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First Dose Treatment Effects With Weekly and Monthly Injectable Buprenorphine (CAM2038) and the Relationship Between Plasma Concentrations and Withdrawal Suppression

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Disclosures

- Michael P. Frost has received consulting/speaking honoraria from Braeburn Inc, consultant fees from Molteni Farmaceutici and Accord Healthcare, and is a shareholder of Pinova Therapeutics
- Edward V. Nunes is an investigator on NIH-funded studies that have received in-kind donations of medications or digital therapeutics from Braeburn Inc, Camurus AB, CHESS Health, Indivior, and Pear Therapeutics
- Michelle R. Lofwall has received consultant fees from Berkshire Biomedical, Braeburn Inc, and Sophrosyne Pharmaceuticals and honorarium for a research talk from Camurus in the last 3 years
- Sharon L. Walsh has received consultant fees for advising on the development and use of products for the treatment of OUD from Cerevel Therapeutics, Braeburn Inc, Kinoxis Therapeutics, Reacx Pharmaceuticals, Titan Pharmaceuticals, and Opiant Pharmaceuticals, and has participated in advisory board meetings with Braeburn Inc in the last 3 years
- Genie L. Bailey and Brian J. Dawson have received consulting/speaking honoraria from Braeburn Inc
- Natalie R. Budilovsky-Kelley, Adam Friedman, Carrie Kaempfer, and Joshua M. Cohen are employees of Braeburn Inc

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Introduction

Early Research

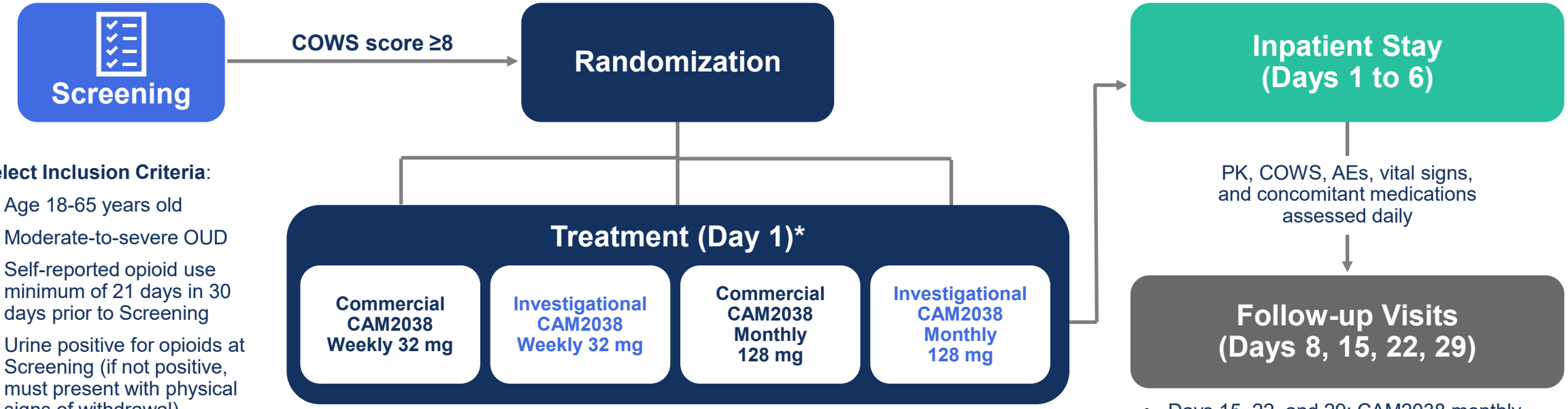
Early research reported an association between higher buprenorphine plasma concentrations and withdrawal suppression and suggested that plasma concentrations of 1 to 2 ng/mL were needed to control withdrawal in patients with opioid use disorder[1–3]

Recent Evidence

More recent research, however, indicates that withdrawal is effectively suppressed in most patients at buprenorphine plasma concentrations as low as 0.1 ng/mL[3,4]

1. Kuhlman JJ Jr, et al. *Addiction*. 1998;93(4):549–559. 2. Greenwald M, et al. *Biol Psychiatry*. 2007;61(1):101–110. 3. Nasser AF, et al. *Clin Pharmacokinet*. 2014;53(9):813-824. 4. Laffont CM, et al. *Front Pharmacol*. 2022;13:1052113. 5. Walsh SL, et al. *Neuropsychopharmacology*. 2024;49(6):1050–1057.

PK Study Design



Select Inclusion Criteria:

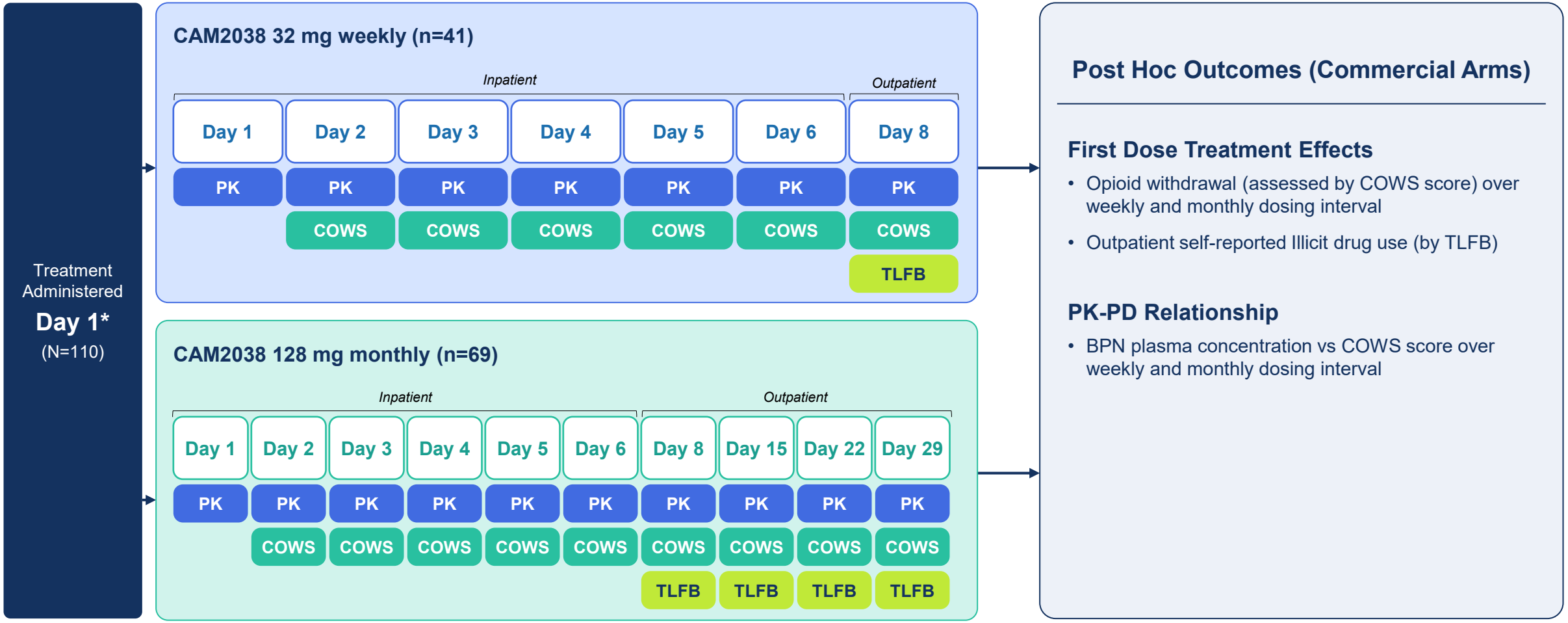
- Age 18-65 years old
- Moderate-to-severe OUD
- Self-reported opioid use minimum of 21 days in 30 days prior to Screening
- Urine positive for opioids at Screening (if not positive, must present with physical signs of withdrawal)
- BMI 18.5 kg/m^2 to 35 kg/m^2

*Participants received SL-BPN 4 mg test dose and were monitored for 4 hours prior to CAM2038 administration

- Days 15, 22, and 29: CAM2038 monthly groups only
- PK, COWS, AEs, self-reported illicit drug use (TLFB), vital signs, and concomitant medications assessed at each follow-up visit

AE, adverse event; BMI, body mass index; COWS, clinical opiate withdrawal scale; OUD, opioid use disorder; PK, pharmacokinetic; SL-BPN, sublingual buprenorphine; TLFB, timeline follow back.

Post Hoc Analysis Design



*During the 2-week period preceding CAM2038 administration (Day -13 to Day 1), participants were assessed for self-reported illicit drug use using timeline follow back (TLFB); prior to CAM2038 administration on Day 1, COWS score was assessed (≥8 required prior to proceeding with SL-BPN 4 mg test dose) and pre- and post- test dose PK samples were collected.

BPN, buprenorphine; COWS, Clinical Opiate Withdrawal Scale; PK, pharmacokinetic; PK-PD, pharmacokinetic-pharmacodynamic; SL-BPN, sublingual buprenorphine; TLFB, timeline follow back.

Baseline Characteristics

	CAM2038 32mg Weekly (n=41)	CAM2038 128 mg Monthly (n=69)
Mean (SD) age	41.1 (10.49)	38.9 (8.27)
Gender at birth, n (%)		
Male	24 (58.5)	43 (62.3)
Female	17 (41.5)	26 (37.7)
Race, n (%)		
White	25 (61.0)	35 (50.7)
Black or African American	14 (34.1)	31 (44.9)
Other	1 (2.4)	2 (2.8)
Not Reported	1 (2.4)	1 (1.4)
Ethnicity, n (%)		
Hispanic or Latino	6 (14.6)	13 (18.8)
Not Hispanic or Latino	31 (75.6)	55 (79.7)
Not Reported or unknown	4 (9.8)	1 (1.4)
Primary opioid used at initiation of treatment, n (%)		
Heroin	9 (22.0)	14 (20.3)
Prescription opioids	8 (19.5)	15 (21.7)
Synthetic opioid (fentanyl)	21 (51.2)	37 (53.6)
Other	3 (7.3)	3 (4.3)

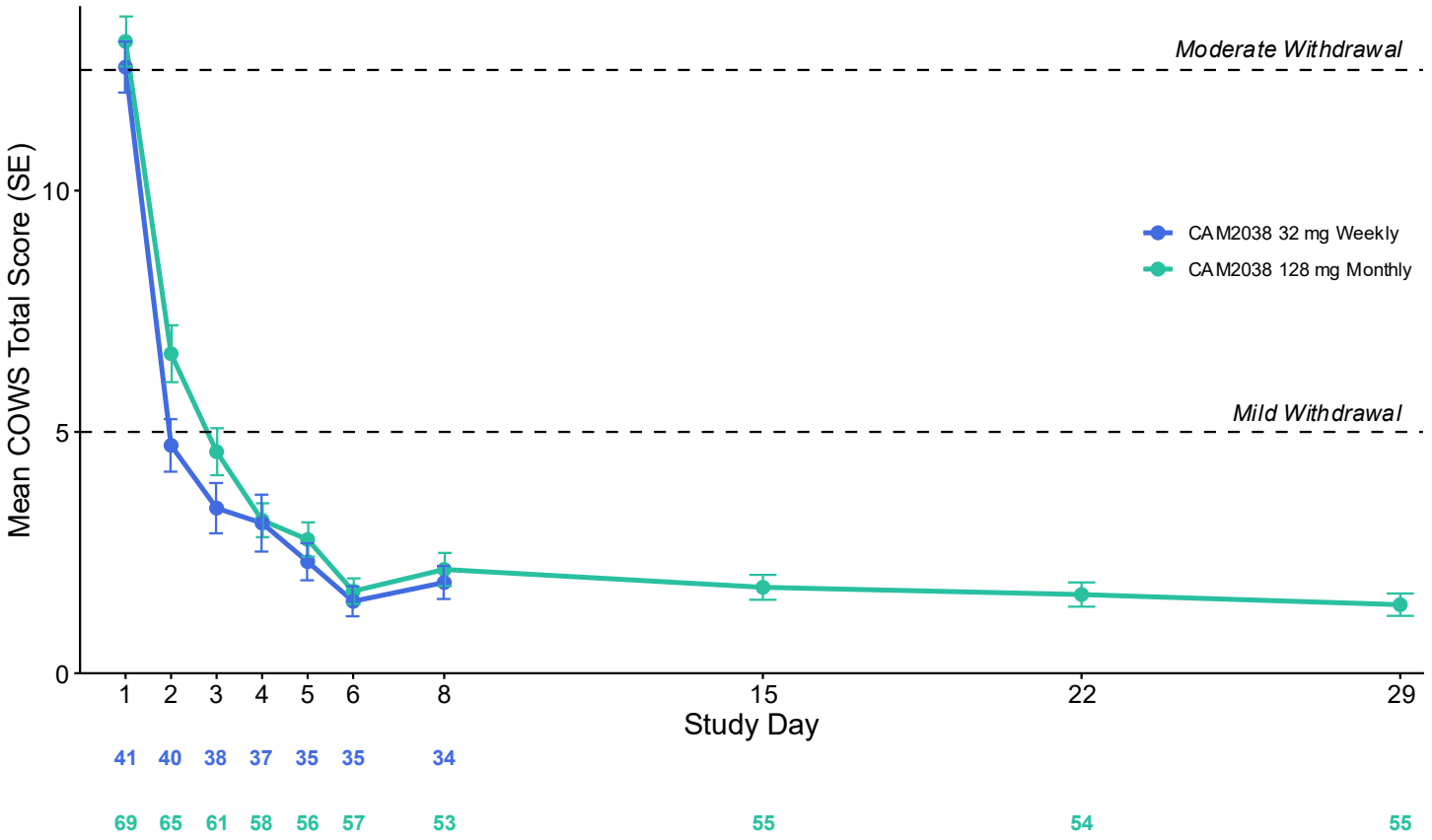
SD, standard deviation.

Baseline Urine Drug Screen Results

	CAM2038 32mg Weekly (n=41)	CAM2038 128 mg Monthly (n=69)
Substance for which UDS was positive, n (%)		
THC	21 (51.2%)	36 (52.2%)
Oxycodone	15 (36.6%)	20 (29.0%)
Fentanyl	27 (65.9%)	47 (68.1%)
Amphetamine	19 (46.3%)	25 (36.2%)
Cocaine	10 (24.4%)	20 (29.0%)
Benzodiazepines	6 (14.6%)	15 (21.7%)
Heroin	3 (7.3%)	3 (4.3%)
Other	23 (56.1%)	36 (52.2%)
Methamphetamine	18 (43.9%)	22 (31.9%)
MDMA	9 (22.0%)	14 (20.3%)
PCP	3 (7.3%)	1 (1.4%)
Morphine	7 (17.1%)	10 (14.5%)

UDS, urine drug screen.

Opioid Withdrawal Suppression Over Time by Treatment Group

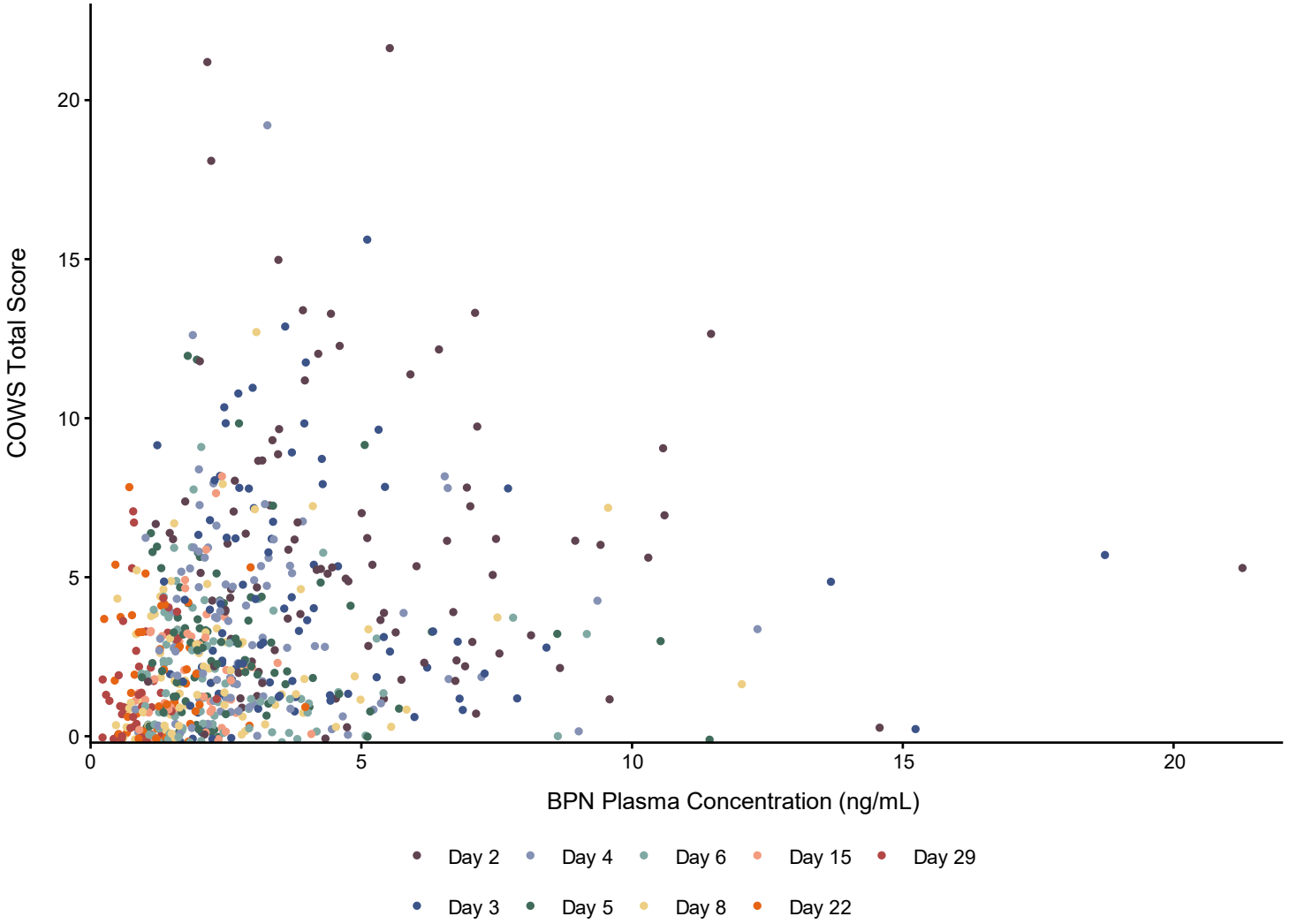


	Mean COWS Score	
Assessment Period	**CAM2038 32 mg Weekly**	**CAM2038 128 mg Monthly**
Baseline (pre-dose)	12.56	13.09
End of dosing interval*	1.88	1.42
Proportion of COWS scores <5	91.2%	94.5%
Prior to dropout	2.50	4.69
Entire study	2.88	2.96

*Day 8 for CAM2038 Weekly; Day 29 for CAM2038 Monthly.

COWS, clinical opiate withdrawal scale; SE, standard error.

BPN Plasma Concentrations vs COWS Scores

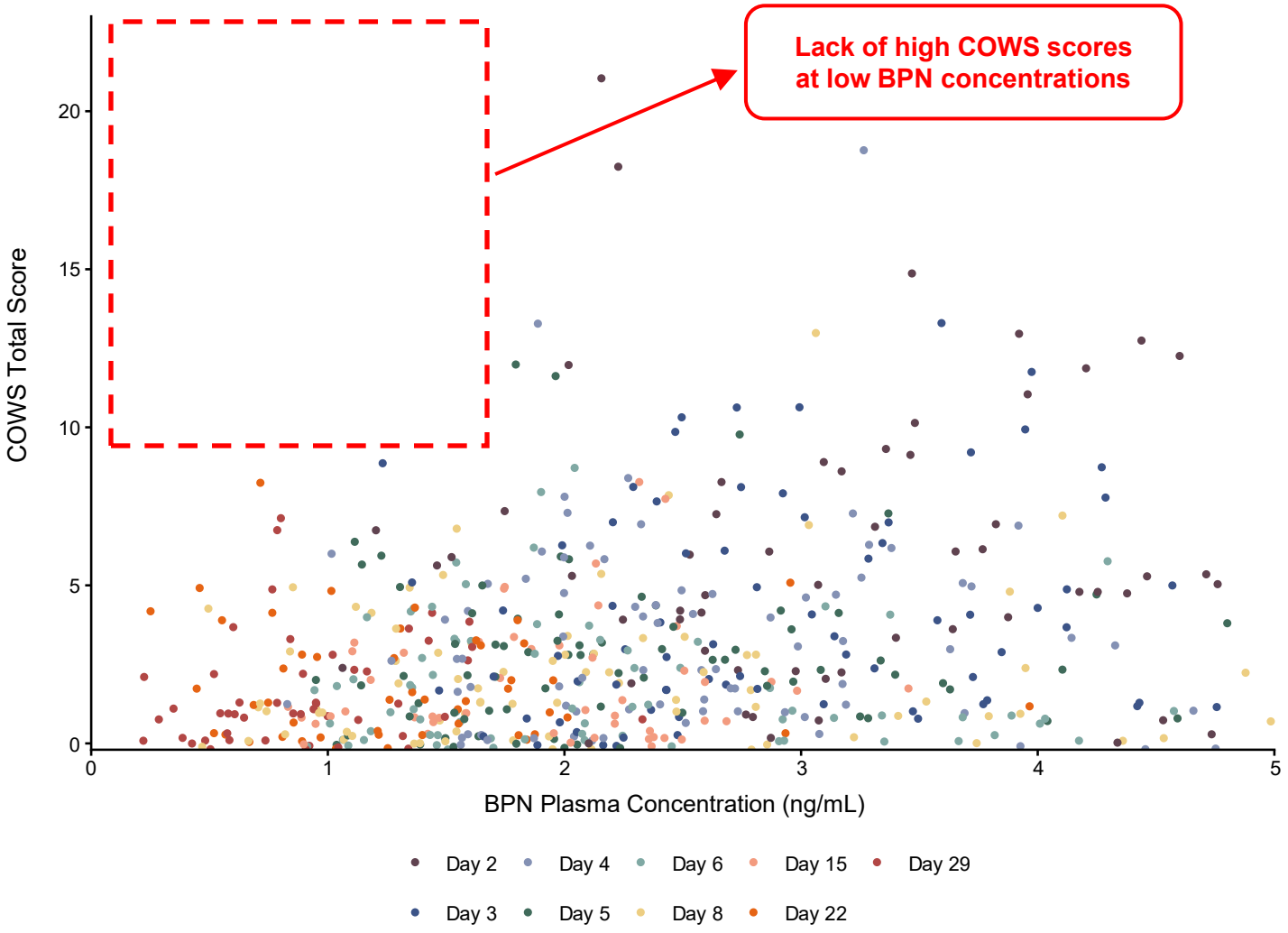


Spearman Correlation Coefficients for BPN Plasma Concentration vs COWS Scores

Timepoint	n	Correlation Coefficient	P value
Day 2	99	-0.025	0.804
Day 3	94	0.135	0.194
Day 4	94	0.089	0.396
Day 5	91	0.014	0.895
Day 6	90	0.002	0.988
Day 8	86	0.136	0.213
Day 15	53	-0.060	0.668
Day 22	54	-0.034	0.810
Day 29	55	0.208	0.127

BPN, buprenorphine; COWS, clinical opiate withdrawal scale.

BPN Plasma Concentrations (0-5 ng/mL) vs COWS Scores



BPN Plasma Concentrations vs COWS Scores

BPN Plasma Concentration, n	COWS Score <5	COWS Score 5-12	COWS Score >12
<2 ng/mL (n=299)	87.3%	12.4%	0.3%
<0.5 ng/mL (n=12)	91.7%	8.3%	0.0%
0.5 to <1 ng/mL (n=69)	92.8%	7.2%	0.0%
1 to <2 ng/mL (n=218)	85.3%	14.2%	0.5%
≥2 ng/mL (n=417)	70.7%	26.4%	2.9%

BPN, buprenorphine; COWS, clinical opiate withdrawal scale.

Self-Reported Illicit Opioid Use Over Time by Treatment Group*

CAM2038 32 mg Weekly

Substance	Baseline (n=40)	Week 1 (n=28)
Opioids	95.0%	14.3%
Cannabis	40.0%	35.7%
Benzodiazepines	2.5%	0.0%
Amphetamines	40.0%	7.1%
Cocaine	5.0%	0.0%
Crack	5.0%	0.0%

CAM2038 128 mg Monthly

Baseline (n=68)	Week 1 (n=56)	Week 2 (n=52)	Week 3 (n=52)	Week 4 (n=51)
92.6%	14.3%	23.1%	17.3%	17.6%
47.1%	28.6%	28.8%	32.7%	29.4%
11.8%	5.4%	3.8%	1.9%	2.0%
39.7%	25.0%	21.2%	21.2%	13.7%
17.6%	0.0%	7.7%	1.9%	3.9%
11.8%	3.6%	5.8%	3.8%	2.0%

*Participants were inpatient from Days 1 to 6; self-reported illicit drug use was assessed by timeline follow back prior to Day 1 administration (baseline) and at outpatient visits on Day 8 (Week 1; lighter blue = inpatient/outpatient), Day 15 (Week 2), Day 22 (Week 3), and Day 29 (Week 4).

Safety

Participants with at least one:	CAM2038 32 mg Weekly (n=41)	CAM2038 128 mg Monthly (n=69)
TEAE related to study drug, n (%)	5 (12.2)	28 (40.6)
Moderate or higher TEAE, n (%)	3 (7.3)	12 (17.4)
Severe or higher TEAE, n (%)	0 (0.0)	3 (4.3)
Life-threatening or higher TEAE, n (%)	0 (0.0)	0 (0.0)
Serious TEAE, n (%)	0 (0.0)	1 (1.4)
Injection site reaction TEAE, n (%)	3 (7.3)	10 (14.5)
TEAE leading to study discontinuation, n (%)	0 (0.0)	1 (1.4)

TEAE, treatment-emergent adverse event.

Limitations

1. This PK-PD analysis was post hoc and exploratory, and was not prospectively designed to evaluate the relationship between buprenorphine plasma concentrations and withdrawal suppression

2. Results were based on single-dose weekly and monthly CAM2038 and further research may be valuable to confirm these findings in a broader clinical context

PK-PD, pharmacokinetic-pharmacodynamic.

Conclusions

- Rapid and sustained opioid withdrawal suppression was observed in participants with moderate-to-severe OUD treated with weekly and monthly CAM2038
- COWS scores <5 were consistently recorded in participants at the end of the weekly and monthly dosing interval, including in those with the lowest observed BPN plasma concentrations
- Self-reported illicit use of opioids and other drugs declined across weekly and monthly dosing intervals
- These findings reinforce known treatment effects of weekly and monthly CAM2038 and indicate that very low BPN plasma concentrations can effectively suppress withdrawal and reduce illicit opioid use

BPN, buprenorphine; COWS, clinical opiate withdrawal scale; OUD, opioid use disorder.