Impact of baseline factors on opioid negative urine tests among patients with opioid use disorder receiving weekly/monthly extended-release injectable buprenorphine (CAM2038) vs daily sublingual buprenorphine/naloxone

S134

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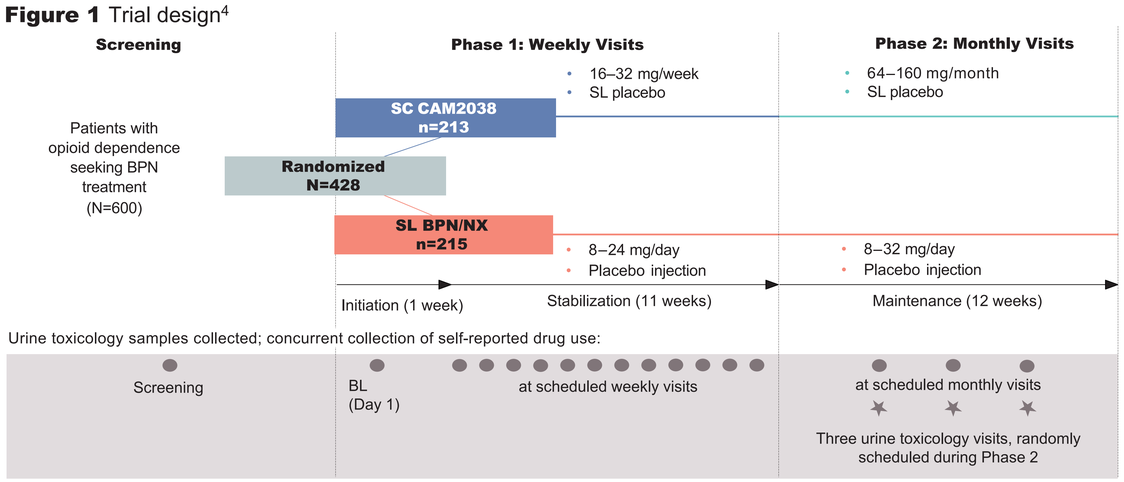
Introduction

- In the USA, OUD has been reported in approximately 2.7 million people; however, the true number may be as high as 7 million people[1,2]
- In 2022, 80,000 opioid overdose deaths were reported in the USA[3]
- Weekly and monthly CAM2038, an SC BPN depot, has been shown to be efficacious for the treatment of OUD in a Phase 3 randomized clinical trial (NCT02651584; **Figure 1**):[4]
  - Overall, 428 participants (men, 61.4%; women, 38.6%; mean [SD] age, 38.4 [11.0] years) were randomized to SL BPN/NX (n=215) or CAM2038 (n=213; **Table 1**)[4]
  - Non-inferiority of CAM2038 to SL BPN/NX was demonstrated for EMA and FDA primary outcomes of mean percentage of opioid-negative urine samples for 24 weeks and responder rate, respectively; responder rate was defined as having no evidence of illicit opioid use in Phase 1 at Week 12 and for at least two of three assessments at Weeks 9 to 11, and in Phase 2 for at least five of six assessments from Weeks 12 to 24, including Month 6[4]
  - CAM2038 was superior to SL BPN/NX on an *a priori* secondary outcome evaluated by a CDF of the proportion of opioid-negative urine samples between Weeks 4 and 24[4]
    - This was also found in patients who inject opioids at baseline, with CDF of the proportion of opioid-negative urine samples between Weeks 4 and 24 being significantly higher in the CAM2038 group versus the SL BPN/NX group (median: 16.7% versus 0%, p<0.001; mean: 30.9% versus 15.4%, p<0.001)[4]
  - CAM2038 achieved similar retention to SL BPN/NX[4]
  - In general, the safety profiles of CAM2038 and SL BPN/NX were comparable, except some mild to moderate injection site reactions[4]
- While CAM2038 has been shown to be efficacious in the treatment of OUD, there are certain BL characteristics that can be poor prognostic factors:[5–7]
  - Injection use (versus oral/intranasal drug use) and psychiatric comorbidities have been found to be poor diagnostic factors for OUD treatment outcomes[5,6]
  - Polydrug users are at an increased risk of on top use and relapse[7]

Figure 1 Trial design[4]



There was a 1-month follow-up after Phase 2.

Table 1 Patient demographics and baseline characteristics of the ITT population from the Phase 3 trial[4]

Characteristic	Treatment group[a] CAM2038 (n=213)	SL BPN/NX (n=215)
Age, years, mean (SD)	38.7 (11.2)	38.0 (10.9)
Male, n (%)	121 (56.8)	142 (66.0)
White, n (%)	159 (74.6)	164 (76.3)
BMI, mean (SD)	26.0 (5.0)	26.0 (5.6)
Primary opioid of use, n (%)		
Heroin	152 (71.4)	151 (70.2)
Prescription opioids	61 (28.6)	64 (29.8)
Fentanyl use, n (%)	62 (29.1)	49 (22.8)
Baseline craving and withdrawal scores, mean (SD)		
COWS score[b]	12 (5.4)	12 (6.0)
SOWS score[c]	32 (15.4)	31 (16.1)
Need-to-use VAS[d]	77 (25.4)	76 (24.9)
Desire-to-use VAS[e]	77 (26.2)	77 (25.4)

[a]No significant differences between groups; [b]Scores range from 0 (no withdrawal) to 48 (severe withdrawal); [c]Scores range from 0 (no withdrawal) to 64 (severe withdrawal); [d]Scores range from 0 (no need to use) to 100 (maximum need to use since the last visit); [e]Scores range from 0 (no desire to use) to 100 (maximum desire to use since the last visit).

Objective

- The aim of this *post hoc* analysis was to evaluate the impact of individual BL factors (i.e. subgroups) on the EMA primary efficacy outcome (UDT) from the Phase 3 trial comparing weekly and monthly CAM2038 with SL BPN/NX among treatment-seeking adults with moderate to severe OUD (N=428)

Methods

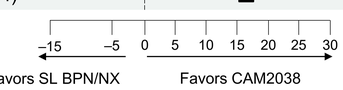
- This was a *post hoc* analysis of an outpatient randomized double-blind, double-dummy 24-week trial comparing weekly and monthly CAM2038 with SL BPN/NX for the treatment of patients with OUD (NCT02651584)[4]
- The primary efficacy outcome measured UDT results negative for illicit opioids between Weeks 1 and 24; a total of 18 urine tests were collected
- UDT results negative for illicit opioids was compared between CAM2038 and SL BPN/NX for the various subgroups of patients with OUD: substance use, concomitant psychiatric disorder, employment status and use of illicit opioids by intravenous route at BL (**Figure 2**)
- Additionally, COWS scores, SOWS scores and need- and desire-to-use opioid VAS outcomes were also assessed in the subgroups with significant impact on the primary outcome

Results

- Demographics and BL characteristics of the ITT population of the Phase 3 trial were comparable between CAM2038 and SL BPN/NX (**Table 1**)
- In the ITT population of the Phase 3 trial, the proportion of urine samples negative for illicit opioids was higher in the CAM2038 group versus the SL BPN/NX group (35.1% versus 28.4%; p<0.001)[4]
- In the subgroup of patients who inject opioids, mean percentage of urine samples negative (with self-report) for illicit opioids was significantly higher in the CAM2038 group (30.6%) versus the SL BPN/NX group (14.3%; p=0.0008; **Figure 2**)
  - The interaction between injection use and treatment was significant (p=0.007)
- In the other subgroups investigated, no significant differences were found between the CAM2038 and SL BPN/NX treatment arms (all p>0.05)
- In the subgroup of patients who inject opioids — as in the ITT population — total scores on the COWS and SOWS were suppressed from Day 1 and throughout the study, without significant differences between the CAM2038 and SL BPN/NX treatment arms
- In the subgroup of patients who inject opioids — as in the ITT population — opioid craving as evaluated by need- and desire-to-use VAS was suppressed from Day 1 and throughout the study, without significant differences between the CAM2038 and SL BPN/NX treatment arms

Figure 2 Mean percentage of urine samples negative for illicit opioids in the subgroups defined at BL

Subgroup/ substance used	CAM2038 % (n)	SL BPN/NX % (n)	Difference (95% CI)
Marijuana			
N	36.7 (140)	28.5 (137)	8.2 (–0.4, 16.7)
Y	32.2 (73)	28.2 (78)	4.0 (–7.6, 15.6)
Methamphetamine			
N	36.8 (166)	30.1 (175)	6.7 (–1.0, 14.4)
Y	29.3 (47)	21.1 (40)	8.2 (–7.1, 23.5)
Benzodiazepine			
N	34.9 (168)	28.5 (168)	6.4 (–1.4, 14.2)
Y	36.0 (45)	28.1 (47)	7.9 (–7.0, 22.8)
Benzoylecgonine[a]			
N	40.6 (148)	35.5 (145)	5.1 (–3.0, 13.2)
Y	22.7 (65)	13.7 (70)	9.0 (–2.9, 20.9)
≥1 other substance used			
N	47.8 (58)	40.2 (66)	7.6 (–4.9, 20.2)
Y	30.4 (155)	23.2 (149)	7.2 (–0.8, 15.2)
≥2 other substances used			
N	39.2 (150)	30.9 (148)	8.3 (0.1, 16.5)
Y	25.5 (63)	22.9 (67)	2.6 (–9.8, 15.0)
Stimulant use[b]			
N	44.1 (109)	38.2 (115)	5.9 (–3.3, 15.1)
Y	25.7 (104)	17.1 (100)	8.6 (–1.0, 18.3)
Benzodiazepines or barbiturates			
N	34.8 (166)	28.0 (167)	6.7 (–1.1, 14.6)
Y	36.4 (47)	29.6 (48)	6.8 (–7.9, 21.4)
Psychiatric disorder			
N	29.1 (132)	25.2 (136)	3.9 (–4.7, 12.5)
Y	44.9 (81)	33.9 (79)	11.0 (–0.1, 22.1)
Employment			
N	32.7 (135)	24.3 (142)	8.4 (–0.1, 16.9)
Y	39.4 (78)	36.5 (73)	2.9 (–8.6, 14.5)
Injection use*			
N	39.5 (108)	41.6 (111)	–2.1 (–11.3, 7.2)
Y	30.6 (105)	14.3 (104)	16.3 (6.8, 25.8)



*p<0.05 test for interaction.
[a]Cocaine metabolite; [b]Stimulants were defined as benzoylecgonine (cocaine) + methamphetamine.

Conclusions

- Treatment with CAM2038 increased the likelihood of no illicit opioid use versus SL BPN/NX in participants injecting opioids at BL
- Other BL factors did not significantly influence the difference in illicit opioid use between SL BPN/NX and CAM2038

Abbreviations: **BMI:** body mass index; **BL:** baseline; **BPN:** buprenorphine; **CI:** confidence interval; **COWS:** Clinical Opiate Withdrawal Scale; **CDF:** cumulative distribution function; **EMA:** European Medicines Agency; **FDA:** US Food and Drug Administration; **ITT:** intention-to-treat; **N:** no; **NX:** naloxone; **OUD:** opioid use disorder; **SC:** subcutaneous; **SD:** standard deviation; **SL:** sublingual; **SOWS:** Subjective Opiate Withdrawal Scale; **UDT:** urine drug test; **VAS:** Visual Analogue Scale; **Y:** yes.

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