



REVIVA PHARMACEUTICALS HOLDINGS, INC. (NASDAQ: RVPH)

Corporate Presentation, November 2023



Forward-Looking Statements

This presentation contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's 1-year Phase 3 open-label extension (OLE) trial evaluating the long-term safety and tolerability of brilaroxazine, the Company's registrational Phase 3 RECOVER-2 trial, the Company's expectations regarding the anticipated clinical profile of its product candidates, including statements regarding anticipated efficacy or safety profile, and those relating to the Company's expectations, intentions or beliefs regarding matters including product development and clinical trial plans, clinical and regulatory timelines, planned or intended additional trials and the timing thereof, planned or intended regulatory submissions and the timing thereof, trial results, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential growth, financing, partnership, expansion and other opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or the Company's financial performance and involve known and unknown risks, uncertainties, and other factors, including the potential impact of the COVID-19 pandemic and the potential impact of sustained social distancing efforts, on the Company's operations, clinical development and clinical trial plans and timelines, which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and the Company's other filings from time to time with the Securities and Exchange Commission (the "SEC"). Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

The Company's SEC filings are available on the SEC's website at www.sec.gov. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which apply only as of the date of this presentation and should not be relied upon as representing the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements, other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

This presentation also contains estimates and other statistical data made by independent parties and by the Company relating to market size and growth and other data about the Company's industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

Key Business Highlights

Company Overview



Late-stage pharmaceutical company developing new therapies for central nervous system, inflammatory, and cardiometabolic diseases

Chemical genomics driven discovery approach

Strong patent portfolio

Lead Asset: Brilaroxazine



Differentiated pharmacology profile as modulator of serotonin and dopamine signaling pathways

Completed pivotal Phase 3 trial in schizophrenia, and topline OLE data anticipated in Q4 2024

Potential for clinical expansion in additional neuropsychiatric and inflammatory diseases

Market Opportunity



Global addressable market size for brilaroxazine:

\$12.6 B for schizophrenia by 2032¹
\$6.4 B for bipolar disorder by 2030²
\$16.8 B for MDD by 2032³
\$32.1 B for ADHD by 2032⁴
\$57.7 B for Psoriasis by 2032⁵
\$10.9 B for PAH by 2030⁶
\$7.5 B for IPF by 2030⁷

(1) Schizophrenia Market by Market.us May 2023. (2) Bipolar Disorder Market by Skyquest Report October 2022. (3) Major Depressive Disorder Market by Future Market Insights May 2022. (4) ADHD market by Polaris Market Research Jan 2023. (5) Psoriasis Market by Precedence Research August 2023. (6) Pulmonary Arterial Hypertension (PAH) by Markets N Research March 2023. (7) Idiopathic Pulmonary Fibrosis (IPF) by Research and Markets June 2023

Extensive Clinical Development Pipeline

Program	Prioritized Target Indications*	Development Phase				
		Discovery	Preclinical	Phase I	Phase II	Phase III
Brilaroxazine – Serotonin/ dopamine modulator (NCE)	Neuropsychiatric					
	Inflammatory					
RP1208 – Triple reuptake inhibitor (NCE)						

Dysfunctional Serotonin or Dopamine Signaling is Implicated in the Pathobiology of Psychiatric Disorders and Inflammatory Diseases

Neuropsychiatric diseases are associated with dysfunctional serotonin and dopamine signaling and dysregulated immune responses

Serotonin signaling is implicated in inflammatory diseases including PAH, IPF and psoriasis

Neuropsychiatric Disorders

Positive Symptoms	D ₂	D ₃	D ₄				
Negative Symptoms	D ₄	5-HT _{1A}	5-HT _{2A}	5-HT ₇			
Cognitive Symptoms	D ₄	5-HT _{1A}	5-HT _{2A}	5-HT ₇			
Depressive Symptoms		5-HT _{1A}	D ₂	5-HT _{2A}	5-HT _{2B}	D ₄	5-HT ₇
ADHD Symptoms	D ₄	5-HT _{1A}	5-HT _{2B}	5-HT ₇			

Pulmonary Diseases (PAH and IPF)

Vasoconstriction	5-HT _{2A}	5-HT _{2B}	
Fibrosis and Inflammation	5-HT _{2A}	5-HT _{2B}	5-HT ₇
Thrombosis	5-HT _{2A}		






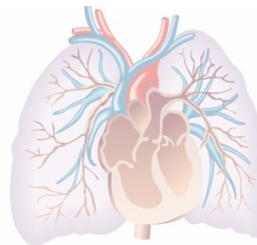
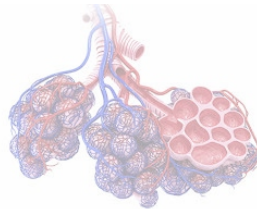
Psoriasis

Immune Dysfunction	D ₂	D ₄	
Inflammation and Fibrosis	5-HT _{2A}	5-HT _{2B}	5-HT ₇



Potential Market Opportunity for Brilaroxazine

Addressing Significant Unmet Medical Needs: Psychiatric Conditions and Immune System Abnormalities

Neuropsychiatric Indications				Inflammatory Indications		
Schizophrenia	Bipolar Disorder	Major Depressive Disorder	ADHD	Psoriasis	Pulmonary Arterial Hypertension (PAH)	Idiopathic Pulmonary Fibrosis (IPF)
						
\$12.6B <i>by 2032¹</i>	\$6.4B <i>by 2030³</i>	\$16.8B <i>by 2032³</i>	\$32.1B <i>by 2032⁴</i>	\$57.7B <i>by 2032⁵</i>	\$10.9B <i>by 2030⁶</i>	\$7.5B <i>by 2030⁷</i>

(1) Schizophrenia Market by Market.us May 2023. (2) Bipolar Disorder Market by Skyquest Report October 2022. (3) Major Depressive Disorder Market by Future Market Insights May 2022. (4) ADHD market by Polaris Market Research Jan 2023. (5) Psoriasis Market by Precedence Research August 2023. (6) Pulmonary Arterial Hypertension (PAH) by Markets N Research March 2023. (7) Idiopathic Pulmonary Fibrosis (IPF) by Research and Markets June2023



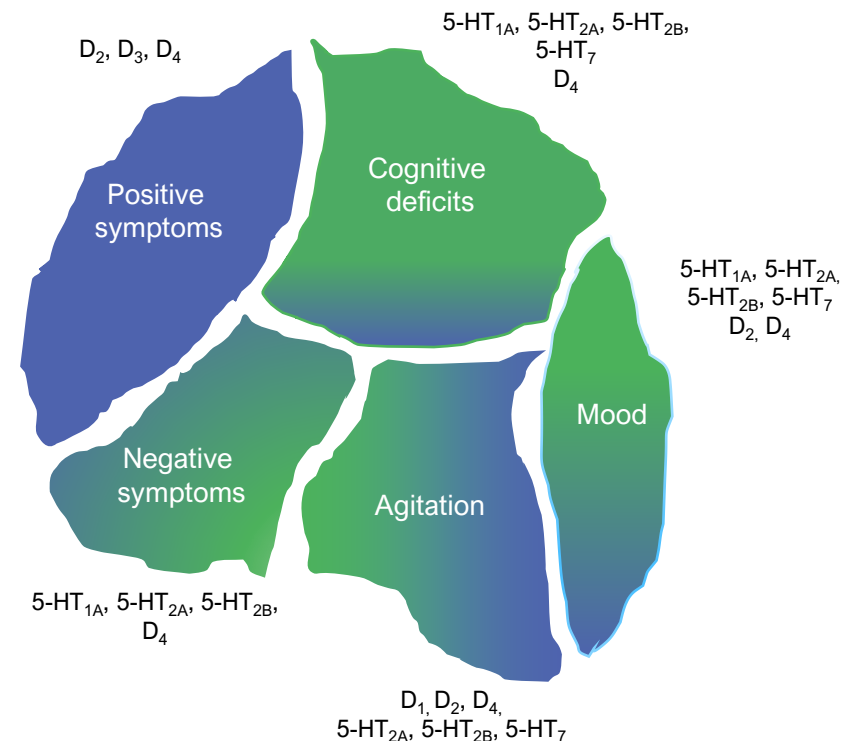
Neuropsychiatric Programs

Schizophrenia | Bipolar Disorder |
Major Depressive Disorder | ADHD

Schizophrenia: Common Psychiatric Condition With Multiple Symptom Domains

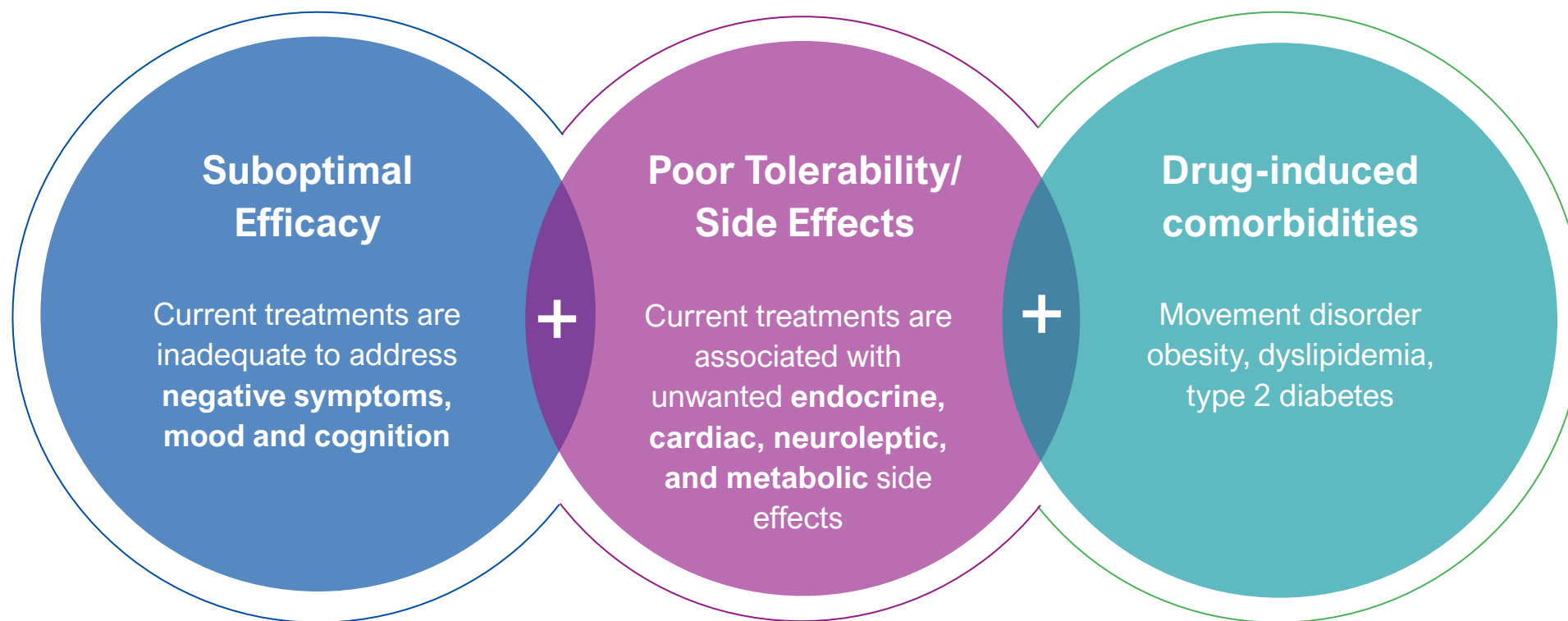
Primarily driven by dysfunctional serotonin and dopamine signaling

- Affects ~1.1% of the world's population
 - ~3.5 million people in the US
 - ~24 million globally
- Leading cause of disability worldwide, with onset in late-teens and early-adulthood
- Requires lifelong treatment
- Up to 30% of patients are treatment refractory
- Neuroinflammation is implicated as a major contributing factor to schizophrenia



No Current Therapies Address All Needs Of Patients With Schizophrenia

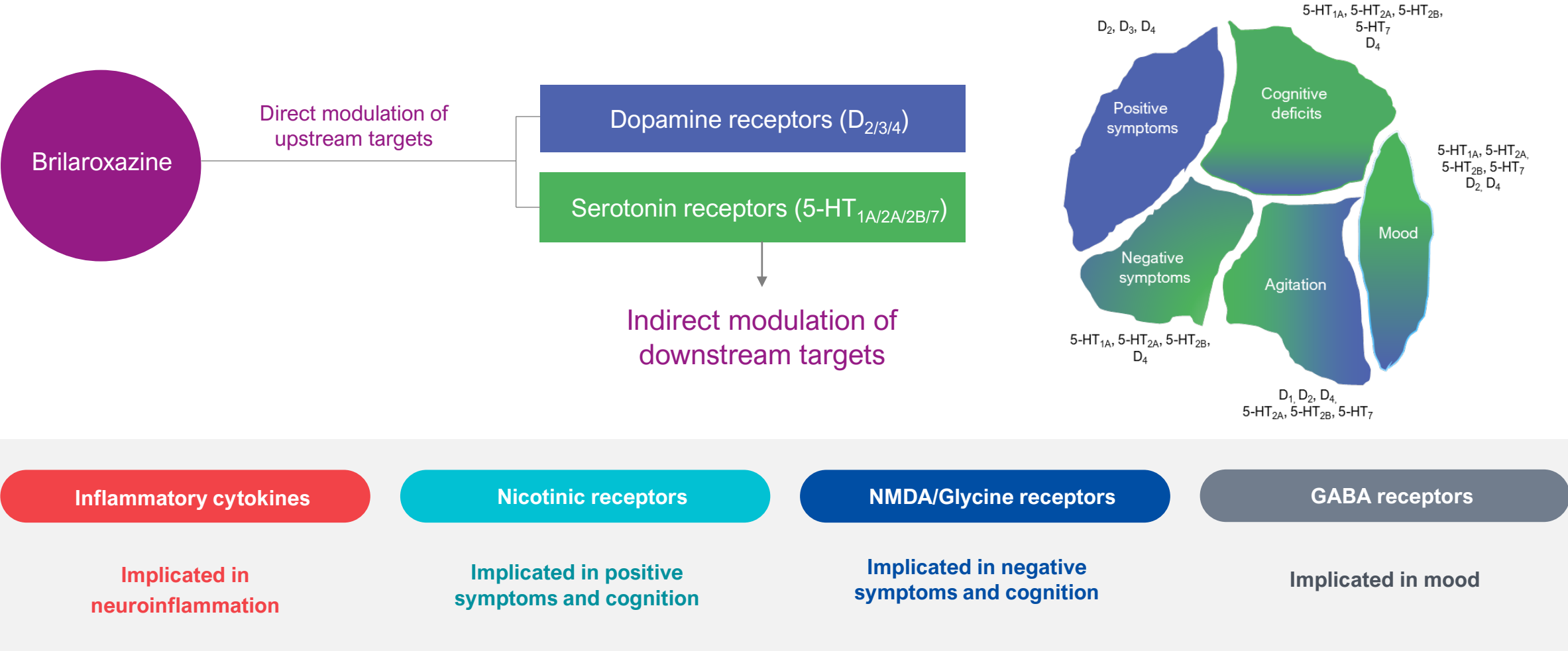
Suboptimal efficacy and side effects of current treatments continue to limit long-term use for this chronic condition



Leading to high discontinuation rates and non-compliance

Brilaroxazine: Novel Serotonin Dopamine Signaling Modulator

Activities on critical pathways implicated in schizophrenia

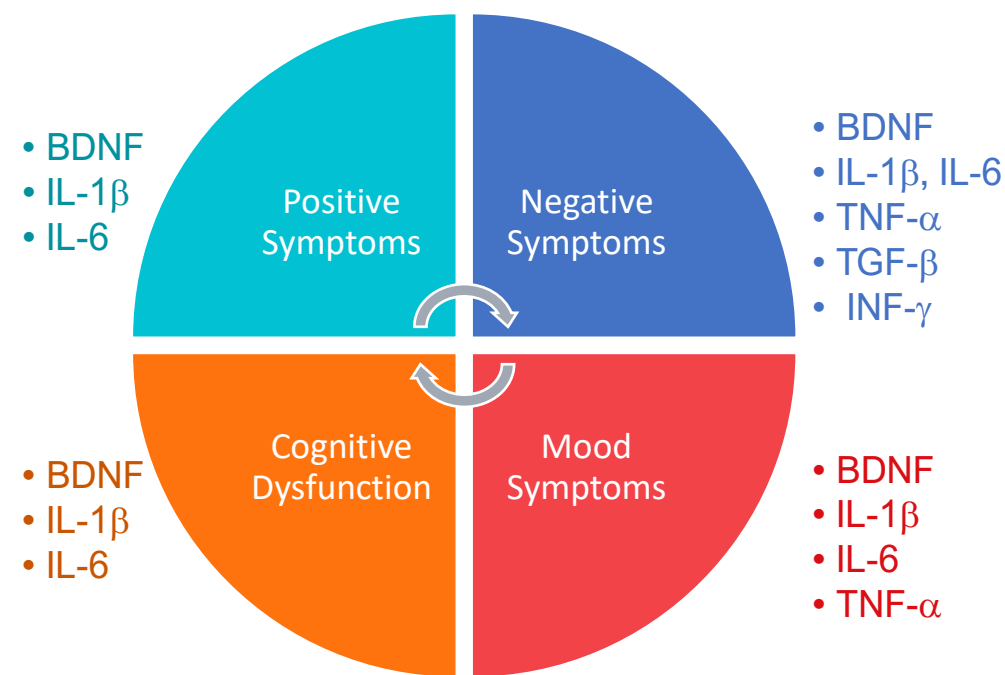


Brilaroxazine Has a Differentiated Target Receptor Activity Profile

Brilaroxazine Receptor Binding Affinities for Schizophrenia Symptoms ¹		
High (K _i , nM)*	Dopamine D ₂	0.4
	Dopamine D ₃	3.7
	Dopamine D ₄	6
	Serotonin 5-HT _{1A}	1.5
	Serotonin 5-HT _{2A}	2.5
	Serotonin 5-HT _{2B}	0.19
	Serotonin 5-HT ₇	2.7
Moderate (K _i , nM)	Nicotine α ₄ β ₂	36.3
	Serotonin 5-HT ₆	51
Weak or no significant activity	No significant activities at therapeutic dose for off-targets 5-HT _{2C} , α _{1,2} , and M ₁₋₄ implicated in cardiometabolic, metabolic, and GI side effects	

*partial agonists for D_{2,3,4} and 5-HT_{1A} receptors

Brilaroxazine reduced proinflammatory cytokines and chemokines implicated in major symptom domains of schizophrenia in animal models^{1,2}



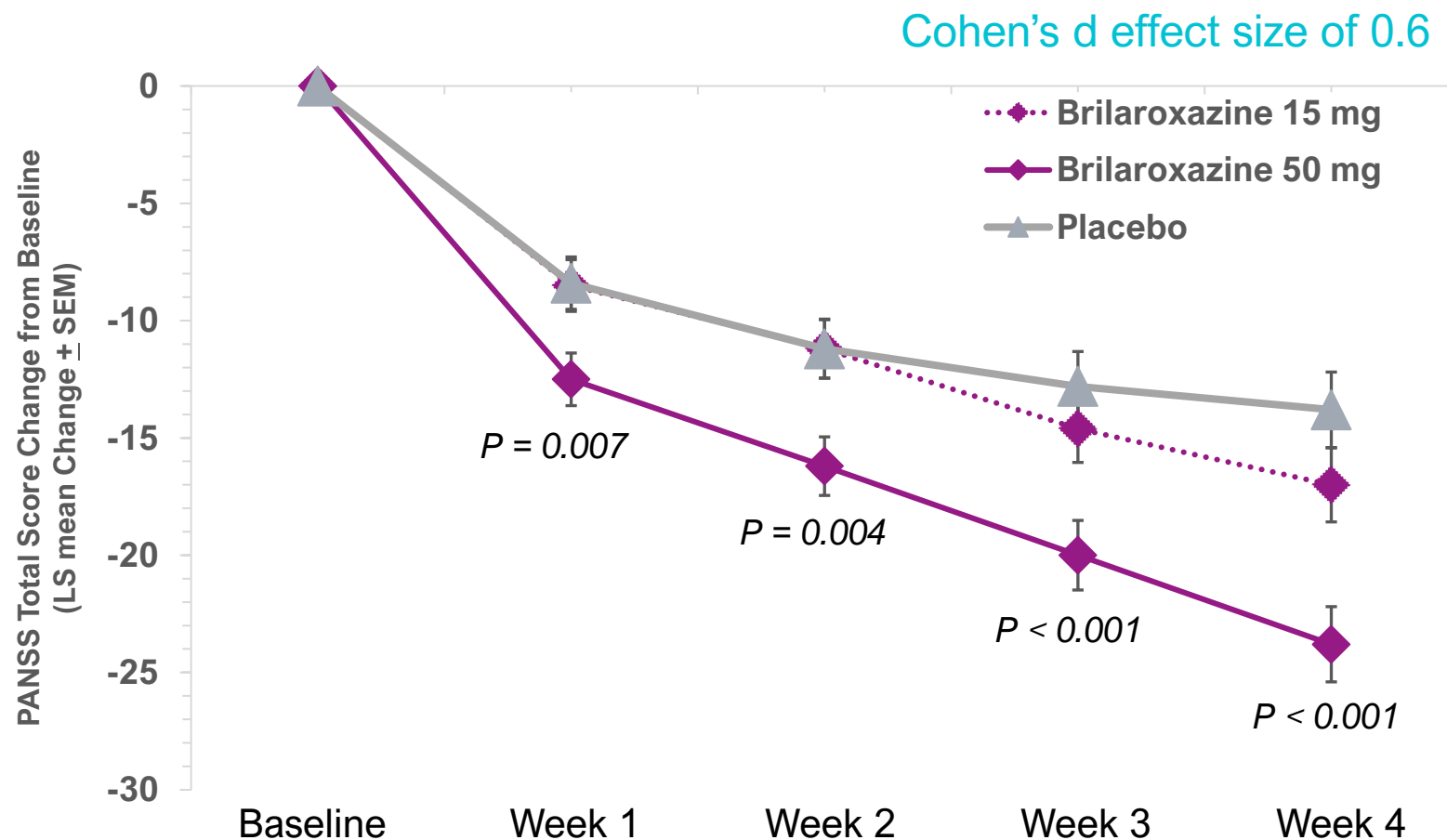
Primary Endpoint: PANSS Total Score At Week 4 For Brilaroxazine Vs. Placebo

10.1-point reduction in PANSS total score vs. placebo at week 4, $p < 0.001$ (-23.9 brilaroxazine 50 mg vs. -13.8 placebo)

RECOVER Phase 3 Trial

PANSS Total Score

- Successfully met PANSS Total Score primary endpoint for brilaroxazine 50 mg
- Statistically significant and clinically meaningful sustained decrease with brilaroxazine 50 mg
- Separation for brilaroxazine 50 mg from placebo within a week
- Brilaroxazine 15 mg numerically separated from placebo



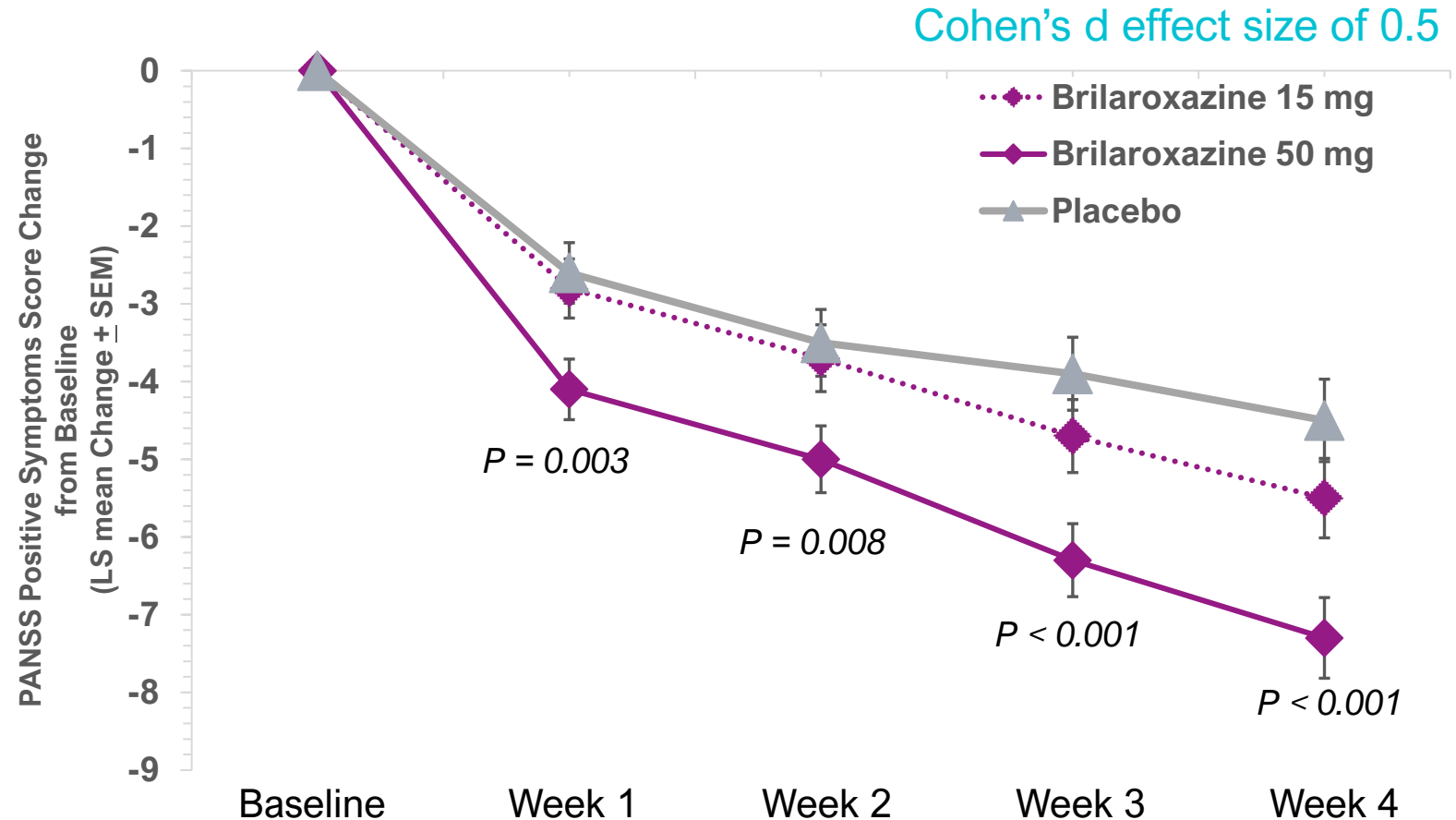
Secondary Endpoint: Positive Symptoms At Week 4 For Brilaroxazine Vs. Placebo

2.8-point reduction in positive symptoms vs. placebo at week 4, $p < 0.001$ (-7.3 brilaroxazine 50 mg vs. -4.5 placebo)

RECOVER Phase 3 Trial

Positive Symptoms

- Successfully met the secondary endpoint positive symptoms
- Statistically significant and clinically meaningful sustained decrease with brilaroxazine 50 mg
- Separation for brilaroxazine 50 mg from placebo within a week
- Brilaroxazine 15 mg numerically separated from placebo



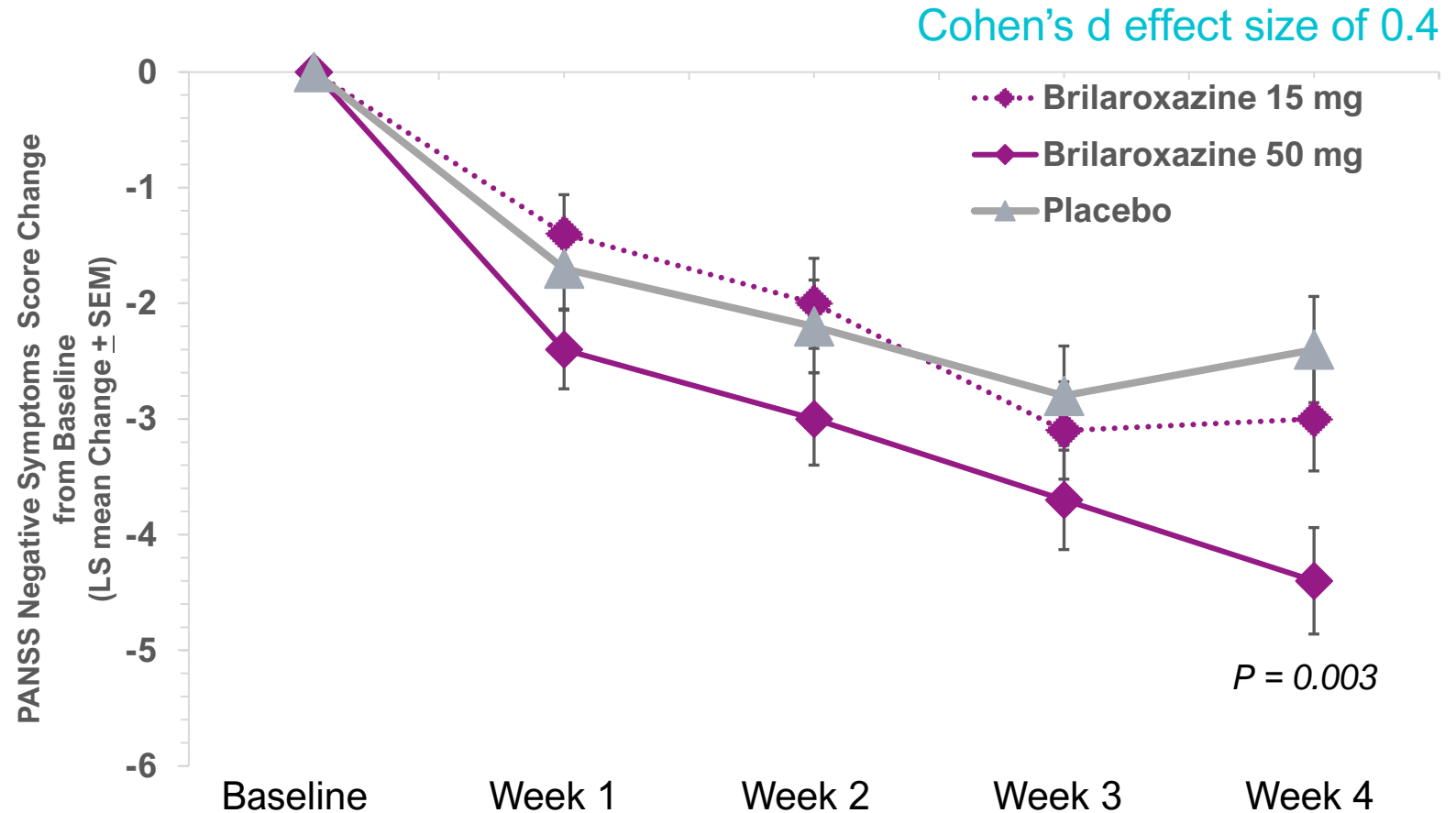
Secondary Endpoint: Negative Symptoms At Week 4 For Brilaroxazine Vs. Placebo

2-point reduction in negative symptoms vs. placebo at week 4, $p = 0.003$ (-4.4 brilaroxazine 50 mg vs. -2.4 placebo)

RECOVER Phase 3 Trial

Negative Symptoms

- Successfully met the secondary endpoint negative symptoms
- Statistically significant and clinically meaningful decrease with brilaroxazine 50 mg
- Separation for brilaroxazine 50 mg from placebo within a week
- Brilaroxazine 15 mg numerically separated from placebo



Secondary Endpoint: Negative Symptoms PANSS Marder Factor At Week 4

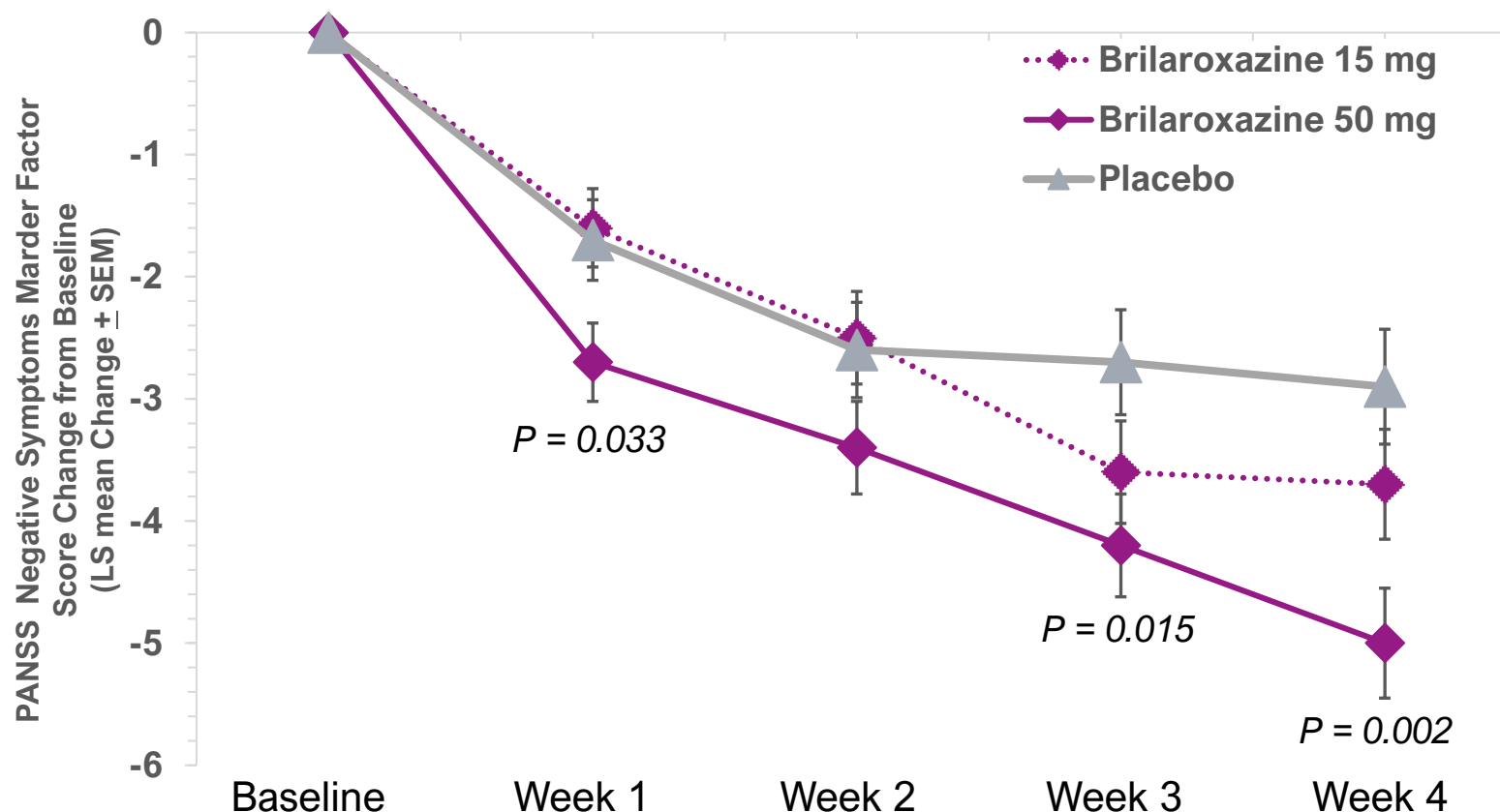
2.1-Point reduction in negative symptoms on Marder factor in brilaroxazine 50 mg vs. placebo at week 4, $p = 0.002$

RECOVER Phase 3 Trial

Negative Symptoms Marder Factor

- Successfully met the secondary endpoint negative symptoms PANSS Marder factor
- Statistically significant and clinically meaningful decrease with brilaroxazine 50 mg
- Separation for brilaroxazine 50 mg from placebo within a week
- Brilaroxazine 15 mg numerically separated from placebo

Cohen's d effect size of 0.4



Secondary Endpoint: PANSS Social Cognition Factors At Week 4

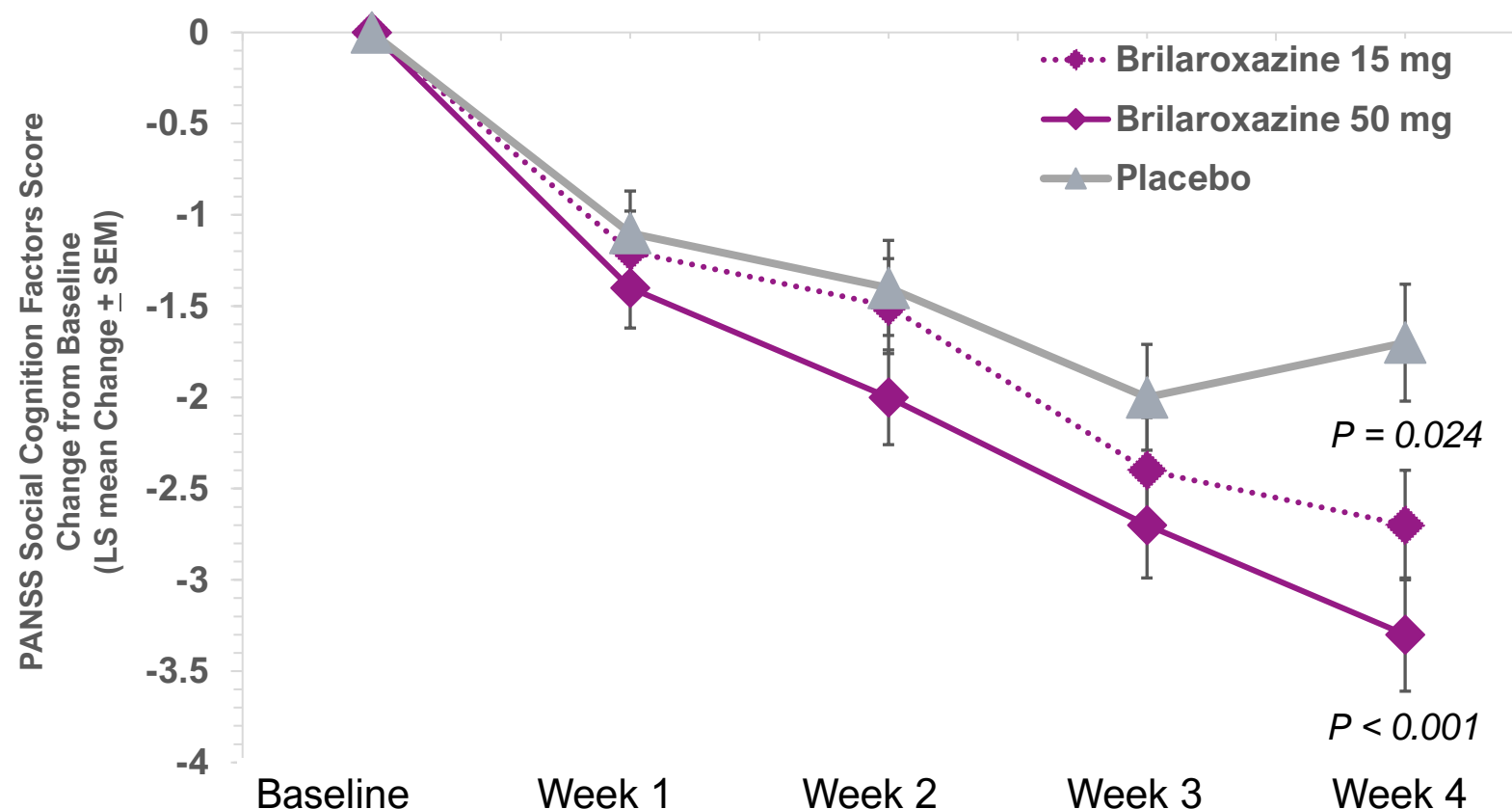
1.6-point reduction in social cognition deficits in brilaroxazine 50 mg vs. placebo at week 4, $p < 0.001$

RECOVER Phase 3 Trial

Social Cognition Deficits

- Successfully met the secondary endpoint social cognition symptoms
- Statistically significant and clinically meaningful decrease with both brilaroxazine 15 mg and 50 mg at week 4
- Separation for brilaroxazine 50 mg from placebo within a week

Cohen's d effect size of 0.5



Secondary Endpoint: PANSS Excitement/Agitation At Week 4

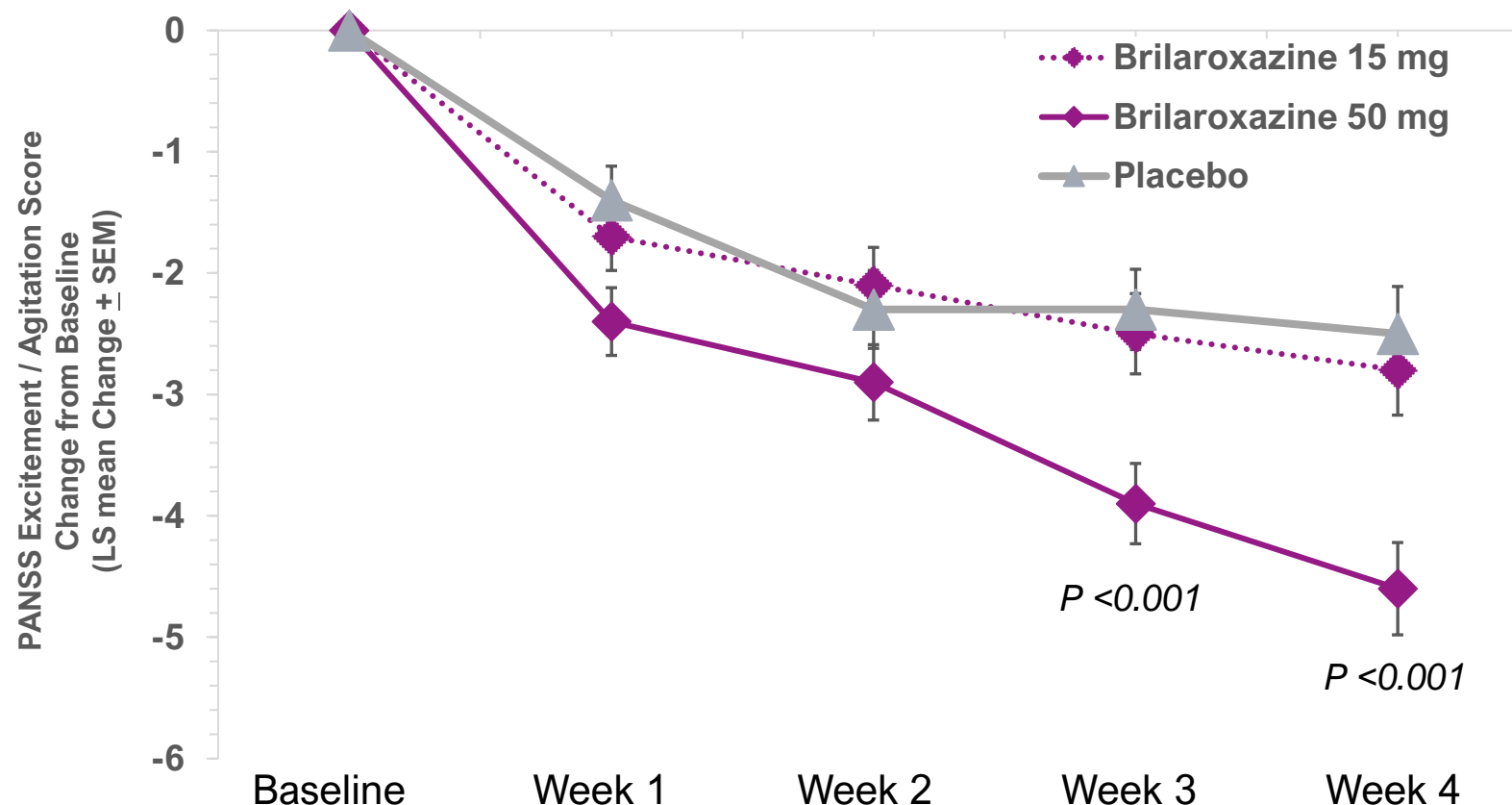
2.1-point reduction in excitement/agitation symptoms in brilaroxazine 50 mg vs. placebo at week 4, $p < 0.001$

RECOVER Phase 3 Trial

Excitement / Agitation Symptoms

- Successfully met the secondary endpoint excitement/agitation symptom
- Statistically significant and clinically meaningful sustained decrease with brilaroxazine 50 mg

Cohen's d effect size of 0.5



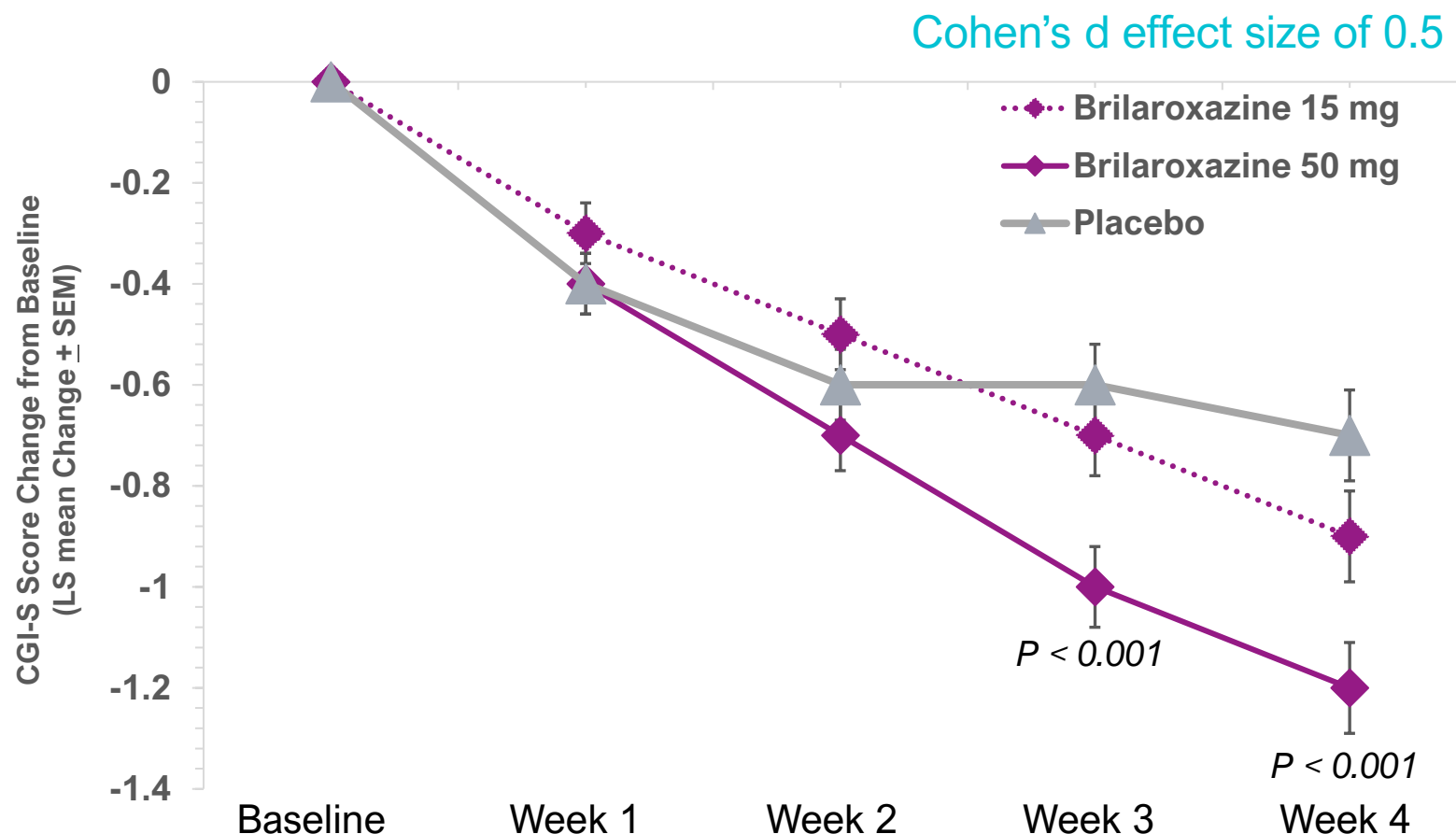
Secondary Endpoint: CGI-S At Week 4 For Brilaroxazine Vs. Placebo

≥1-point reduction in CGI-S score in brilaroxazine 50 mg vs. placebo at week 4, $p < 0.001$

RECOVER Phase 3 Trial

CGI-S Score ≥ 1-Point Reduction

- Successfully met the secondary endpoint CGI-Severity score
- Statistically significant and clinically meaningful sustained decrease with brilaroxazine 50 mg
- Brilaroxazine 15 mg numerically separated from placebo at weeks 3 and 4



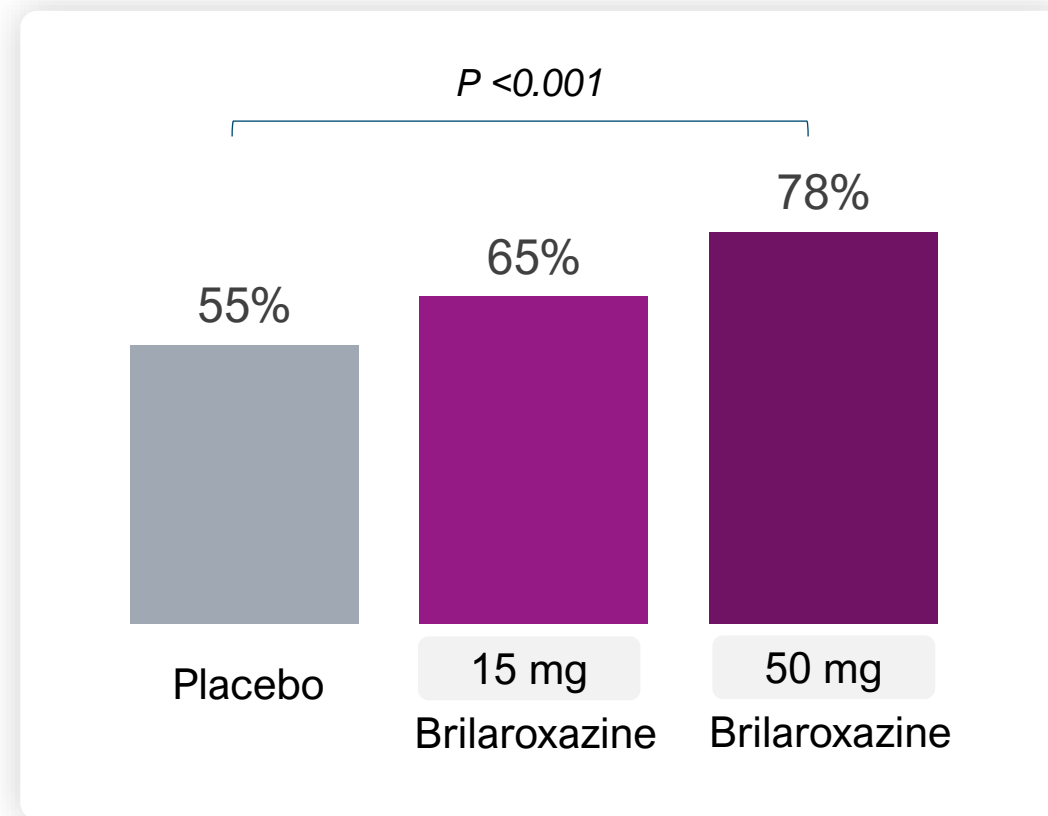
Secondary Endpoint: CGI-S At Week 4 For Brilaroxazine Vs. Placebo

Proportion of subjects with ≥ 1 point(s) improvement on the CGI-Severity scale from baseline

RECOVER Phase 3 Trial

CGI-S score ≥ 1 -point improvement

- Study successfully met secondary endpoint CGI-Severity score
- 78% of subjects on brilaroxazine 50 mg achieved a statistically significant ≥ 1 -point improvement in CGI-Severity scale from baseline vs. placebo
- 65% of subjects on brilaroxazine 50 mg achieved ≥ 1 -point improvement in CGI-Severity scale from baseline vs. placebo



Secondary Endpoint: Personal And Social Performance (PSP) At Week 4

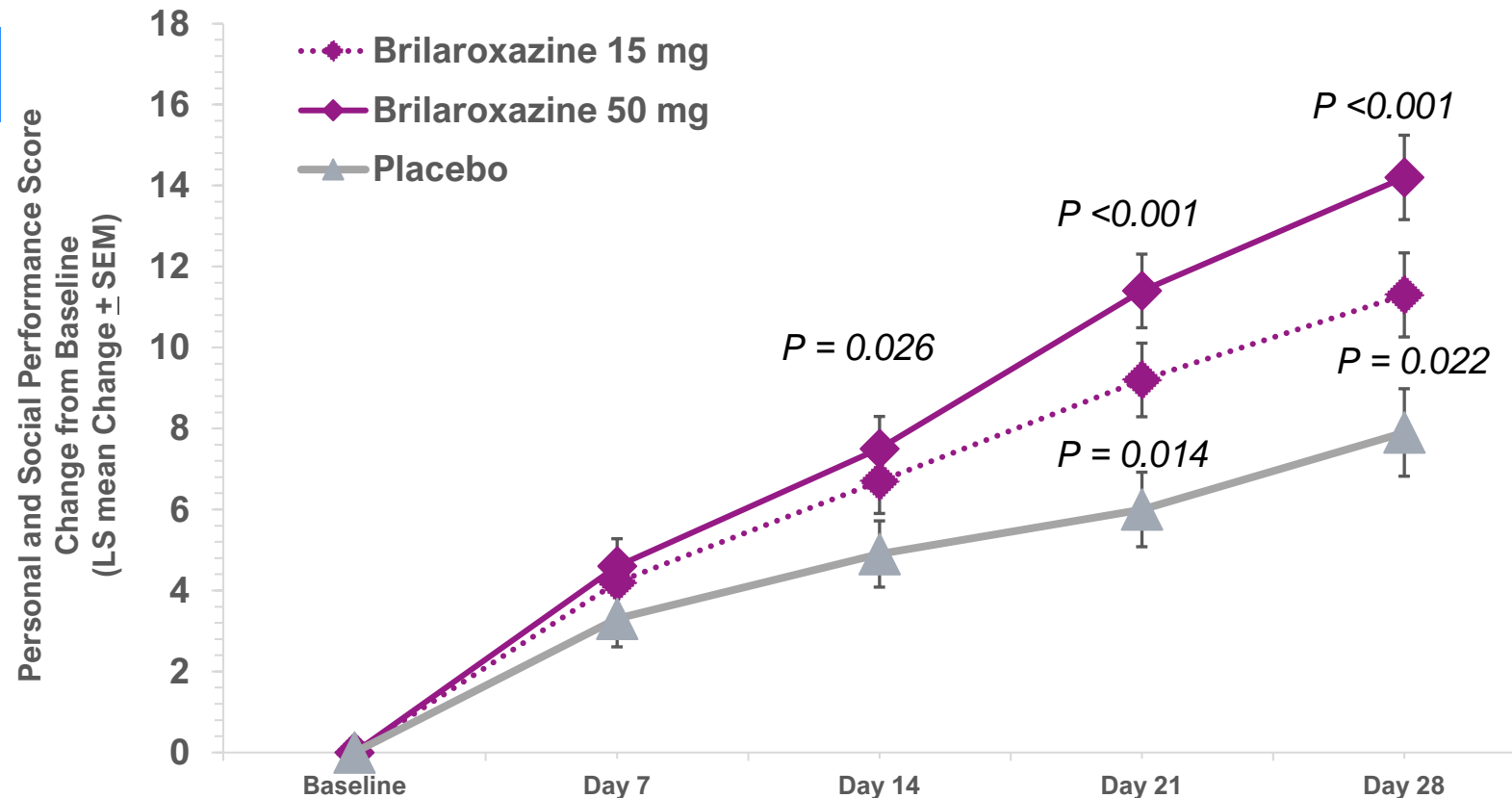
6.3-point improvement in PSP score in brilaroxazine 50 mg vs placebo at week 4, $p < 0.001$

RECOVER Phase 3 Trial

Personal and Social Performance

- Successfully met the secondary endpoint personal and social performance
- Statistically significant and clinically meaningful sustained improvement with both brilaroxazine 15 mg and 50 mg

Cohen's d effect size of 0.5



Statistically Significant And Clinically Meaningful Improvements Across All Major Symptom Domains With Brilaroxazine 50 Mg Vs. Placebo At Week 4

RECOVER Phase 3 Trial

	Brilaroxazine 50 mg vs. Placebo at week 4 Point Reduction / Improvement	Cohen's d Effect Size	P Value
PANSS Total Score	10.1	0.6	< 0.001 ✓
Positive Symptoms	2.8	0.5	< 0.001 ✓
Negative Symptoms	2.0	0.4	0.003 ✓
Negative Symptoms Marder Factor	2.1	0.4	0.002 ✓
PANSS Social Cognition	1.6	0.5	< 0.001 ✓
PANSS Excitement/Agitation	2.1	0.5	< 0.001 ✓
Personal and Social Performance	6.3	0.5	< 0.001 ✓
CGI-S score	≥1	0.5	< 0.001 ✓

RECOVER Trial Topline Tolerability Results: Brilaroxazine Vs Placebo

Well-tolerated safety profile

Brilaroxazine was generally well tolerated

- Overall TEAEs rates 34.5% in brilaroxazine 15 mg, 35.5% in 50 mg, and 30% in placebo
- One serious TEAE reported in brilaroxazine 50 mg was not related to the study drug
- Two serious TEAEs reported in the brilaroxazine 15 mg were deemed not to be related to the study drug
- No incidence of suicidal ideation
- No significant change in bodyweight, blood glucose levels, lipids levels, or endocrine hormones (prolactin, thyroid hormone) compared to placebo

The most common brilaroxazine TEAEs (>5%) were mild to moderate in severity

Common brilaroxazine TEAEs were headache (<6%) and somnolence ($\leq 7.5\%$) generally transient in nature

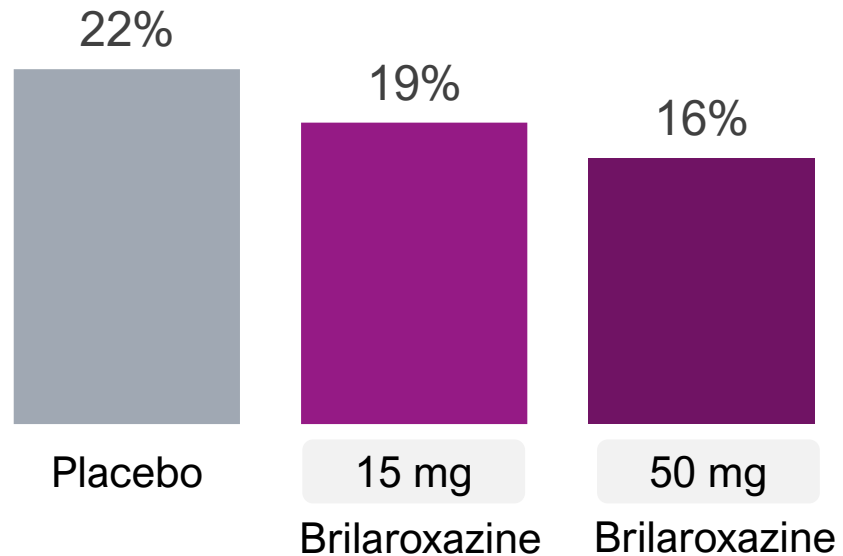
Brilaroxazine adverse events of special interest (AESI) were mild to moderate in severity

- Weight gain 2.1% in 15 mg and 5.9% in 50 mg brilaroxazine and 2.9% in placebo
- Akathisia 0.7% and EPS 0.7% in 50 mg brilaroxazine and none in 15 mg and placebo
- Elevated LDL level none in brilaroxazine and 2.9% in placebo
- Low HDL level 0.7% in 15 mg, 1.4% in 50 mg brilaroxazine and 1.4% in placebo

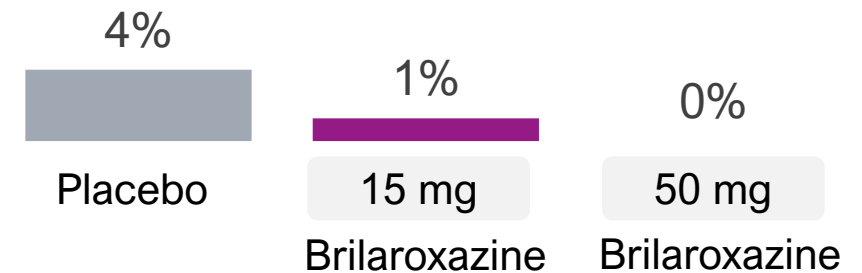
RECOVER Trial Discontinuation Rates: Brilaroxazine Vs. Placebo

19% (N=78) total discontinuation rate in the study

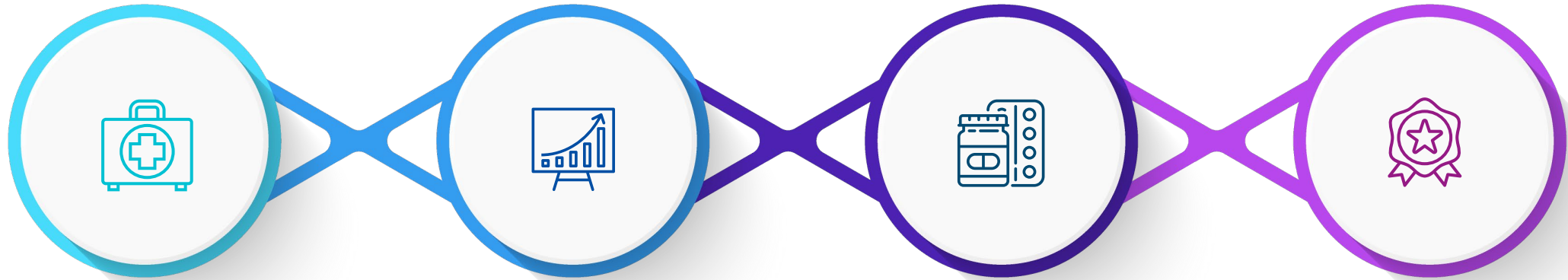
Discontinuation Rate



Discontinuation Due to Side Effects



Clinically Meaningful And Statistically Significant Improvements In Positive And Negative Symptoms Of Schizophrenia With Safety Profile Comparable To Placebo



RECOVER Successfully met primary endpoint for brilaroxazine 50 mg with reduction in PANSS score

Improvement in all major symptom domains

Well-tolerated with side effects comparable to placebo

Low discontinuation rate comparable to placebo

Next Steps

Phase 3 RECOVER-2 trial expected to be initiated in Q1 2024 and completed in early 2025

Topline data from OLE trial expected in Q4 2024

Planned New Drug Application (NDA) submission to the FDA expected in 2025

Brilaroxazine: Consistent Findings in 50 mg Dose in Phase 2 and Phase 3 Studies

Robust efficacy on primary endpoint and key secondary endpoints and low discontinuation rate, lower than placebo

Key Metrics	PHASE 3 RECOVER (N=411 4-wk) NCT05184335	PHASE 2 REFRESH (N=234 4-wk) NCT01490086
Primary Endpoint (Brilaroxazine 50 mg vs Placebo)		
PANSS Total Score	-10.1 P<0.001 (Effect Size, 0.6)	-10.7 P<0.01
Secondary Endpoint (Brilaroxazine 50 mg vs Placebo)		
PANSS Positive Score	-2.8 P<0.001 (Effect Size, 0.5)	-3.04 P=0.03
PANSS Negative Score	-2.1 P<0.003 (Effect Size, 0.4)	-2.04 P=0.04
CGI-S Score	-0.5 P<0.001 (Effect Size, 0.5) Improvement ≥ 1, 78%	-0.5 P=0.02 Improvement ≥ 1, 72%
Discontinuation Rate (Brilaroxazine 50 mg vs Placebo)		
Related to any reasons	16% (50mg) vs 22% (placebo)	12% (50mg) vs 28% (placebo)
Related to TEAEs in 50mg	0	1.7% (1-subject)

Lower Drug-Drug Interactions (DDIs) with Brilaroxazine vs Standards of Care

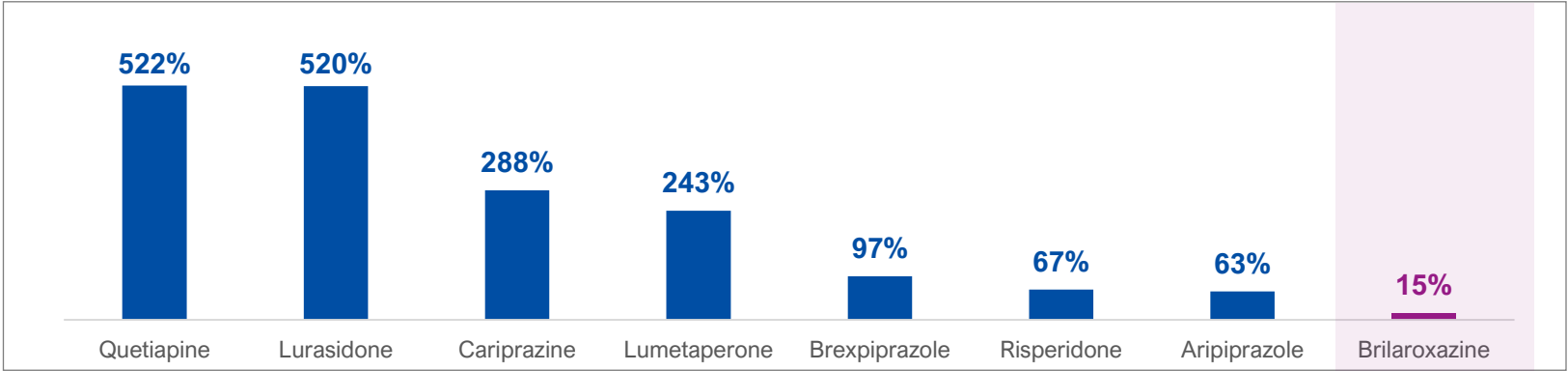
DDIs and polypharmacy alter plasma drug concentrations, and can impact efficacy and side effect profiles of a drug¹¹ | ~50% of prescribed drugs and over 25% of approved antipsychotics are known to cause drug interactions in the presence of a strong CYP3A4 inhibitor drug

Change in drug concentration with a CYP3A4 Inhibitor

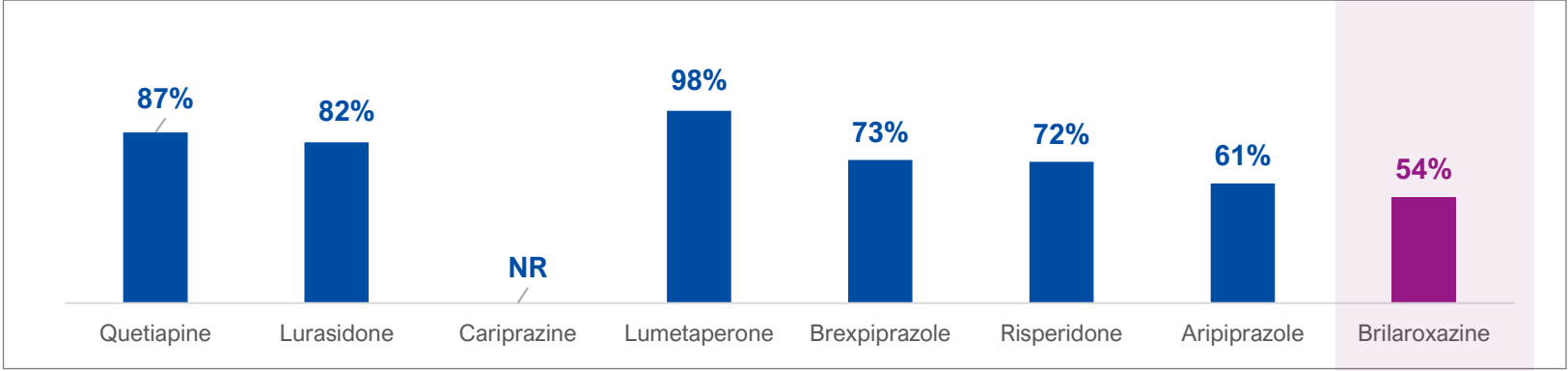
Antipsychotic	Fold increase vs brilaroxazine
Brilaroxazine	--
Aripiprazole	4.2x
Risperidone	4.5x
Brexpiprazole	6.5x
Lumetaperone	16.2x
Cariprazine	19.2x
Lurasidone	34.7x
Quetiapine	34.8x

*Olanzapine⁹ not evaluated; metabolized by CYP1A2¹⁰

% Increase in drug concentration (AUC) with a CYP3A4 Inhibitor



% Decrease in drug concentration (AUC) with a CYP3A4 Inducer



Lower is better

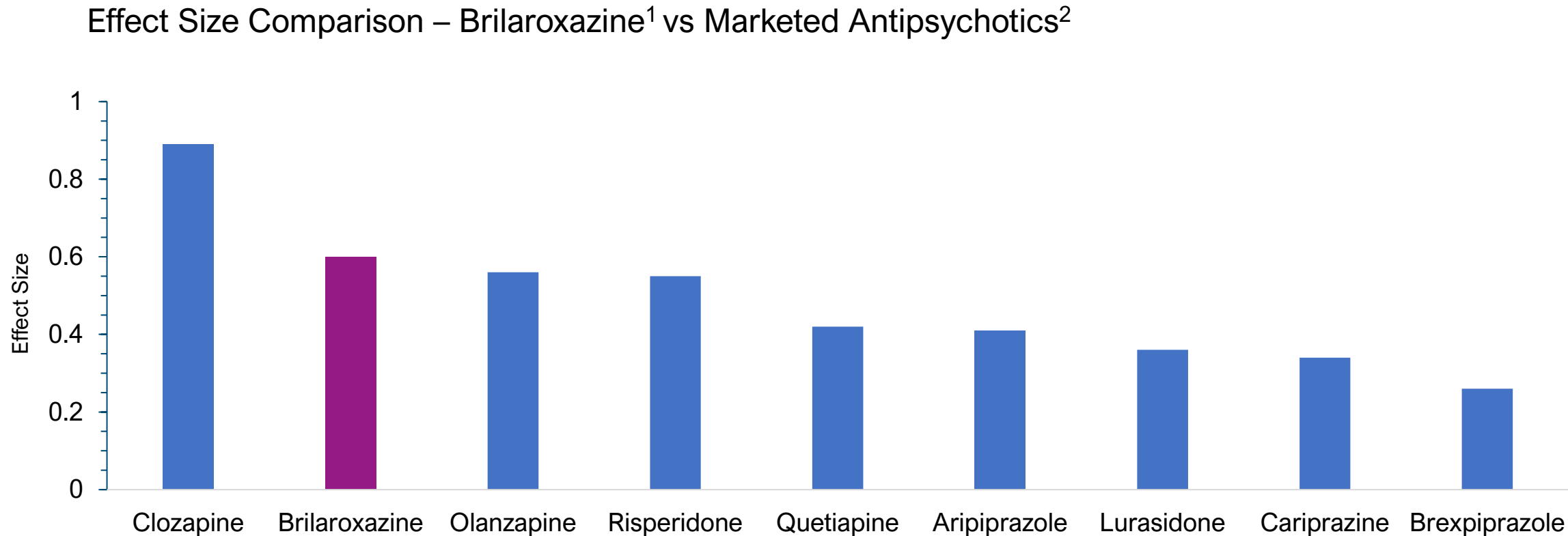
Ongoing Clinical Program Sets The Stage Regulatory Path Forward

Regulatory discussions with FDA on planned New Drug Application (NDA) submission

PHASE 2 REFRESH NCT01490086	✓	PHASE 3 RECOVER NCT05184335	✓	PHASE 3 OLE NCT05184335	PHASE 3 RECOVER-2 TBD
N = 234 Acute schizophrenia or schizoaffective disorder		N = 412 Acute schizophrenia		N = 100 completers Stable schizophrenia	N = 450 Acute schizophrenia
Efficacy and safety of brilaroxazine vs placebo		Efficacy and safety of brilaroxazine vs placebo		Long-term safety and tolerability of brilaroxazine	Efficacy and safety of brilaroxazine vs placebo
3:3:2 Randomized, 4-week, double-blind, placebo-controlled, multicenter		1:1:1 Randomized, 4-week, double-blind, placebo-controlled, multicenter		Open label, one group. 1-year outpatient extension of RECOVER	1:1:1 Randomized, 6-week, double-blind, placebo-controlled, multicenter
Once daily brilaroxazine 15, 30, 50 mg		Once daily brilaroxazine 15, 50 mg		Once daily brilaroxazine 15, 30, 50 mg flexible dose	Once daily brilaroxazine 30, 50 mg with primary & secondary endpoints same as RECOVER
FDA indicated potential for 'Superior Safety' label claim		Completed with topline results announced in October 2023		Topline data expected Q4 2024	Completion expected Q2 2025

Benchmark Comparison of Treatment Effect Size Across Phase 3 Studies

Olanzapine and risperidone are the most prescribed antipsychotics in acute schizophrenia treatment



Source: (1) Brilaroxazine phase 3 topline results announced by Reviva; (2) Huhn M et al. Lancet 2019, 394:939-951; Comparison data presented here are not from the head-to-head studies

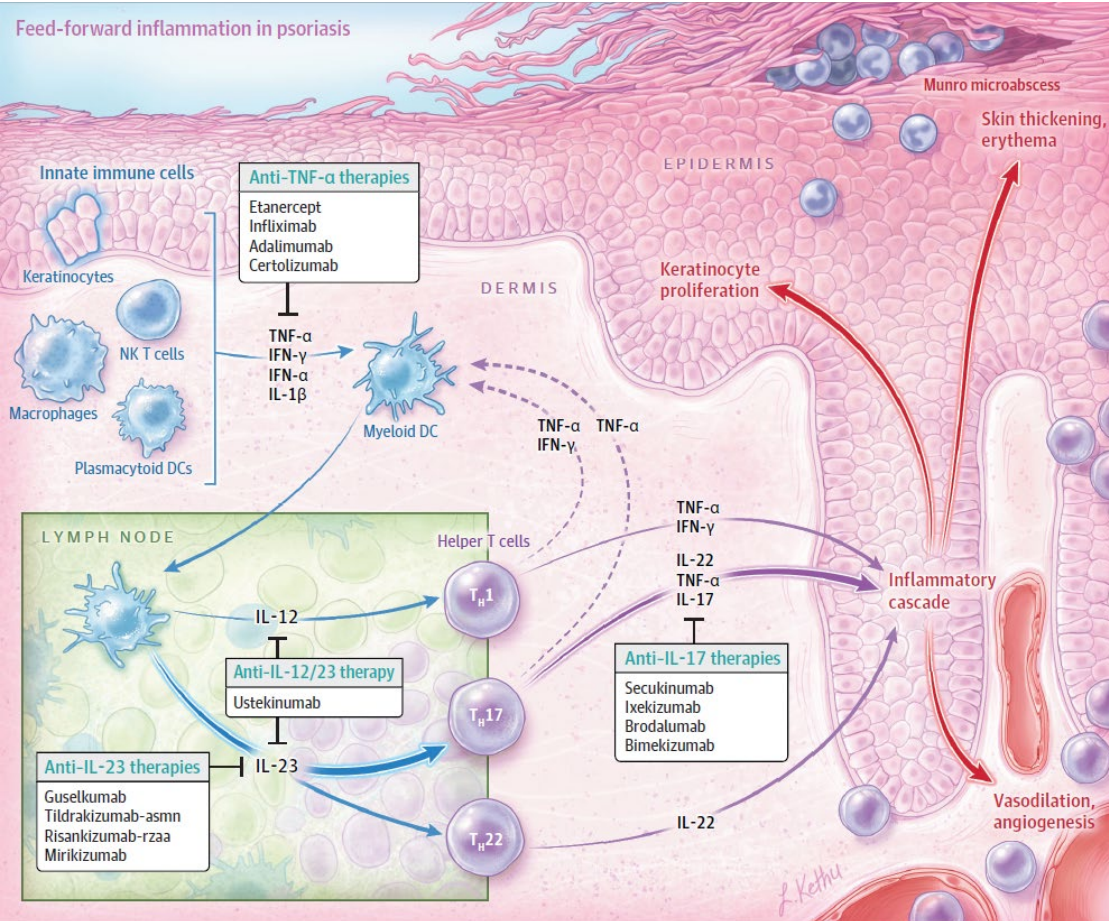
A doctor in a white lab coat with a stethoscope around their neck, holding a large X-ray of a human chest. The X-ray shows the ribcage and lung fields. The doctor is standing in front of a window with a blue frame.

Inflammatory / Immune Disease Programs

Psoriasis | Pulmonary Arterial Hypertension (PAH) |
Idiopathic Pulmonary Fibrosis (IPF)

Brilaroxazine has Potential to Treat Psoriasis

Inflammatory skin disease driven by dysfunctional serotonin-dopamine signaling

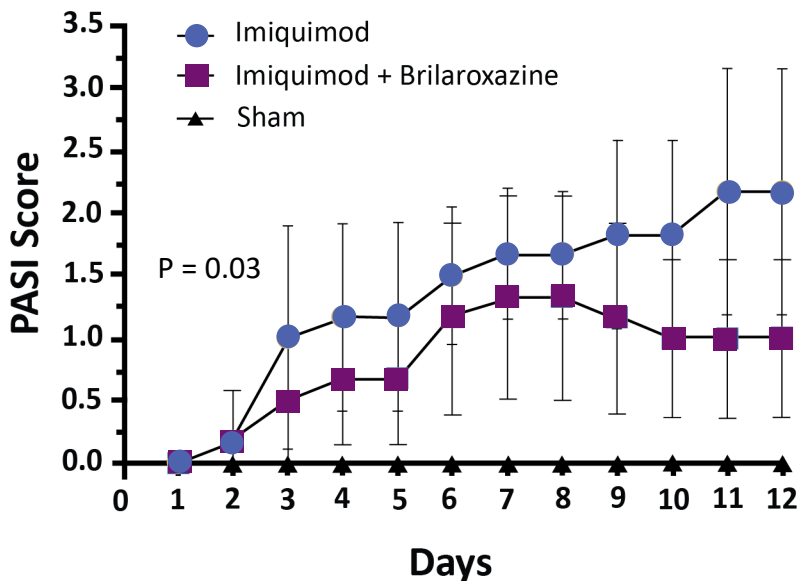


- Approx 3% of the US population and an estimated 125 million people worldwide suffer from psoriasis
- An estimated one-third of neuropsychiatric and neurodegenerative disease patients suffer from psoriasis
- Currently there is no cure for psoriasis
 - Topical corticosteroids therapies remain the cornerstone for treating mild psoriasis
 - Biologics that inhibit cytokines TNF-α, p40IL-12/13, IL-17, and p19IL-23, and oral PDE-4 inhibitor for moderate to severe plaque psoriasis

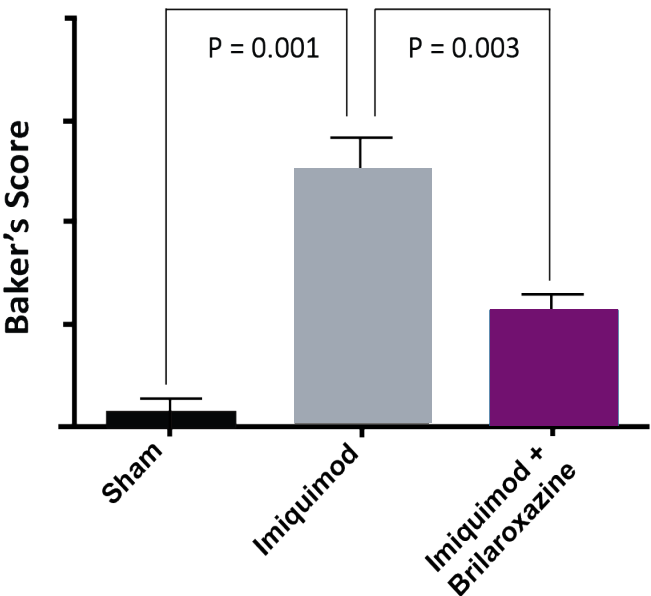
Brilaroxazine Demonstrated Encouraging Preclinical Efficacy

In an imiquimod induced mouse model of psoriasis

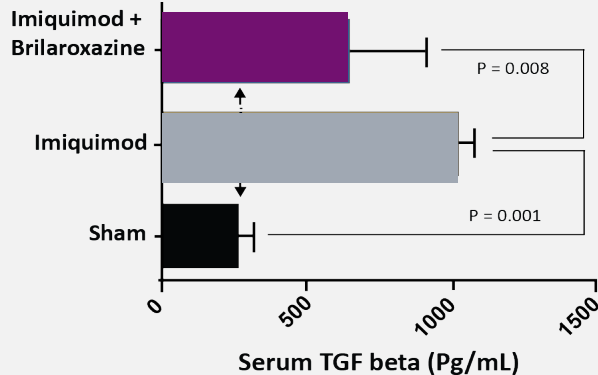
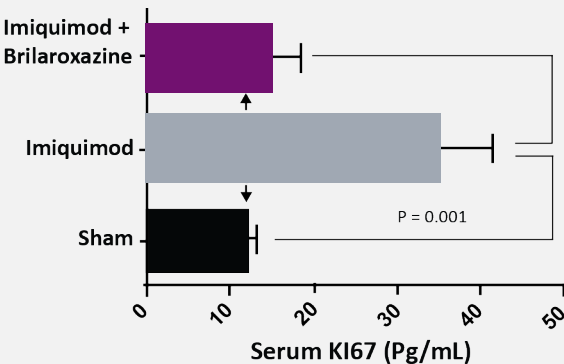
Psoriasis Area Severity Index (PASI)



Psoriasis Severity by Baker Score



Decrease in anti-inflammatory and proliferation cytokine (KI67) and profibrotic chemokine (TGF-β)



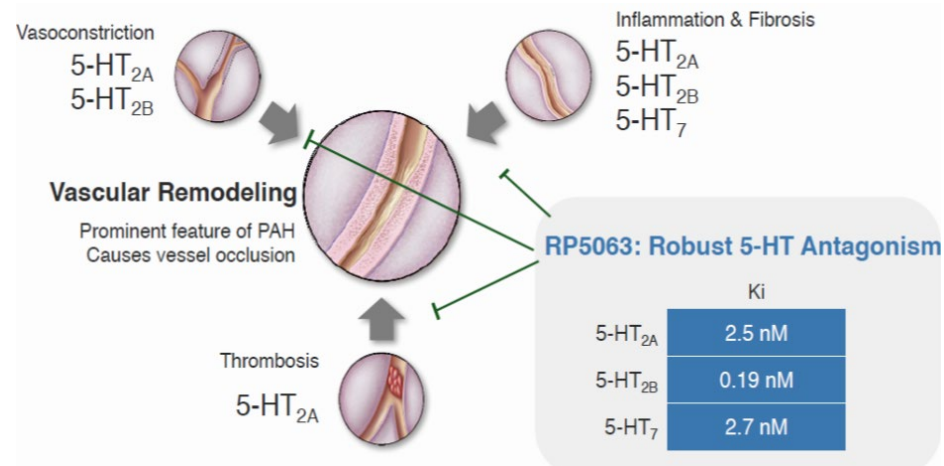
Brilaroxazine topical liposomal gel significantly decreased

- Psoriasis area severity index (P= 0.03)
- Clinical severity of psoriasis, Baker score (p=0.003)
- Proinflammatory and proliferation cytokine, KI67 (P=0.001)
- Profibrotic chemokine, TGF-β (P=0.001)

Brilaroxazine: Potential to Delay PAH and IPF Disease Progression

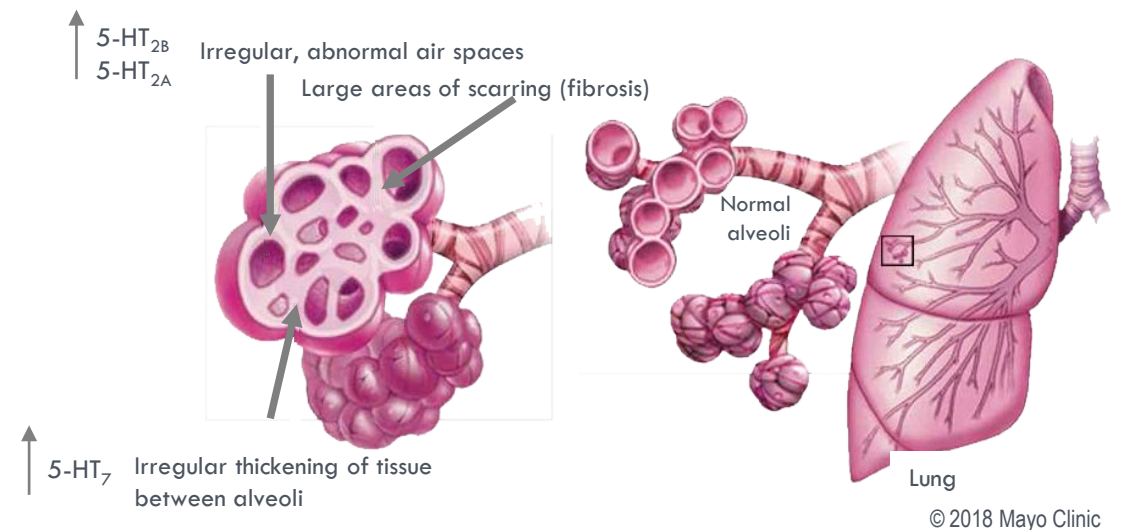
PAH and IPF are Orphan Diseases that involve dysfunctional serotonin signaling

Lung Vascular Remodeling in PAH



- PAH and IPF are rare, chronic, and debilitating conditions
- No therapies significantly delay disease progression
- Patients experience elevated plasma serotonin (5-HT) levels, increased expression of 5-HT_{2A/2B/7} receptors & inflammatory cytokines in lungs

Lung Alveoli Remodeling in IPF



- Lung vascular/alveoli remodeling occurs due to inflammation, fibrosis, and pulmonary hypertension
- Brilaroxazine has robust antagonism against serotonin receptors involved in vasoconstriction, fibrosis, blood clots, and inflammation

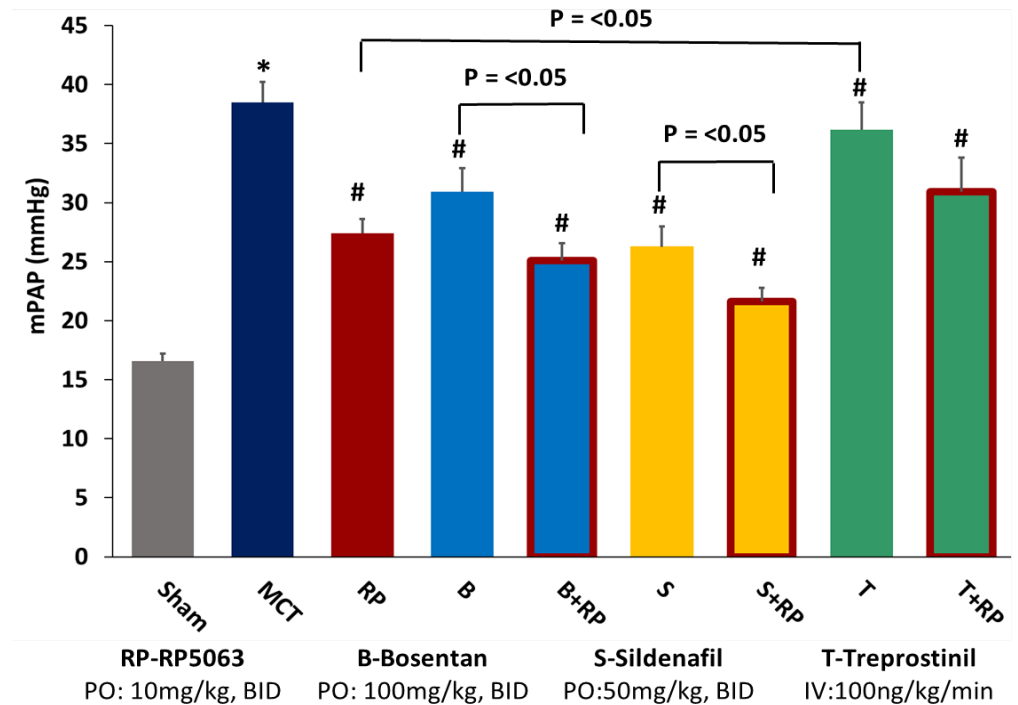
Brilaroxazine: Encouraging Results in PAH Translational Rodent Models

Potential for Improved Treatment Effect Compared to Standard of Care

Brilaroxazine alone and co-administered with standard of care for PAH

- Mitigated PAH in MCT and Sugen-Hypoxia rodent models
- Decreased respiratory resistance and restored blood oxygen saturation
- Decreased vascular remodeling and fibrosis in the small vessels
- Mitigated inflammation & reduced small vessel thickness
- Significantly reduced inflammatory cytokines $\text{TNF}\alpha$, $\text{IL-}\beta$, IL-6 , and chemokine LTB4

Brilaroxazine mitigates pulmonary hypertension and lung fibrosis/collagen



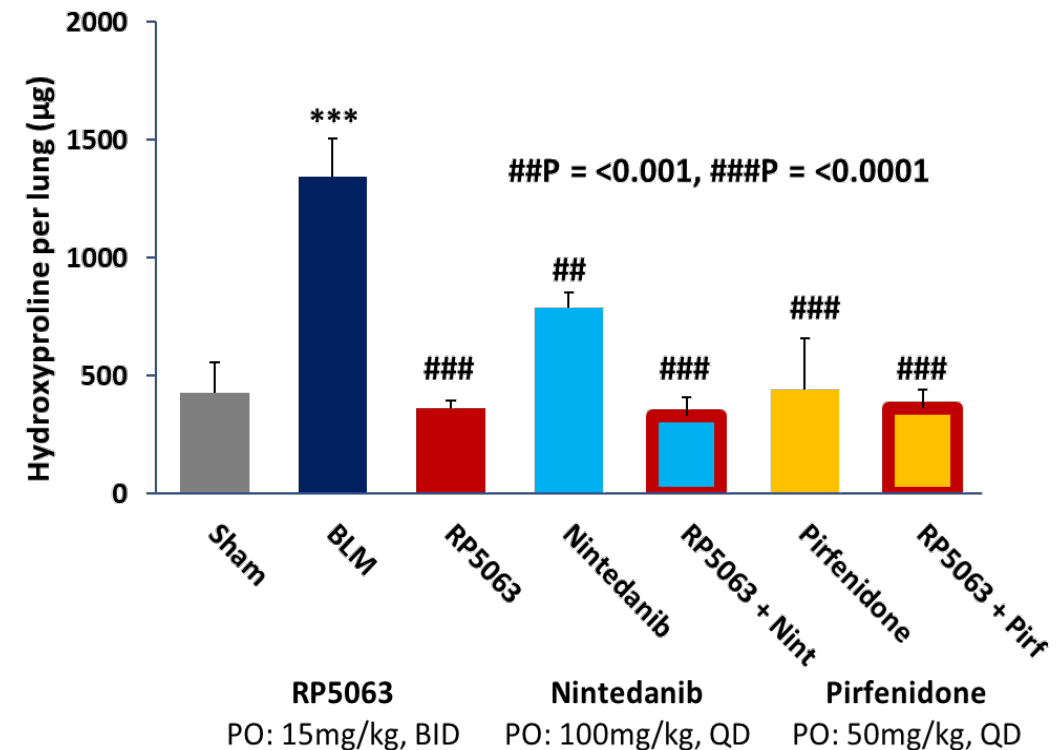
Brilaroxazine: Encouraging Results in Bleomycin-Induced IPF Rodent Model

Potential for Improved Treatment Effect Compared to Standard of Care

Brilaroxazine both alone and co-administered with standard of care for IPF

- Mitigated lung fibrosis and collagen deposits
- Decreased respiratory resistance & improved blood oxygen saturation
- Restored body weight and cardiac output
- Reduced the IPF biomarkers BALF cell counts, hydroxyproline, and blood lactate levels
- Decreased cytokines RANTES, $\text{IFN}\gamma$, MCP1, IL-6, and IL-17
- Improved survival rates

Brilaroxazine mitigates lung fibrosis / collagen (Decrease in Hydroxyproline)



Brilaroxazine: Ready for Phase 2 Trials in PAH and IPF

FDA granted Orphan Drug Designation

Brilaroxazine Phase 2 trials in PAH and IPF

- Preclinical evidence supports the use of Brilaroxazine in PAH and IPF
- Generally well-tolerated in clinical studies for schizophrenia in >250 patients
- Completed long-term regulatory toxicology studies
- Manufactured API and drug products (clinical trial materials)
- Oral once daily dosing, potential to develop once daily inhaler for enhanced effect and convenience

Key regulatory milestones achieved

- FDA reviewed preclinical pharmacology, toxicology, CMC, and clinical Phase 1 safety data for initiating a Phase 2 study
- FDA reviewed and provided guidance on Phase 2/3 clinical development plan and a potential “Disease Modifying Agent” label claim
- FDA granted Orphan Drug Designation for the treatment of PAH and IPF

Experienced Management Team

20+ years of experience in drug discovery and clinical development



Laxminarayan Bhat, PhD
Founder, President and CEO



Narayan Prabhu, CPA
Chief Financial Officer



Sangita Ghosh, PhD
Sr VP Pharm Development

Seema Bhat, MS, CTDM, PMP
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Kevin Charrier
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