MindMed

Opioid Use Disorder: Zolunicant's Potential For Unmet Treatment Needs

Thursday May 19, 2022 11:00 AM ET

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The United States federal government regulates drugs through the Controlled Substances Act. The Company works with a non-hallucinogenic synthetic derivative of the psychedelic substance ibogaine, known as "18-MC", which is a synthetic organic molecule designed around a common coronaridine chemical backbone. 18-MC is not a Schedule I substance in the United States and the Company does not foresee it becoming a Schedule I substance due to its non-hallucinogenic properties. While the Company is focused on programs using psychedelic inspired compounds and classic psychedelics, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates. The Company is a neuro-pharmaceutical drug development company and does not deal with psychedelic substances except within laboratory and clinical trial settings conducted within approved regulatory frameworks. The Company's products will not be commercialized prior to applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended uses is successfully developed.]

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Agenda

Robert Barrow, CEO, Director of MindMed	MindMed Introduction
Stuart Gitlow, MD, MPH, MBA	Overview of substance use disorders
Kelly E. Dunn, PhD, MBA	Current treatment landscape for opioid use disorder and the unmet medical need in the management of opioid withdrawal
MindMed Leadership	MM-110 (zolunicant) clinical development program and its therapeutic potential in substance use disorders
Moderated by Mr. Barrow	Q&A

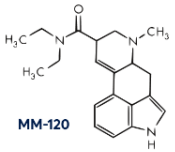
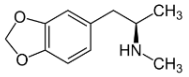
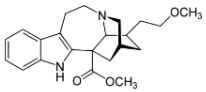
Business Highlights

Our mission is to deliver on the therapeutic potential of psychedelics and other novel targets to treat brain health disorders

- Leader in developing psychedelic product candidates to treat brain health disorders
- Diversified pipeline of clinical programs targeting significant unmet medical needs
- IP and R&D strategies to maximize market exclusivity and protection
- Leveraging decades of research on clinical and preclinical potential of product candidates
- Industry-leading expertise in drug and digital medicine development and commercialization
- Fully funded through key clinical readouts and into 2024

Advancing Multiple Generations of Drug Candidates

Our strategy is to deliver on well-characterized psychedelic candidates and next generation candidates with enhanced drug profiles

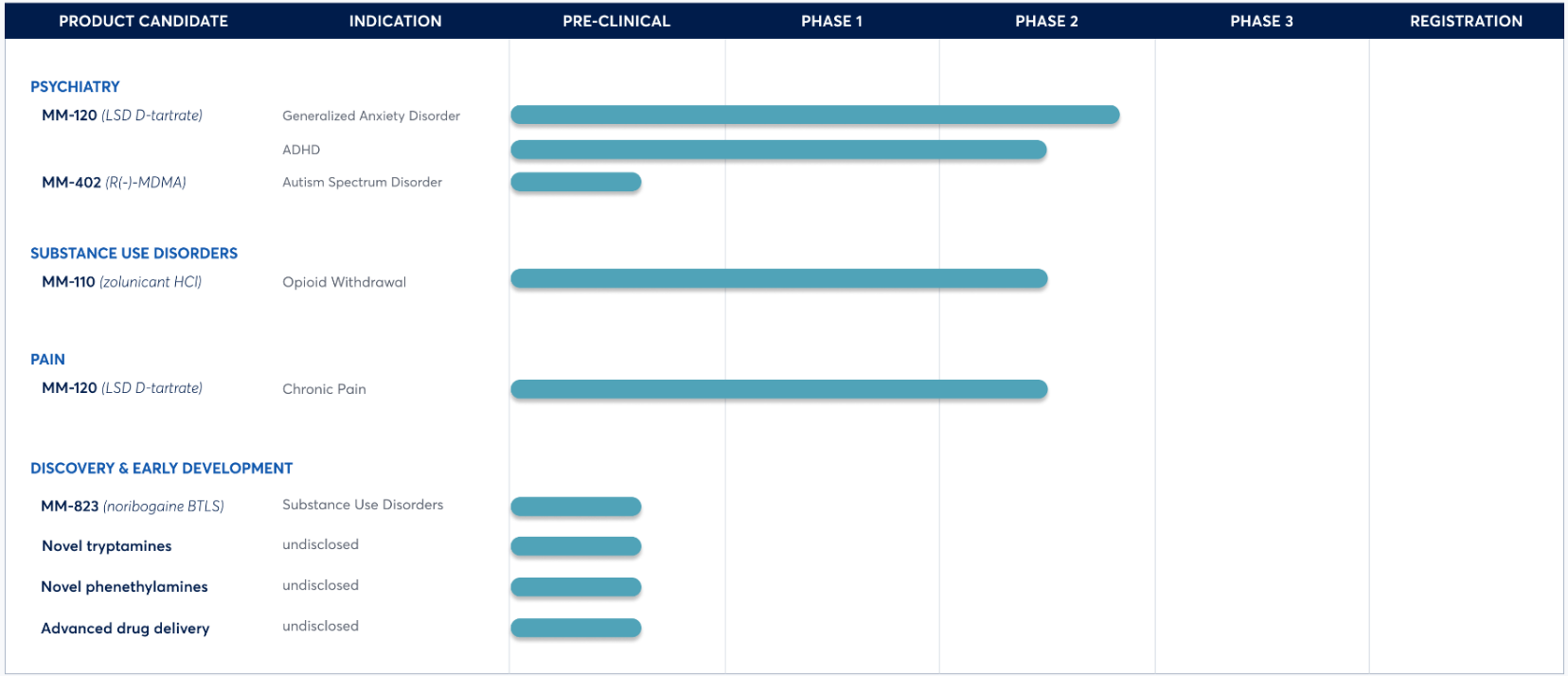
	CONCEPT	MINDMED PRODUCT CANDIDATES	PIPELINE EXPANSION OPPORTUNITIES
CLASSIC PSYCHEDELICS	• Clinical evidence of efficacy [1] • Well-characterized pharmacology • Accelerated development potential	 MM-120	• Expanded clinical indications • Psychedelics with distinct PK/PD  DMT  Mescaline Universitätsspital Basel
2ND GENERATION / OPTIMIZED	• Enhanced pharmacology • Overcome safety liabilities • Increased IP potential	 MM-402	• Advanced drug delivery • Novel treatment models • Novel treatment regimen
3RD GENERATION / NCES	• Analogues of classic psychedelics • Require full development program • Strongest IP potential	 MM-110	• Novel tryptamines • Novel phenethylamines • Non-hallucinogenic analogues

1. Gasser 2014; J. Nerv. Ment. Dis.; 202(7).

IP: intellectual property; DMT: N,N-dimethyltryptamine; NCE: new chemical entity; PD: pharmacodynamics; PK: pharmacokinetics

Research & Development Pipeline

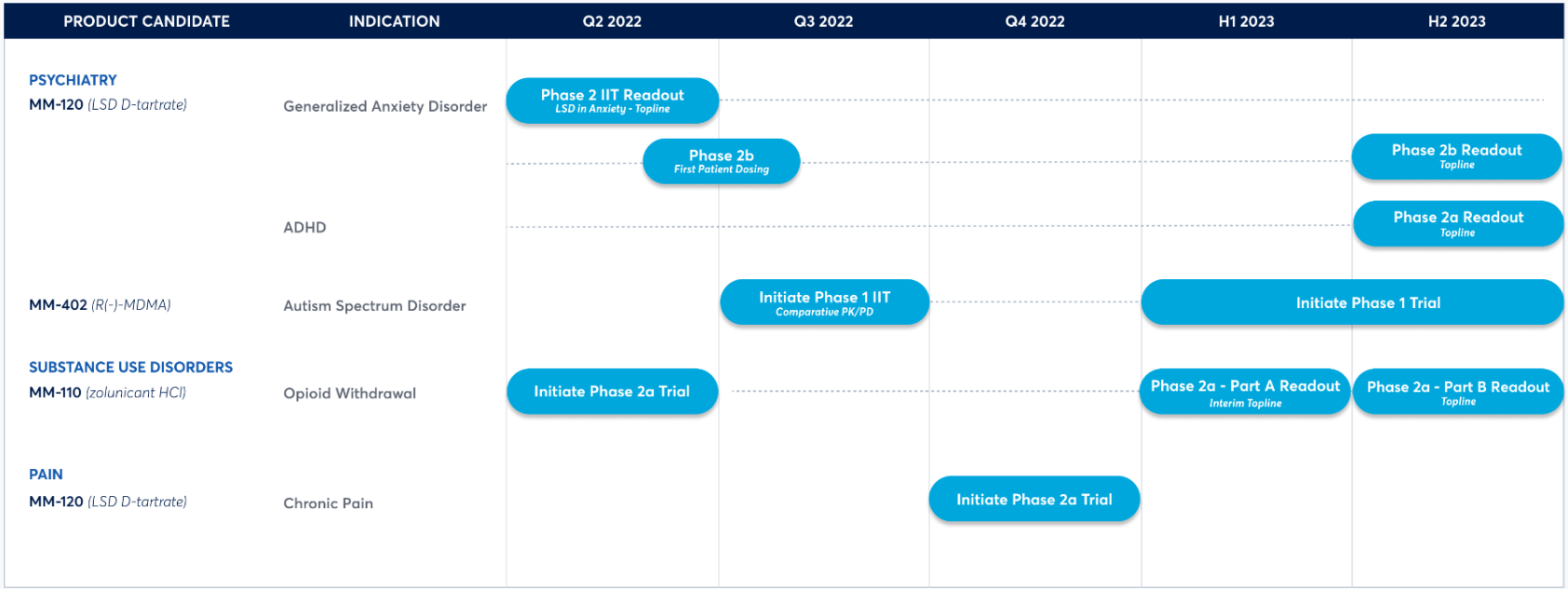
Our pipeline diversification offers potential opportunities across therapeutic areas and mechanisms of action



ADHD: Attention-Deficit/Hyperactivity Disorder

Upcoming Portfolio Milestones

MindMed's clinical research portfolio creates multiple near-term and intermediate catalysts



ADHD: Attention-Deficit/Hyperactivity Disorder; IIT: investigator-initiated trial; R&D: research & development; ESOE: early sign of efficacy

Stuart Gitlow, MD, MPH, MBA

Dr. Gitlow, Past President of the American Society of Addiction Medicine and Past Chair of the AMA's Council of Science and Public Health

Kelly E. Dunn, PhD, MBA

Dr. Dunn, Associate Professor in the Behavioral Pharmacology Research Unit within the Department of Psychiatry and Behavioral Sciences in the Johns Hopkins University School of Medicine

Supervised Opioid Withdrawal Unmet Need and 18-MC

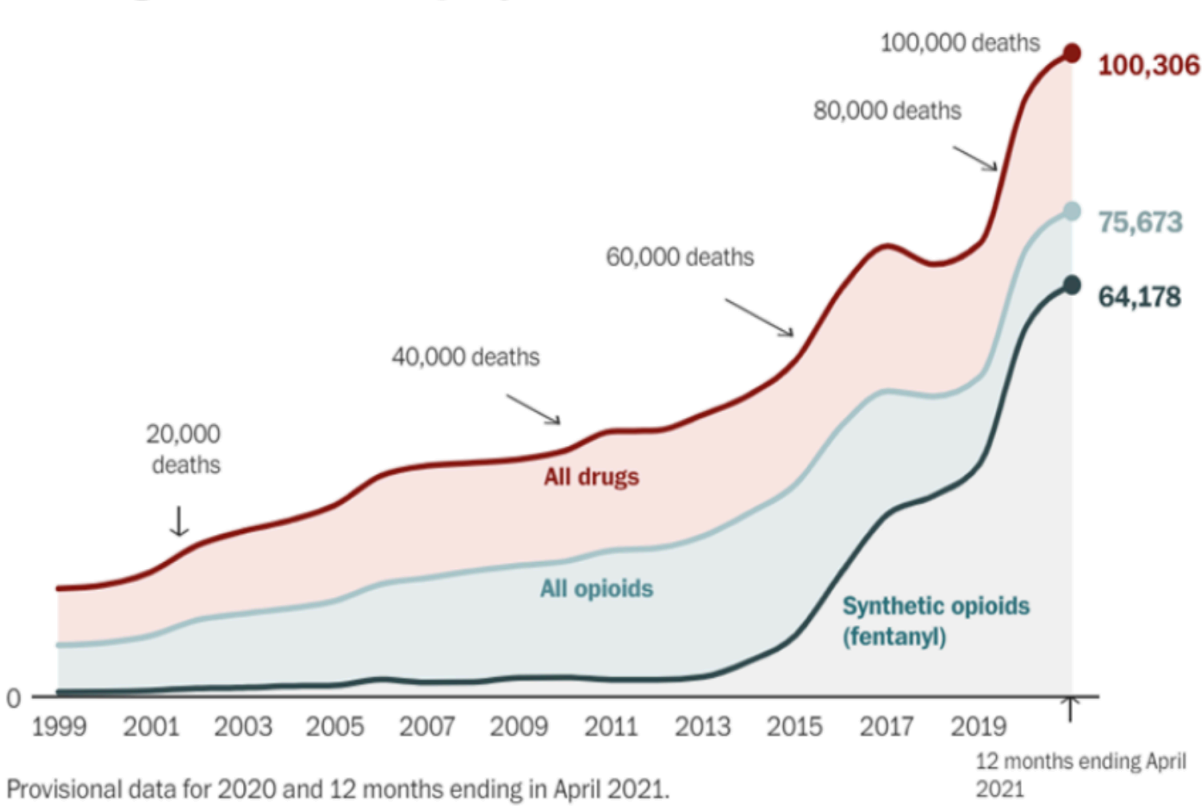
Kelly E Dunn, Ph.D., MBA; JHUSOM

Disclosures (past 3 years)

- Mind Med, Inc.; Canopy Corporation; Beckley-Canopy Corporation

MOR
MARYLAND OPIOID RESEARCH

Waves 1 – 4 of the Opioid Crisis



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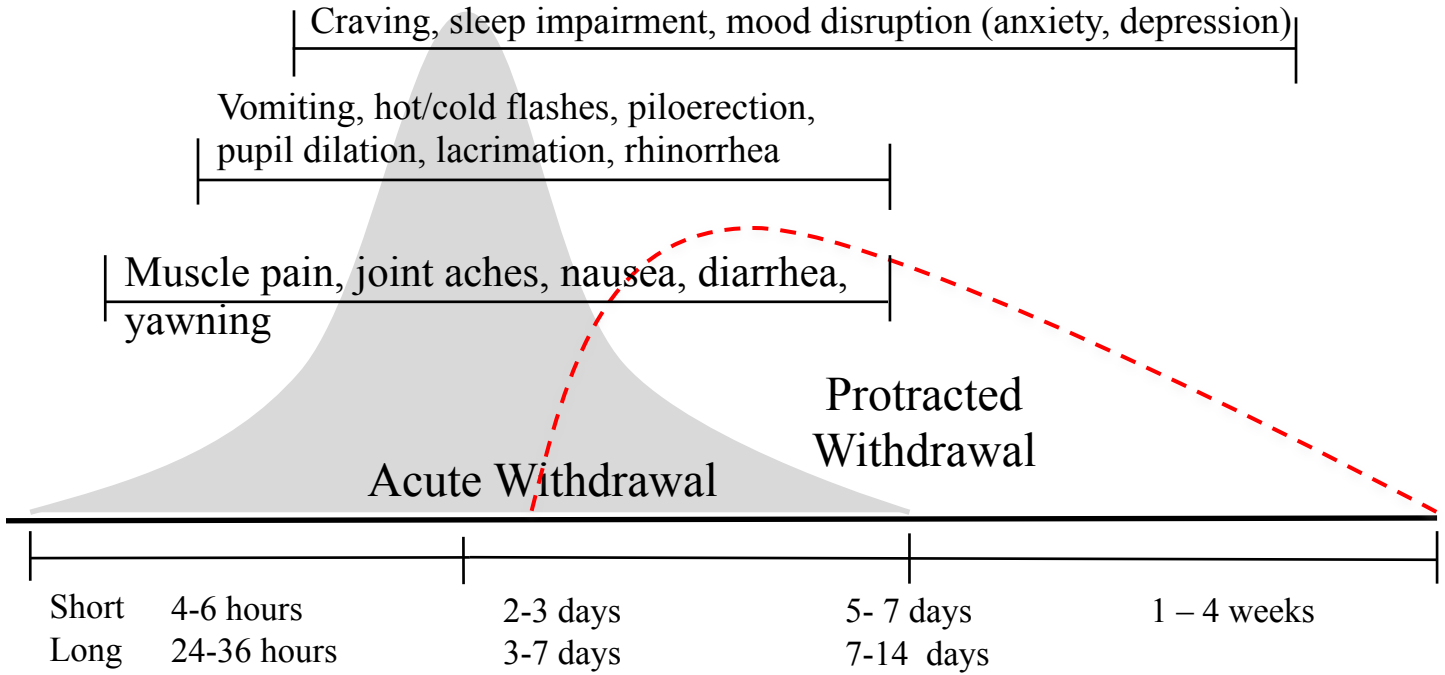
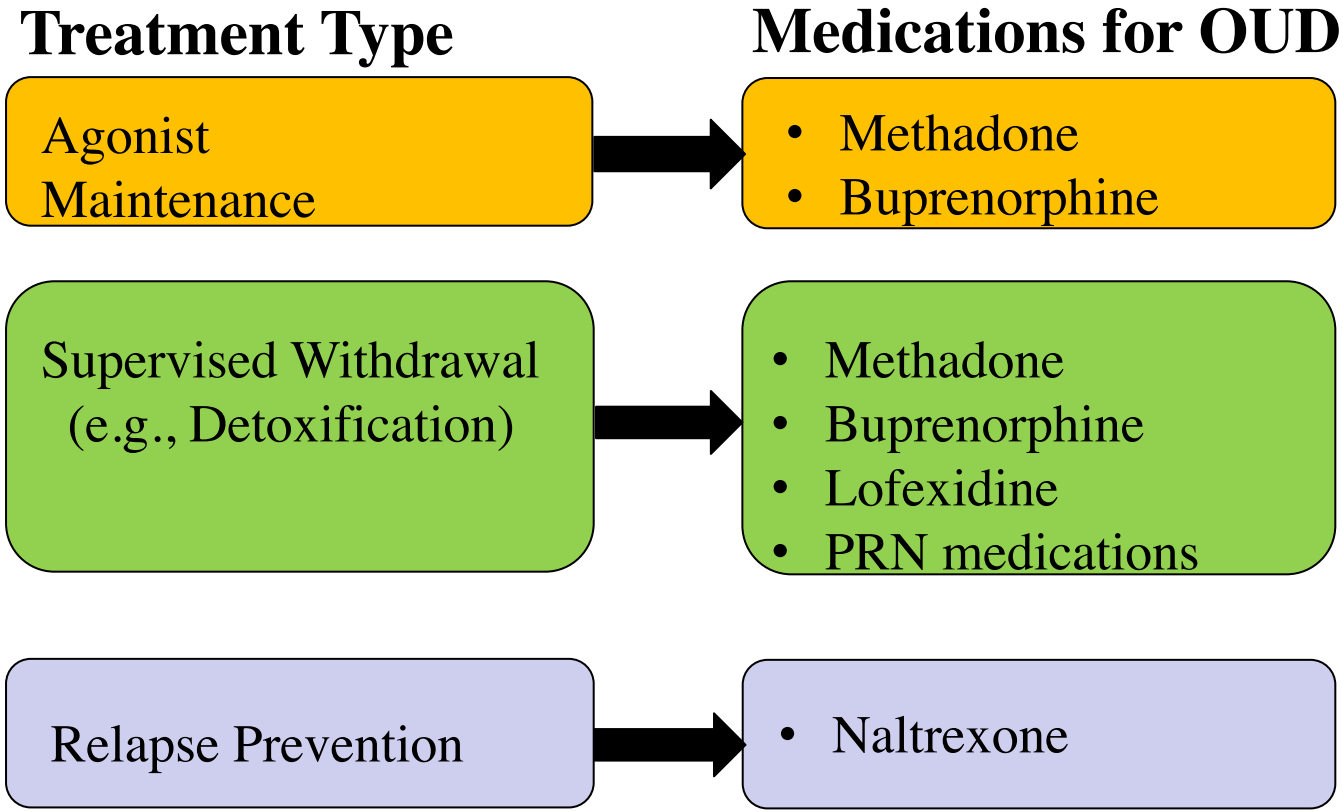
Opioid Withdrawal Syndrome

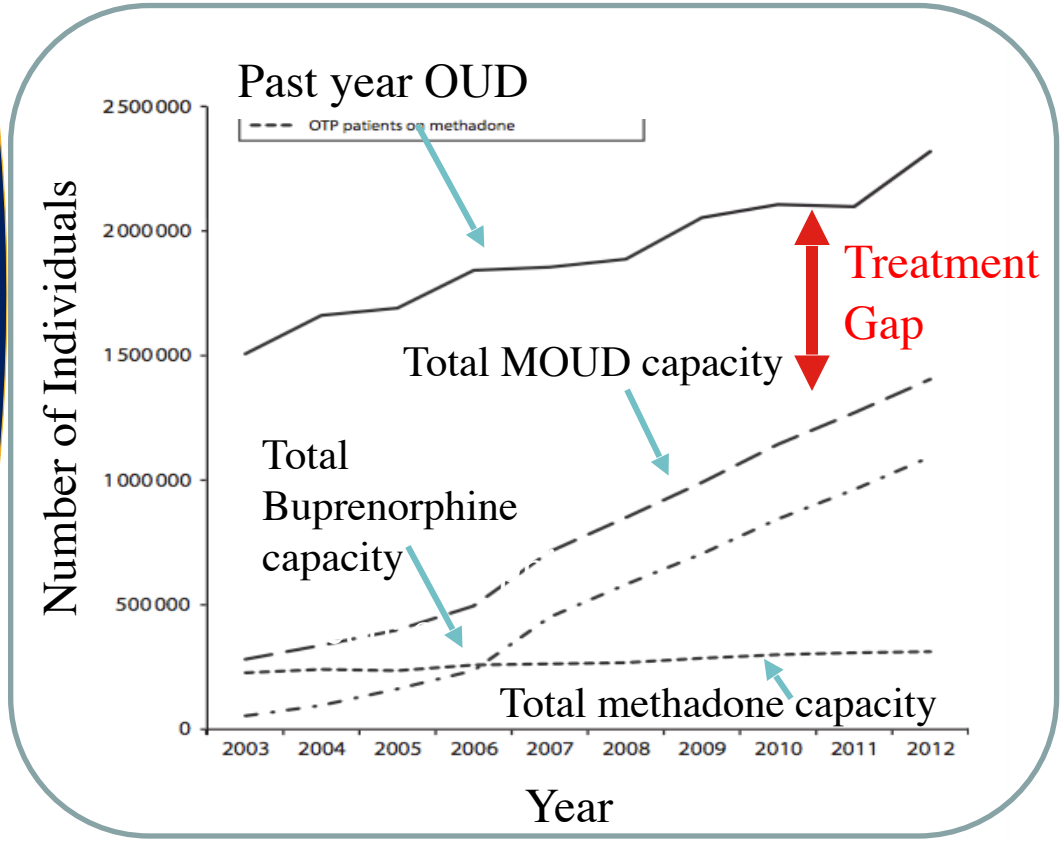


Dunn et al., 2019, JPET

Current OUD Treatment Options



Significant Agonist Treatment Gap



96% of states had rates of OUD that exceeded capacity

In 78% of states, the majority of maintenance clinics were at ≥80%

Jones et al., 2015, AJPH

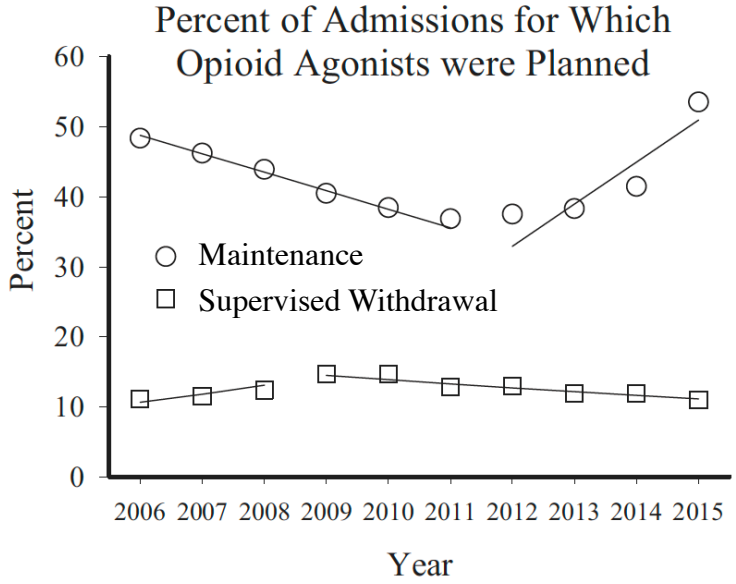
Supervised Withdrawal Treatment

Benefits

- Available
- Patient preference
- Continuum of care

Challenges

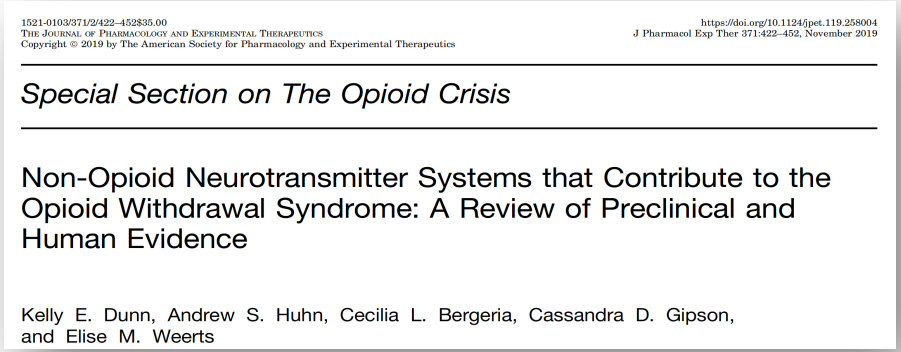
- Poor withdrawal management
- Risk of fatal overdose
- No standardization



Most supervised withdrawal programs do not offer opioid medications

Dunn et al., 2019, JSAT

Non-opioid Treatment Options



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THE JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS

https://doi.org/10.1124/jpet.119.258004
J Pharmacol Exp Ther 371:422–452, November 2019

Special Section on The Opioid Crisis

Non-Opioid Neurotransmitter Systems that Contribute to the Opioid Withdrawal Syndrome: A Review of Preclinical and Human Evidence

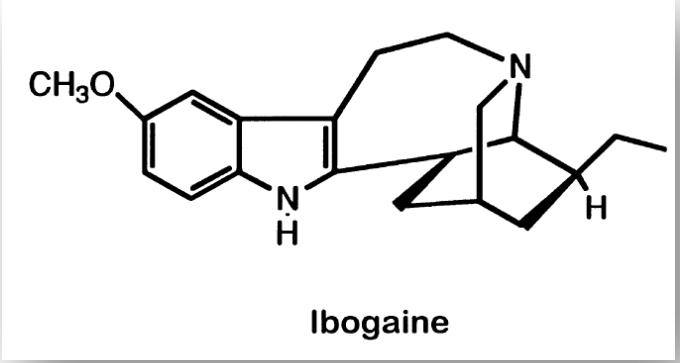
Kelly E. Dunn, Andrew S. Huhn, Cecilia L. Bergeria, Cassandra D. Gipson, and Elise M. Weerts

Ibogaine

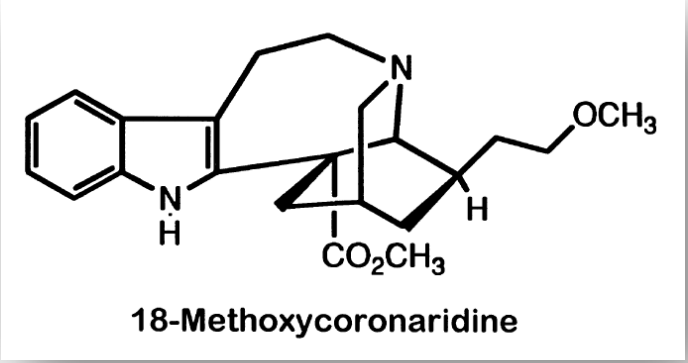
- Used internationally
- Efficacy supported by retrospective chart reviews, case studies, and survey studies (no RCTs available)
- Generally administered as a bolus dose for supervised withdrawal
- Narrow therapeutic window, elevated cardiac risk

18-MC

- Synthetic iboga alkaloid congener, derived from ibogaine
- Different mechanism of action- antagonist on alpha 3, beta 4 nicotinic receptor
- Better safety profile?



Ibogaine

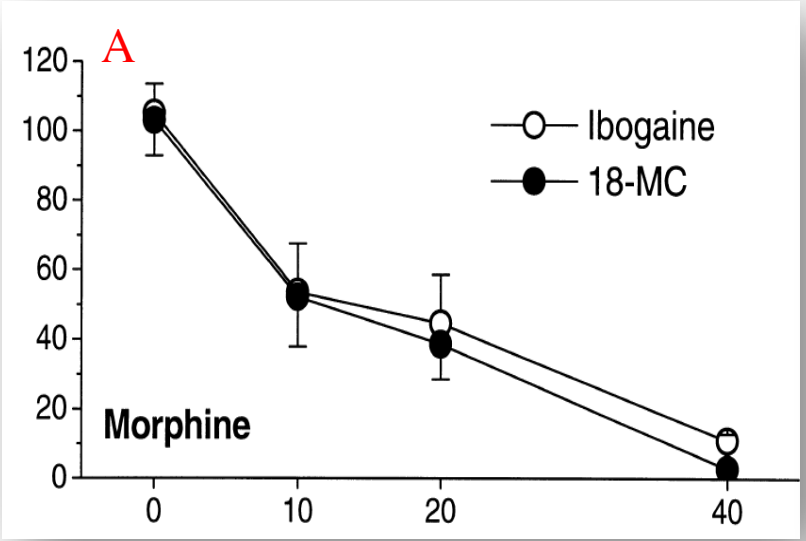


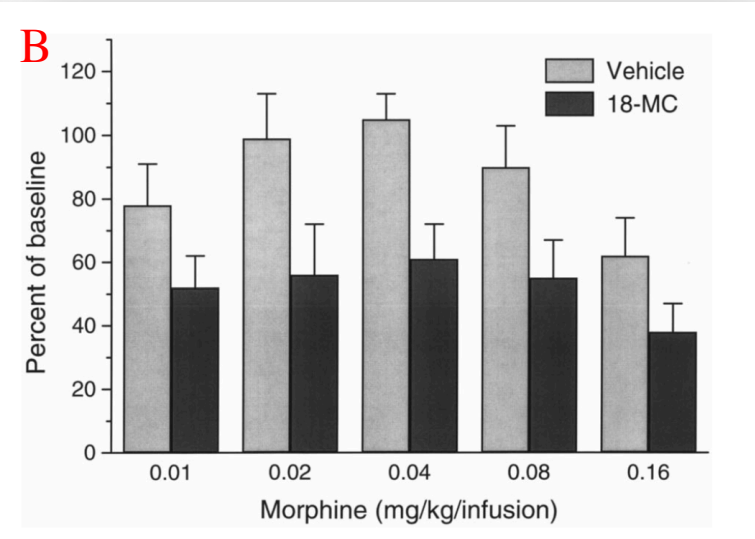
18-Methoxycoronaridine

Glick & Maisonneuve, 2000

Reduces Morphine Self-administration

18-MC shifts the dose-response curve for morphine self-administration down, decreasing its efficacy (not potency) relative to (A) Ibogaine and (B) control

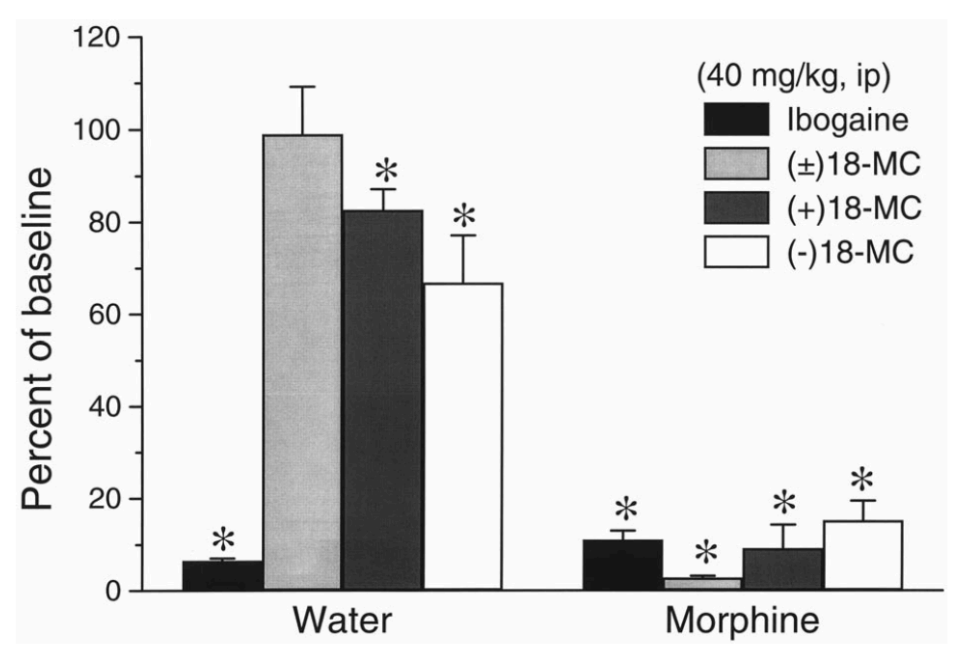




Glick & Maisonneuve, 2000

Maintains Activity on Natural Reinforcers

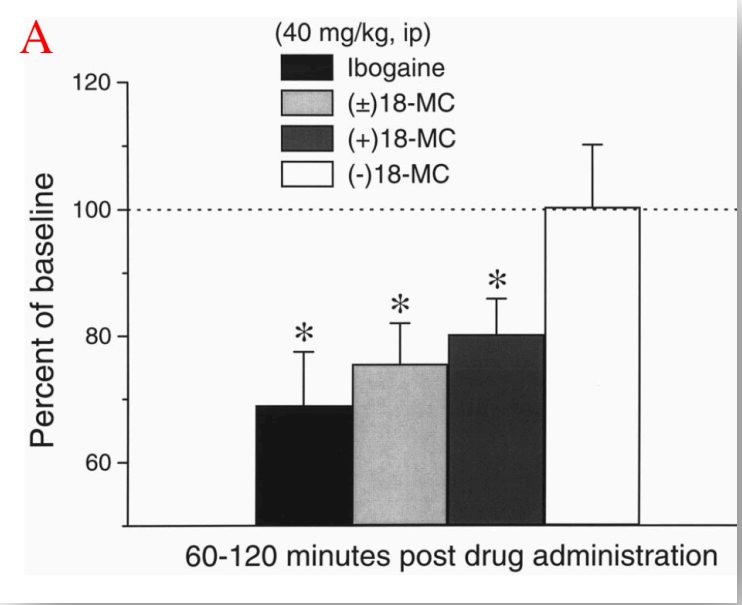
In contrast to Ibogaine, 18-MC does not reduce responding for a natural reinforcer, suggesting specificity of effects

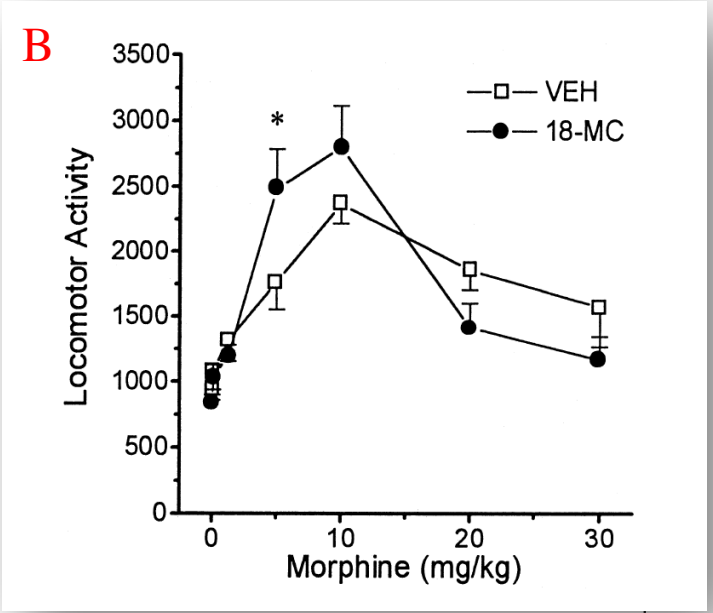


Glick & Maisonneuve, 2000

Reduces Dopamine Release

18-MC decreases (A) extracellular dopamine release in the accumbens and (B) dopamine sensitization following chronic morphine exposure



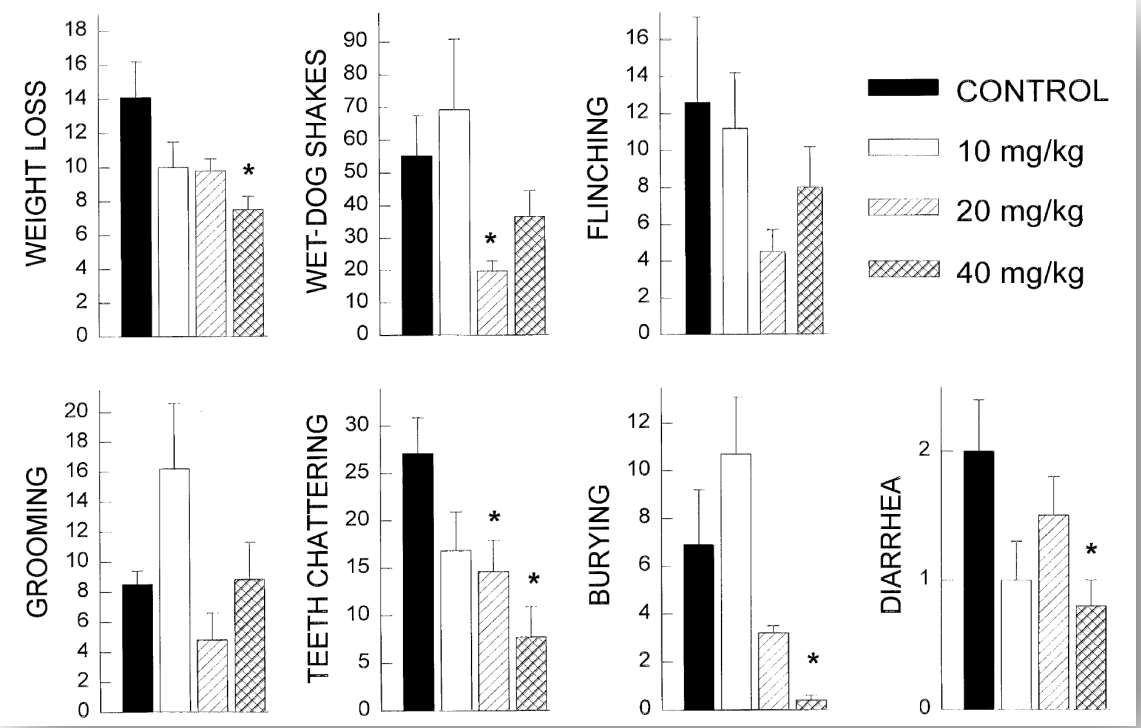


Glick & Maisonneuve, 2000

Szumlinski et al., 2000

Reduces Withdrawal Severity

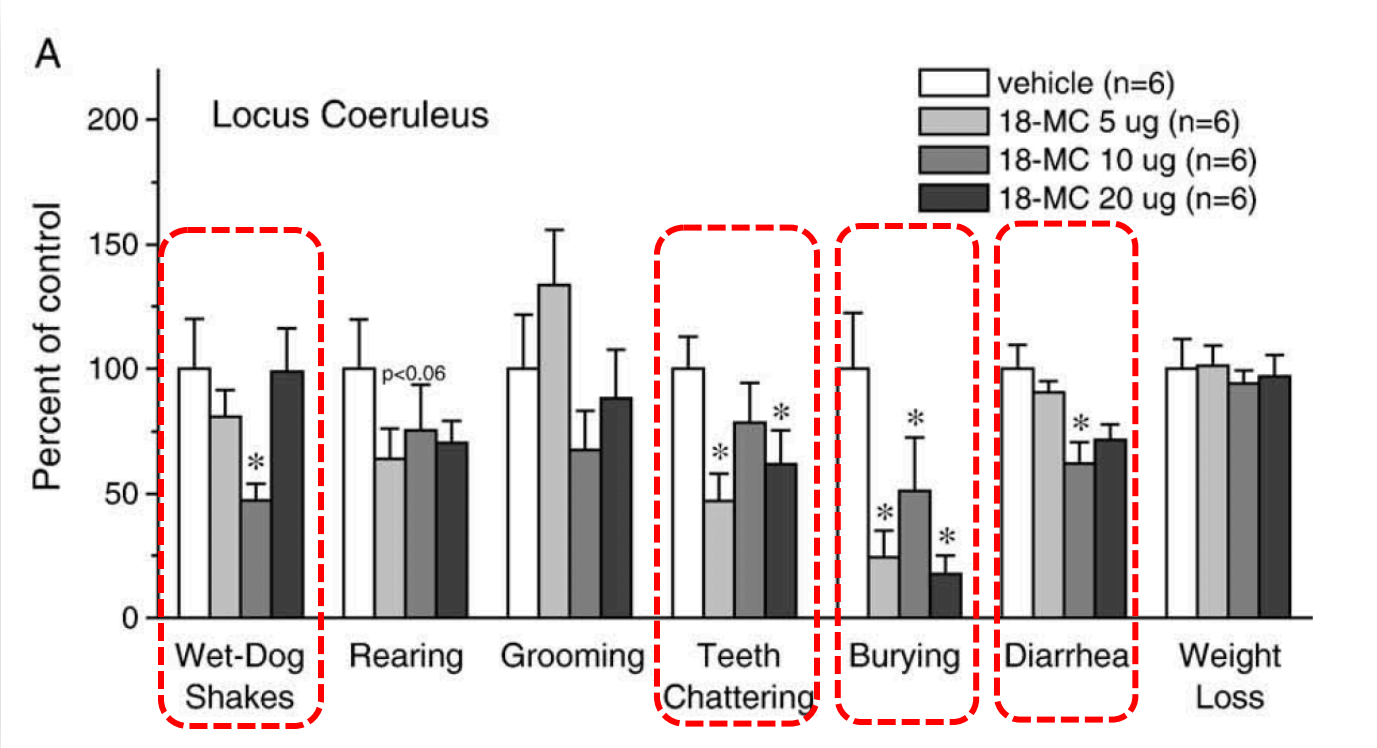
18-MC reduces severity of some withdrawal symptoms (not direct overlap with ibogaine).



Rho & Glick, 1998

Reduces Withdrawal Severity

Reductions likely driven by locus coeruleus



Panchal et al., 2005

Summary

	Ibogaine	18-MC
Primary mechanism of action	Less specific- low affinity agonist on NMDA, 5HT3, sigma-2, serotonin transporter; nicotinic antagonist	More specific- low affinity for opioid receptors and 5-HT3, antagonist at alpha 3 beta 4 nicotinic receptors
Opioid reinforcement	Decreased morphine self-administration	Decreased morphine self-administration
Natural reinforcers	Decreased responding for water	None noted
Withdrawal Severity	Decreases	Decreases, likely driven by activity in locus coeruleus
Adverse effects	Bradycardia; hallucinations; tremors	None noted (TBD?)

So Why Now?

Lofexidine (Lucemyra)

- Alpha-2 adrenergic agonist
- Approved by FDA in 2018 for indication of "mitigation of opioid withdrawal symptoms"
  - Recognized to not eliminate symptoms
- Not intended as OUD treatment
- Created a new approval pathway and indication

18-MC vs. Lofexidine

	18-MC	Lofexidine
Primary mechanism of action	New mechanism of action for OUD: Low affinity for opioid receptors and 5-HT3, antagonist at alpha 3 beta 4 nicotinic receptors	Well-established mechanism of action: Alpha-2 adrenergic agonist (autonomic nervous system)
Efficacy for withdrawal	TBD (supported by preclinical work)	Mild-Moderate (high variability in response) reduction of autonomically- mediated symptoms
Abuse Potential	None recognized	None recognized
Side Effect Profile	(TBD) Appears to be minimal	Bradycardia, mild cardiac risk, dosing adjusted for renal and kidney function
Medication Schedule	TBD (bolus dosing?)	QID, necessary dose taper

Overall Summary

- There remains a need to identify mechanistically-informed opioid withdrawal medications
- 18-MC may leverage some benefits observed with ibogaine in a safer manner
- Lofexidine established an FDA pathway for approval
- Lofexidine has some weaknesses that may limit its adoption or impact
- A cocktail treatment approach would be preferable

MM-110

Zolunicant HCl

Key Milestones

Phase 1 Topline Data Readout
Q2 2022 | Phase 1

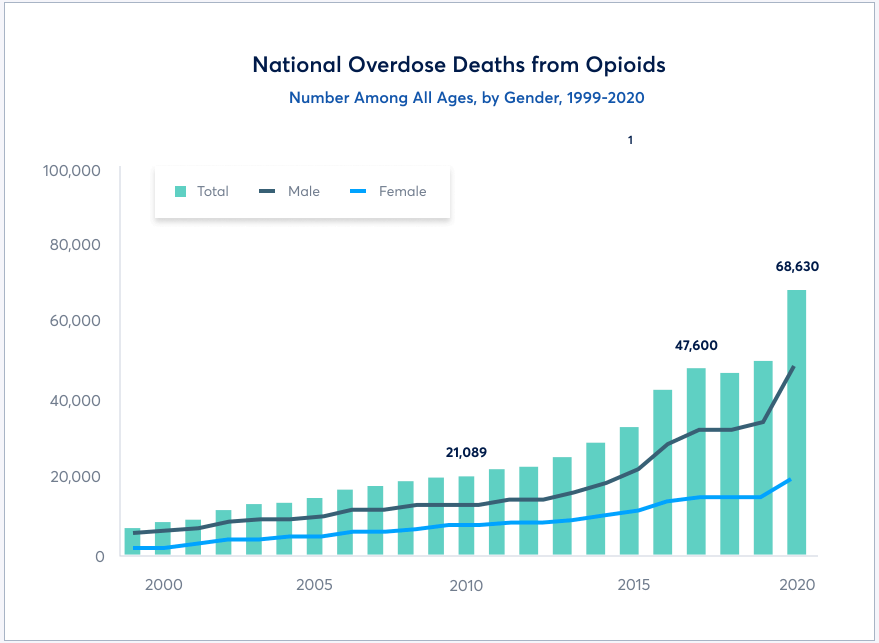
Opioid W/D Study Initiation
Q2 2022 | Phase 2a

Opioid W/D ESOE Readout
Q1 2023 | Phase 2a (Part A)

ESOE: early sign of efficacy; W/D: withdrawal

Significant Unmet Need for Opioid Use Disorder (OUD) Treatments

Dangerous relapses during withdrawal period are mediated by withdrawal symptoms



68,630 people in the US overdosed on opioids in 2020 [1]

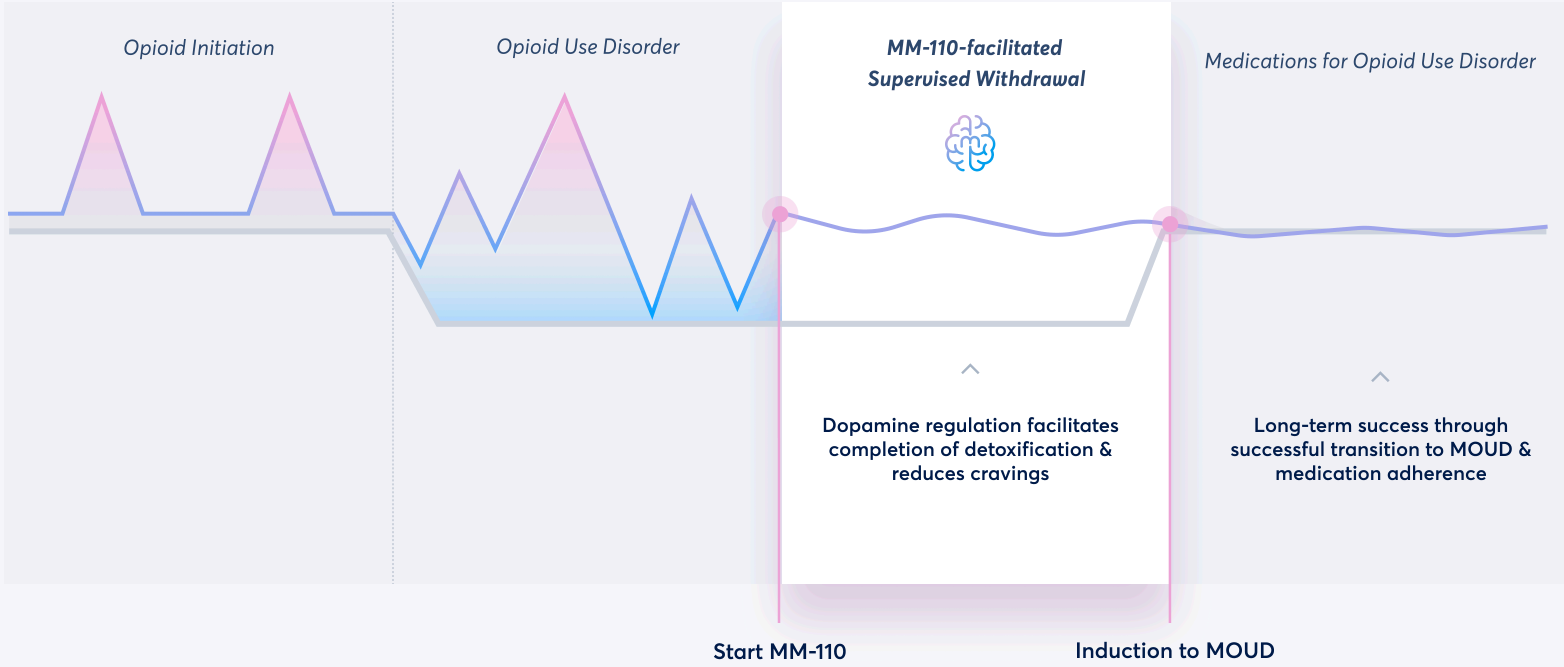
225% increase in opioid overdoses from 2010 to 2020 [1]

89% naltrexone induction failures were early relapses [1]

1. DrugAbuseStatistics.org/opioid-epidemic

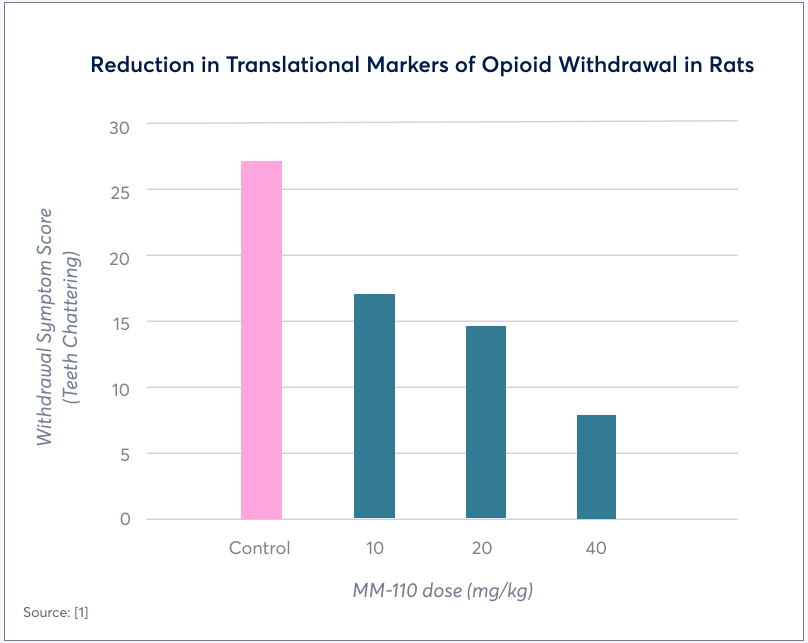
MM-110 | Novel Mechanism to Address a Critical Gap in OUD Treatment

Mechanism of action and target product profile complement standard-of-care and address a critical gap in available treatment landscape

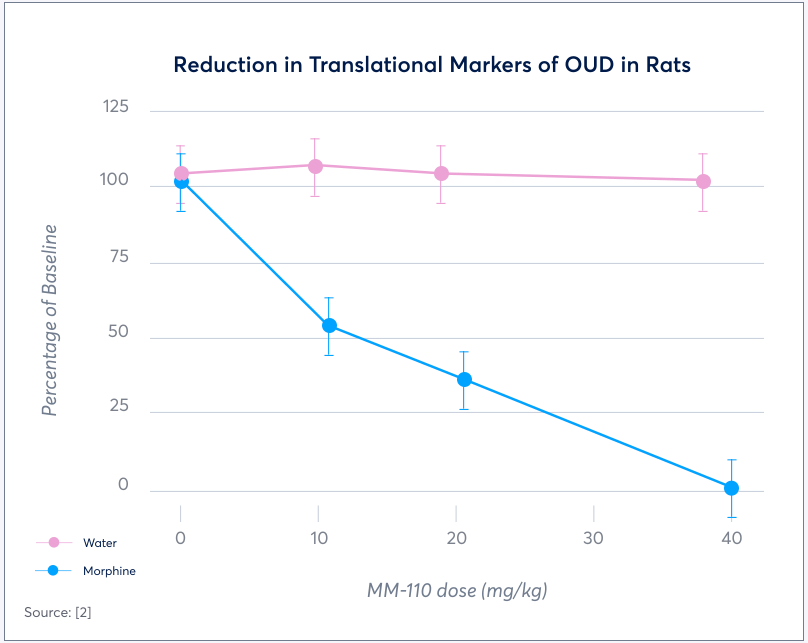


MM-110 | Strong Preclinical Activity on Key Translational Outcomes

A single dose of MM-110 mitigates withdrawal symptoms and opioid self-administration in preclinical models[1,2]



Source: [1]



Source: [2]

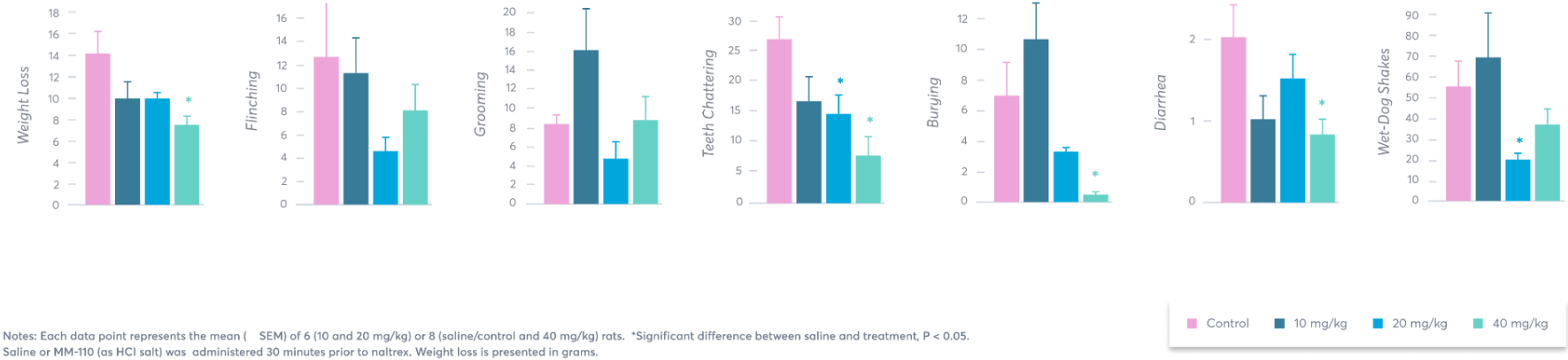
1. Rho & Glick 1998; NeuroReport; 9.
2. Maisonneuve & Glick 2003; Pharmacol Biochem Behav; 75.

MM-110 | Strong Preclinical Activity on Key Translational Outcomes

A single dose of MM-110 mitigates withdrawal symptoms and opioid self-administration in preclinical models[1,2]

Morphine Withdrawal Following a Single Dose of 10, 20 or 40 mg/kg MM-110 in Rats

(Rho & Glick 1998)



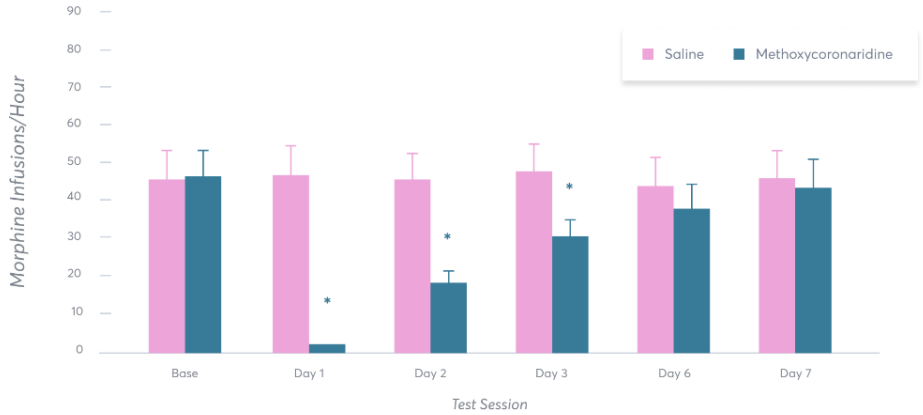
Notes: Each data point represents the mean (SEM) of 6 (10 and 20 mg/kg) or 8 (saline/control and 40 mg/kg) rats. *Significant difference between saline and treatment, P < 0.05. Saline or MM-110 (as HCl salt) was administered 30 minutes prior to naltrex. Weight loss is presented in grams.

1. Rho & Glick 1998; NeuroReport; 9.
2. Maisonneuve & Glick 2003; Pharmacol Biochem Behav; 75.

MM-110 | Strong Preclinical Activity on Key Translational Outcomes

A single dose of MM-110 mitigates withdrawal symptoms and opioid self-administration in preclinical models[1,2]

Self-Administration of Morphine over Seven Days after a Single Intraperitoneal Dose of 40 mg/kg MM-110 in Rats (Glick 1996)



Notes: Each data point represents the mean (SEM) of six rats. 'Base' is the baseline rate of responding, calculated as the average of 3 sessions preceding drug or saline treatment. *Significant differences between baseline and treatment, P<0.05 - 0.01. A single IP dose of 40 mg/kg MM-110 (as HCl; or 36.4 mg/kg freebase equivalent) was administered 15 minutes prior to Day 1 self-administration session. Morphine self-administration consisted of approximately 0.04 mg/kg/infusion over a 1 hour test session.

1. Rho & Glick 1998; NeuroReport; 9.
2. Maisonneuve & Glick 2003; Pharmacol Biochem Behav; 75.

MM-110 | Phase 1 Study Results - Key Takeaways

Phase 1 study results support progression of MM-110 (zolunicant) into planned upcoming Phase 2 clinical program

- **Well-tolerated** up to 500 mg per day in Single Ascending Dose (SAD) and 60 mg per day in the Multiple Ascending Dose (MAD)
- **Linear PK** maintained across the tested doses and frequencies
- **Clinical effects** align with potent CNS engagement
- **QOD regimen** aligns with preclinical evidence & offers potential to be a more effective regimen in opioid withdrawal

MM-110 | Phase 1 SAD/MAD Dosing Cohorts

Participants received up to 650mg of MM-110 on a single day or were administered up to 180mg/day for seven days or placebo

SUBSTANCE USE DISORDERS | **MM-110** *(zolunicant HCl; 18-MC)* | Indication: Opioid Withdrawal | PHASE 1

Cohort(s)	Zolunicant Dose Group BID	Safety (N=72)	
		Zolunicant n (%)	Placebo n (%)
1	4 mg	5 (6.9)	2 (2.8)
2	8 mg	5 (6.9)	2 (2.8)
3	12 mg	5 (6.9)	2 (2.8)
4	16 mg	5 (6.9)	2 (2.8)
8	25 mg	5 (6.9)	2 (2.8)
9	40 mg	5 (6.9)	2 (2.8)
10	75 mg	5 (6.9)	2 (2.8)
11	150 mg	5 (6.9)	2 (2.8)
12, 15	250 mg	10 (13.9)	4 (5.6)
13	325 mg	1 (1.4)	1 (1.4)
	Total:	**51 (70,8)**	**21 (29.2)**

Cohort	Zolunicant Dose Group BID x 7 Days	Safety (N=72)	
		Zolunicant n (%)	Placebo n (%)
5	2 mg	5 (13.9)	2 (5.6)
6	5 mg	5 (13.9)	2 (5.6)
7	10 mg	5 (13.6)	2 (5.6)
14	30 mg	5 (13.6)	2 (5.6)
16	90 mg	6 (16.7)	2 (5.6)
	Total:	**26 (72.2)**	**10 (27.8)**

- SAD well tolerated at doses up to 500mg/day
- MAD well tolerated at doses up to 60mg/day

Source: MindMed internal study documents

MM-110 | Phase 1 SAD/MAD Adverse Event Tables

Treatment emergent adverse events were mild or moderate in severity and resolved without sequelae

SUBSTANCE USE DISORDERS | **MM-110** *(zolunicant HCl; 18-MC)* | Indication: Opioid Withdrawal | **PHASE 1**

SOC/PT	Zolunicant x 1 Day n (%)										
	4 mg BID (N=5)	8 mg BID (N=5)	12 mg BID (N=5)	16 mg BID (N=5)	25 mg BID (N=5)	40 mg BID (N=5)	75 mg BID (N=5)	150 mg BID (N=5)	250 mg BID (N=10)	325 mg BID (N=5)	Placebo (pooled) N=21
Any Related TEAE	0	**0**	**1 (20)**	**1 (20)**	**2 (40)**	**0**	**1 (20)**	**1 (20)**	**7 (70)**	**1 (100)**	**4 (19)**
Eye Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1 (100)**	**0**
Vision Blurred	0	0	0	0	0	0	0	0	0	1 (100)	0
GI Disorders	**0**	**0**	**0**	**0**	**2 (40)**	**0**	**1 (20)**	**0**	**3 (30)**	**0**	**1 (4.8)**
Abdominal Distention	0	0	0	0	0	0	1 (20)	0	0	0	0
Abdominal Pain	0	0	0	0	0	0	0	0	1 (10)	0	1 (4.8)
Nausea	0	0	0	0	2 (40)	0	0	0	3 (30)	0	0
Vomiting	0	0	0	0	0	0	0	0	1 (10)	0	0
General Disorders & Admin. Site Conditions	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1 (100)**	**0**
Fatigue	0	0	0	0	0	0	0	0	0	1 (100)	0
Musculoskeletal & Connective Tissue Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2 (20)**	**0**	**0**
Limb Discomfort	0	0	0	0	0	0	0	0	1 (10)	0	0
Muscle Tightness	0	0	0	0	0	0	0	0	1 (10)	0	0
Nervous System Disorders	**0**	**0**	**1 (20)**	**1 (20)**	**2 (40)**	**0**	**0**	**1 (20)**	**6 (60)**	**1 (100)**	**2 (9.5)**
Ataxia	0	0	0	0	0	0	0	0	0	1 (100)	0
Disturbance in Attention	0	0	0	0	0	0	0	0	0	1 (100)	0
Dizziness	0	0	0	1 (20)	1 (20)	0	0	0	4 (40)	0	2 (9.5)
Headache	0	0	1 (20)	0	1 (20)	0	0	1 (20)	0	0	1 (4.8)
Presyncope	0	0	0	0	0	0	0	0	1 (10)	0	0
Visual Perseveration	0	0	0	0	0	0	0	0	1 (10)	0	0
Psychiatric Disorders	**0**	**0**	**0**	**0**	**1 (20)**	**0**	**0**	**0**	**0**	**0**	**1 (4.8)**
Abnormal Dreams	0	0	0	0	0	0	0	0	0	0	1 (4.8)
Bradyphrenia	0	0	0	0	1 (20)	0	0	0	0	0	0

SOC/PT	Zolunicant x 1 Day n (%)					
	4 mg BID (N=5)	5 mg BID (N=5)	10 mg BID (N=5)	30 mg BID (N=5)	90 mg BID (N=5)	Placebo (pooled) N=21
Any Related TEAE	**0**	**2 (40)**	**0**	**2 (40)**	**5 (83.3)**	**1 (10)**
Eye Disorders	**0**	**0**	**0**	**0**	**1 (16.7)**	**1 (10)**
Blepharospasm	0	0	0	0	0	1 (10)
Visual Impairment	0	0	0	0	1 (16.7)	0
GI Disorders	**0**	**1 (20)**	**0**	**2 (40)**	**2 (33.3)**	**1 (10)**
Musculoskeletal & Connective Tissue Disorders	**0**	**0**	**0**	**0**	**0**	**1 (10)**
Muscle Twitching	0	0	0	0	0	1 (10)
Nervous System Disorders	**0**	**1 (20)**	**0**	**1 (20)**	**1 (16.7)**	**1 (10)**
Dizziness	0	1 (20)	0	0	0	0
Headache	0	0	0	1 (20)	1 (16.7)	0
Muscle Contractions Involuntary	0	0	0	0	0	1 (10)
Paraesthesia	0	0	0	1 (20)	0	0
Psychiatric Disorders	**0**	**1 (20)**	**0**	**0**	**3 (50)**	**0**
Abnormal Dreams	0	1 (20)	0	0	0	0
Anhedonia	0	0	0	0	1 (16.7)	0
Depressed Mood	0	0	0	0	1 (16.7)	0
Mania	0	0	0	0	1 (16.7)	0

Note: SOC and PT were assigned using MedDRA version 23.0. Multiple events in the same SOC and PT were counted only once at each level of summation. Percentages were ased on the number of subjects in the Safety population.

Related refers to the Investigator's assessment that the TEAE was possibly, probably, or had a highly probable relatedness to the study drug.

MM-110 | Phase 1 SAD/MAD Adverse Event Summaries

Across the SAD and MAD cohorts, only 5 TEAE led to discontinuation of MM-110 and there were no serious adverse events

SUBSTANCE USE DISORDERS | **MM-110** *(zolunicant HCl; 18-MC)* | Indication: Opioid Withdrawal | PHASE 1

	Zolunicant BID x 1 day n (%)									
	4 mg (N=5)	8 mg (N=5)	12 mg (N=5)	16 mg (N=5)	25 mg (N=5)	40 mg (N=5)	75 mg (N=5)	150 mg (N=5)	250 mg (N=10)	325 mg (N=1)
TEAE	1 (20)	0	2 (40)	2 (40)	4 (80)	2 (40)	4 (80)	3 (60)	10 (100)	1 (100)
Related TEAE	0	0	1(20)	1(20)	2 (40)	0	1 (20)	1 (20)	7 (70)	1 (100)
Drug withdrawn due to TEAE	0	0	0	0	0	0	0	0	1 (10)	1 (100)

	Zolunicant BID x 7 day n (%)					
	2 mg (N=5)	5 mg (N=5)	10 mg (N=5)	30 mg (N=5)	90 mg (N=5)	Placebo (pooled) N=21
TEAE	4 (80)	5 (100)	5 (100)	5 (100)	6(100)	8 (80)
Related TEAE	0	2 (40)	0	2 (40)	5 (83.3)	1 (10)
Drug withdrawn due to TEAE	0	0	0	0	4 (66.7)	0

- Clinical laboratory parameters and electrocardiograms were assessed with no findings of clinical concern across the administered dose ranges

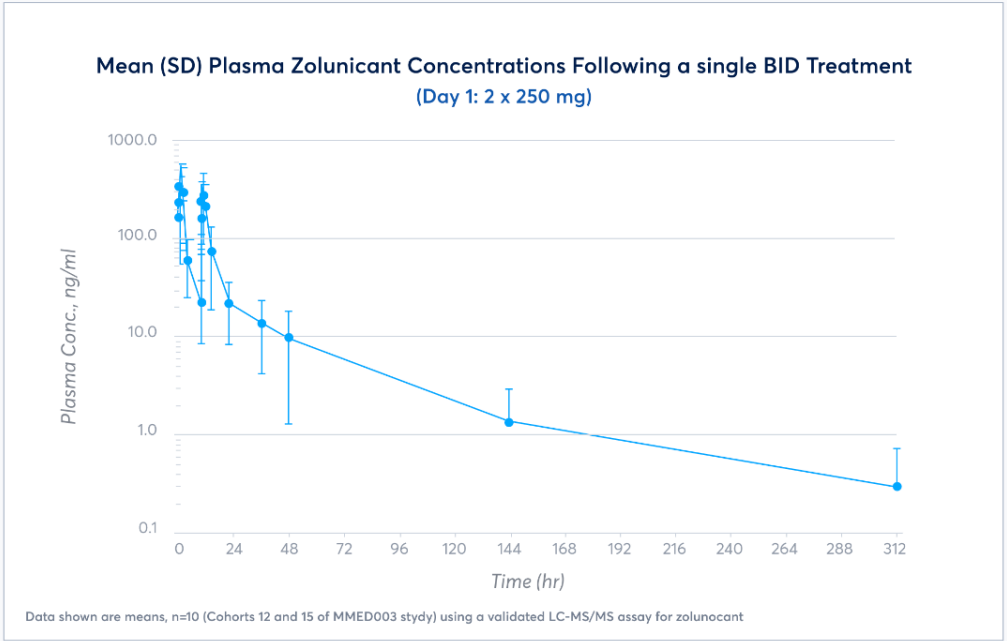
Related refers to the Investigator's assessment that the TEAE was possibly, probably, or had a highly probable relatedness to the study drug.

Source: MindMed internal study documents

MM-110 | Phase 1 SAD PK Curve

A linear pharmacokinetic profile was observed even at the highest doses

SUBSTANCE USE DISORDERS | **MM-110** *(zolunicant HCl; 18-MC)* | Indication: Opioid Withdrawal | PHASE 1



Source: MindMed internal study documents

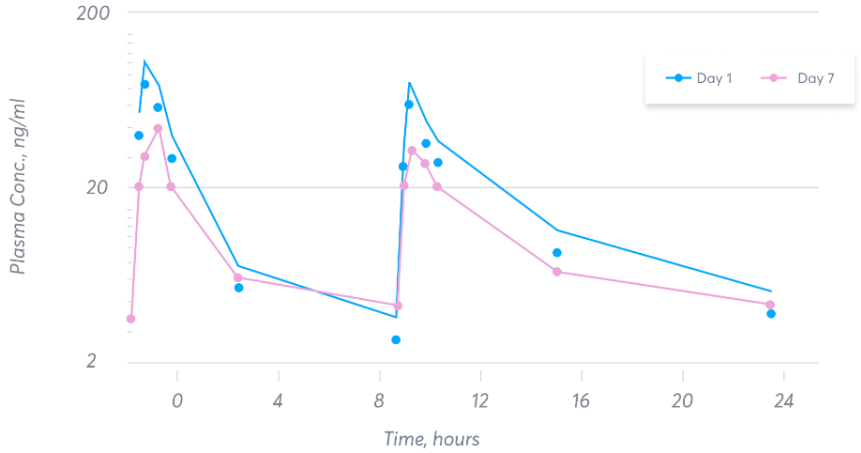
ESOE: early sign of efficacy; POC: proof of concept; QOD: Every Other Day (dosage timing); SOWS: Subjective Opiate Withdrawal Scale

MM-110 | Phase 1 MAD Comparison PK Curve

The pharmacokinetic profile was maintained across the tested doses and SAD/MAD dosing schedules.

SUBSTANCE USE DISORDERS | **MM-110** *(zolunicant HCl; 18-MC)* | Indication: Opioid Withdrawal | PHASE 1

Comparison of Mean Plasma Zolunicant Concentration Profiles on Day 1 and Day 7 during Multiple Dosing with Zolunicant at 30 mg BID (60 mg/day)



Data shown are means, n=5 (Cohort 14 of Study MMED003) using validated LC-MS/MS assay for zolunicant

Source: MindMed internal study documents

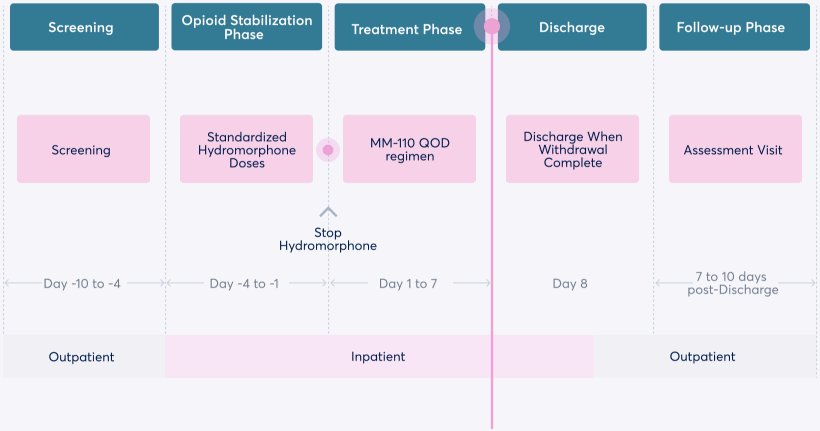
ESOE: early sign of efficacy; POC: proof of concept; QOD: Every Other Day (dosage timing); SOWS: Subjective Opiate Withdrawal Scale

MM-110 | Phase 2a Supervised Withdrawal in Opioid Use Disorder

Gated two-part study design provides opportunity for early signs of efficacy (ESOE) and informs randomized proof of concept design

SUBSTANCE USE DISORDERS | **MM-110** *(zolunicant HCl; 18-MC)* | Indication: Opioid Withdrawal | PHASE 2A

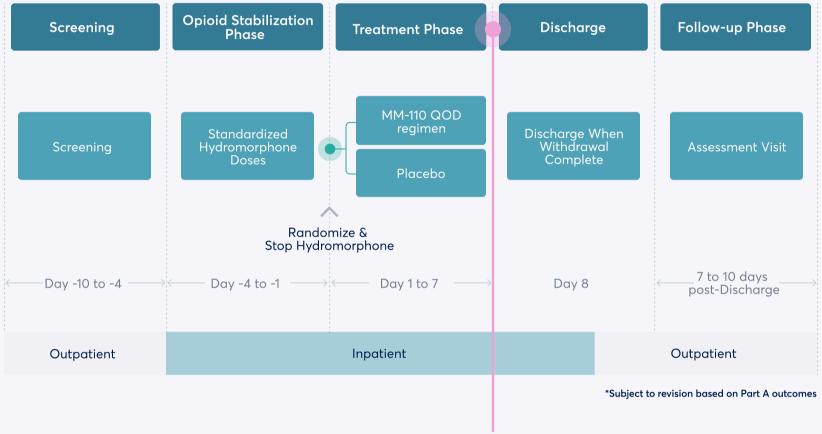
Part A | Open-Label Early Sign of Efficacy in Opioid Withdrawal (n=10)



Primary Endpoint

Mean SOWS-Gossop score over first 5 days of Treatment Phase

Part B | Randomized Placebo-Controlled POC in Opioid Withdrawal (n=42/arm*)



*Subject to revision based on Part A outcomes

Interim Readout

Primary Endpoint

Mean SOWS-Gossop score over first 5 days of Treatment Phase

Source: MindMed internal study documents

ESOE: early sign of efficacy; POC: proof of concept; QOD: Every Other Day (dosage timing); SOWS: Subjective Opiate Withdrawal Scale

Q&A