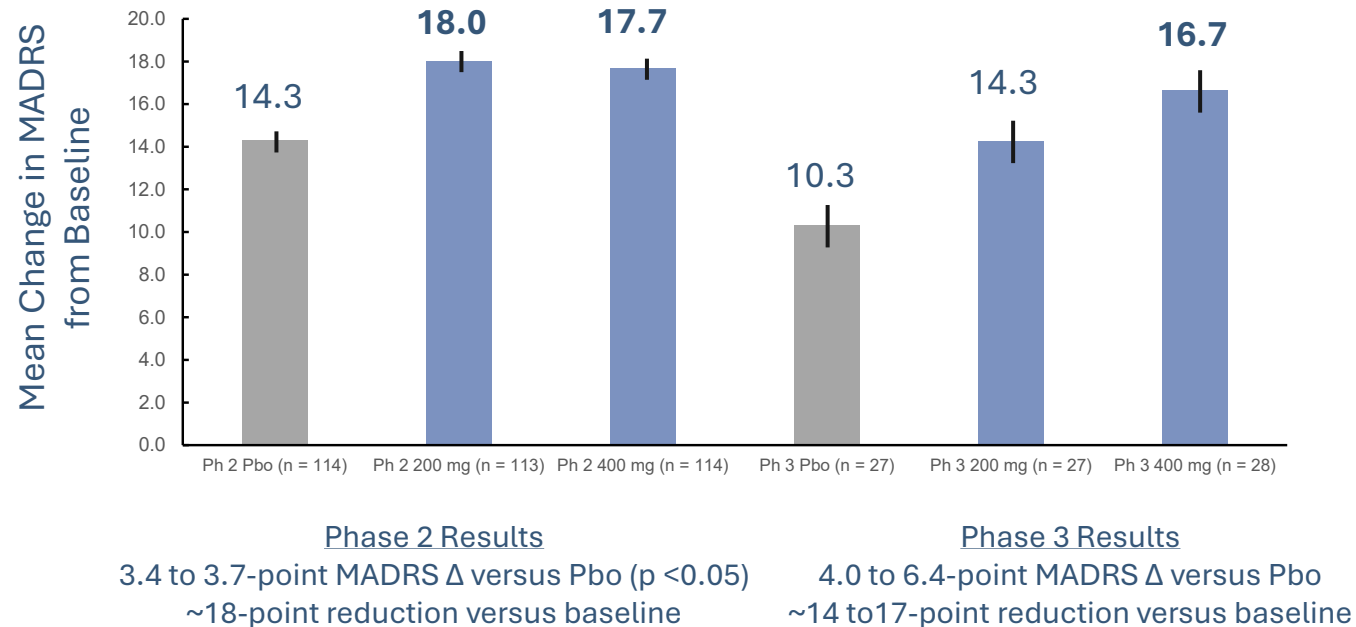
- Placebo (n=105)
- Amineptine 200 mg/d (n=101)
- Amisulpride 50 mg/d (n=107)

- MDD and BPD characterized by a similar imbalance in neurotransmitters regardless of underlying pathology²
- Among the four APs approved for SCZ / MDD or TRD and studied in BPD, 75% succeeded in treatment of BPD

¹Boyer P, et al. Neuropsychobiology. 1999;39(1):25-32. Amineptine is a tricyclic antidepressant; ² Clin Psychol Rev. 2005 May;25(3):307-39

Clinical Experience of SEP-4199, a Non-Racemic Form of Amisulpride, Further Supports Potential of LB-102 in BPD

SEP-4199 Phase 2¹ and Phase 3 Trial² Results in BPD
MADRS Δ from Baseline at 6 weeks



MADRS Δ of approved agents (~2 to 6.5)

Comments

- Two trials of SEP-4199 support its antidepressant effect in BPD patients
- Approximately 17-point reduction in MADRS from baseline in two trials
- Phase 2 - Statistically significant results in all patients (U.S. +EU +JP), n = 341
- Phase 3 - MADRS Δ of ~6 prior to stopping for business reasons unrelated to data
- Average Pbo rate in recent BPD trials ~12.2-point reduction from baseline

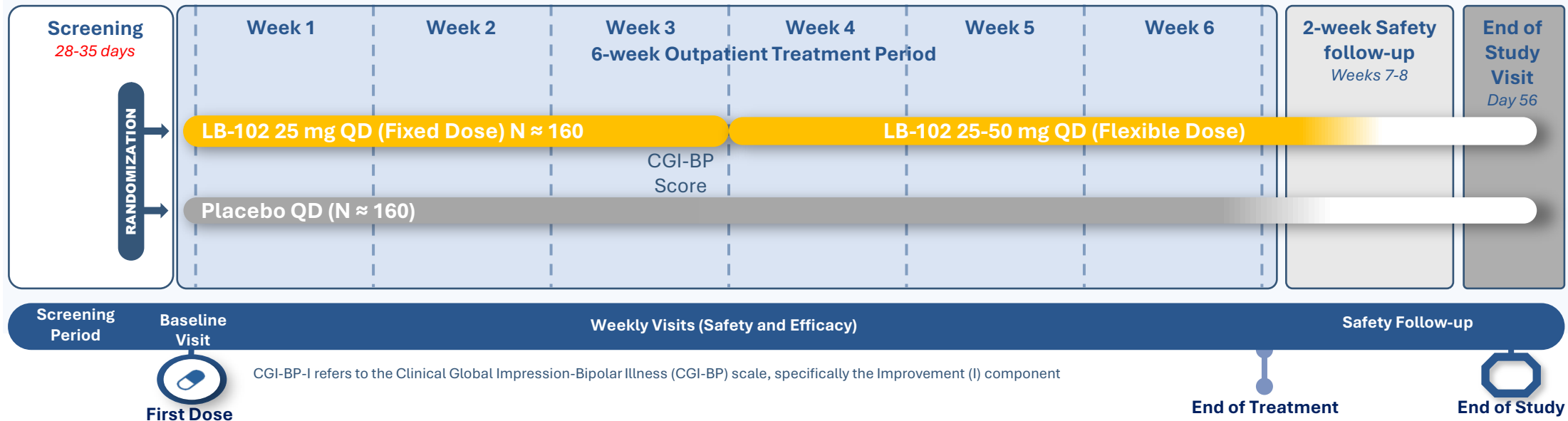
¹Journal of Affective Disorders. 2022;296(10209):549-558; Phase 2 results depicted are from secondary endpoint of US+EU+JP cohorts; Primary analysis was U.S.+EU cohorts only. Note that this trial did not meet its primary endpoint.

²<https://clinicaltrials.gov/study/NCT05169710?intr=SEP-4199&rank=2&tab=results>;

Registrational Quality Phase 2 Trial Designed to Achieve Differentiation

Outpatient, double-blinded, placebo-controlled, oral, once daily fixed-flexible dose in bipolar depression, with 6-week treatment duration

- ~ 320 patients, 30 sites, U.S. only, two arms
- 25 mg fixed dose (first 3 weeks), flexible dose 25-50 mg (Weeks 4-6), randomized 1:1
- Primary endpoint: MADRS-10, all LB-102 treated patients vs Placebo
- Secondary endpoints: MADRS-6, CGI-BP, Cognition, Anhedonia, Safety, and tolerability
- Flexible dose trials typically have better signal detection than fixed dose trials¹



CGI-BP-I refers to the Clinical Global Impression-Bipolar Illness (CGI-BP) scale, specifically the Improvement (I) component

¹Kahn et al, Neuropsychopharmacology 2003 Mar;28(3):552-7

Targeting Phase 2 Initiation in 1Q 2026 with Topline Data Anticipated in 1Q 2028

- Trial design finalized with KOL input
- Investigational new drug (IND) submission expected in 4Q 2025
- Operationally ready: CTM on track, CRO selected
- Principal investigator selected: Dr. Maurizio Fava



¹ Subject to positive topline data readout

Investment Highlights

Advancing a Phase 3 ready asset in schizophrenia (SCZ) with differentiated clinical profile

Phase 2 SCZ trial demonstrated statistically significant benefit versus placebo at all doses studied

Positive FDA feedback offering potential for SCZ approval with one successful Phase 3 trial

Strong scientific and clinical rationale for planned Phase 2 clinical trial in bipolar depression (BPD)

Future indication expansion opportunities including major depression (MDD)

Composition of matter IP with protection expected to 2041¹

Multibillion-dollar sales potential for LB-102 as treatment for SCZ, BPD and MDD²

¹ Includes estimated Hatch-Waxman extension, composition of matter IP expires 2037; LB-102 patent portfolio includes: 7 U.S. issued, 11 foreign issued, 7 U.S. pending, and 19 foreign pending patents; ² Proprietary company data

LB Pharmaceuticals Inc

Thank you!

