Patient satisfaction and experience with weekly/monthly sustained-release injectable buprenorphine

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BACKGROUND

- Opioid use disorder (OUD) is an escalating public health crisis; provisional estimates suggest more than 49,000 fatal overdoses involving opioids occurred in 2017[1]
- CAM2038 is an extended-release buprenorphine (BPN) injection with weekly and monthly dosing options supplied as a prefilled, small-volume injection for the treatment of OUD
- Patient satisfaction is an important healthcare outcome used as a measure of quality of care in OUD.[2,3] Evidence suggests that patient satisfaction is a signal for positive outcomes in OUD treatment[4]

METHODS

- A phase 3, open-label, 12-month (48-week), flexible-dosing, safety and tolerability study (NCT02672111) evaluated CAM2038 for the treatment of OUD. Here, we report patient-reported experience measures collected from a sponsor-issued, nonvalidated survey
- Inclusion criteria: Moderate to severe OUD; age 18–65 years; currently treated with sublingual buprenorphine or buprenorphine/naloxone (SL BPN) or seeking to initiate BPN treatment and with no BPN treatment for ≥60 days
- Exclusion criteria: Moderate to severe substance use disorder defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, for any substance other than opioids, caffeine, or nicotine; chronic pain requiring opioid treatment; acquired immune deficiency syndrome; and recent or current suicidal ideation or behavior based on the Columbia Suicide Severity Rating Scale
- New-to-treatment participants were initiated with CAM2038 weekly
- Participants converted from SL BPN treatment were transitioned to treatment with CAM2038 weekly or monthly at doses corresponding to their prior daily treatment (**Table 1**)
- Individualized dose adjustments and changes in visit frequency were permitted as per the investigator's clinical judgement, in consultation with the participant, at any time during the treatment phase
- At months 6 and 12, participants completed surveys rating the importance of various characteristics regarding BPN treatment on a scale of 1 to 7, where 1 was "not important" and 7 was "extremely important"
  - Items addressed: ease of travel, daily adherence, privacy, lack of need for daily medication and regular trips to the pharmacy, accidental pediatric exposure, and access by others to medications
- At months 6 and 12, participants converting from SL BPN also completed surveys rating participant satisfaction with CAM2038 relative to previous treatment with SL BPN on a 5-unit scale from "much worse" to "much better"

Table 1. Doses of CAM2038 weekly and monthly for participants converting from sublingual buprenorphine or sublingual buprenorphine/naloxone

SL BPN	CAM2038 weekly[a]	CAM2038 monthly[b]
≤6 mg	8 mg (0.16 mL)	N/A
8–10 mg	16 mg (0.32 mL)	64 mg (0.18 mL)
12–16 mg	24 mg (0.48 mL)	96 mg (0.27 mL)
18–24 mg	32 mg (0.64 mL)	128 mg (0.36 mL)
26–32 mg	N/A	160 mg (0.45 mL)

[a]Participants were allowed dose adjustments as needed with CAM2038 weekly at scheduled visits or with 8 mg SC supplemental injections at unscheduled visits up to a maximum weekly dose of 40 mg per week.
[b]Participants who needed additional temporary buprenorphine were allowed a maximum of 2 supplemental injections of 8 mg CAM2038 per week; dose adjustments could be made at investigator discretion at scheduled visits.
N/A, not applicable; SC, subcutaneous; SL BPN, sublingual buprenorphine.

RESULTS

- A total of 228 adult participants were enrolled from December 14, 2015, to April 12, 2017; 190 participants were receiving SL BPN at entry and 37 were new to treatment (**Table 2**)
  - 188/227 (82.8%) participants completed 24 weeks of treatment and 167/227 (73.6%) participants completed 48 weeks of treatment
- All new-to-treatment participants were positive for illicit opioids at baseline; the percentage of the composite of illicit opioid-negative urine samples and self-reports at last study visit increased to 63.0% at end of treatment period. For participants converted from SL BPN, the percentage of participants negative for illicit opioids increased from 78.4% on day 1 to 82.8% at end of treatment period
- A total of 110 (48.4%) participants completed surveys at month 6 (34 participants new to treatment and 76 converted from SL BPN); 162 (71.4%) participants completed surveys rating the importance of various characteristics regarding BPN treatment and participant satisfaction with CAM2038 as compared with previous treatment with SL BPN at 12 months (29 participants new to treatment and 133 converted from SL BPN)

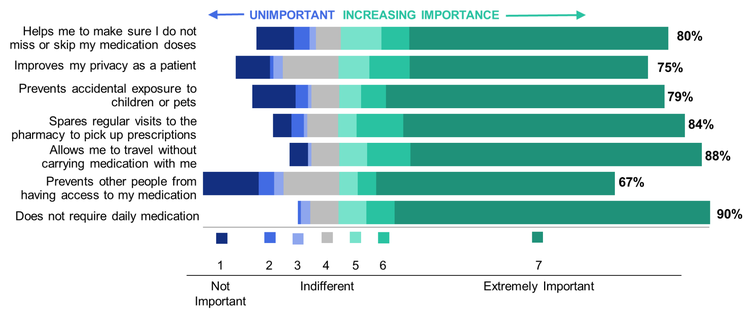
Table 2. Demographics and clinical characteristics at baseline (overall safety population)

Category	Converted from SL BPN n = 190	New to treatment n = 37	Overall N = 227
Age, mean (SD), y	41.3 (9.6)	41.8 (9.4)	41.4 (9.6)
Sex			
Male	119 (62.6)	24 (64.9)	143 (63.0)
Female	71 (37.4)	13 (35.1)	84 (37.0)
Race			
White	183 (96.3)	20 (54.1)	203 (89.4)
Black or African American	3 (1.6)	17 (45.9)	20 (8.8)
Other	4 (2.1)	0	4 (1.8)
Substance abuse history			
Opioid use disorder (DSM-5) diagnosis[a]	57 (82.6)	37 (100.0)	194 (85.5)
Time from first opioid abuse, y, mean (SD)	4.7 (8.5)	15.7 (9.0)	14.8 (8.6)
Time from first diagnosis, y, mean (SD)	9.8 (7.6)	10.0 (8.6)	9.8 (7.8)
Heroin as primary opioid of use	97 (51.1)	37 (100.0)	134 (59.0)
Injection as route of heroin abuse	80 (42.1)	14 (37.8)	94 (41.4)
Meets DSM-5 criteria for current use			
Benzodiazepines	9 (4.7)	0	9 (4.0)
Cannabinoids	15 (7.9)	1 (2.7)	16 (7.0)
Cocaine	0	1 (2.7)	1 (0.4)
Heroin	15 (7.9)	37 (100.0)	52 (22.9)
Nicotine	129 (67.9)	32 (86.5)	161 (70.9)
Other	2 (1.1)	0	2 (0.9)
Baseline withdrawal and cravings, mean (SD)			
COWS at baseline	2.0 (2.7)	10.6 (3.7)	3.4 (4.3)
SOWS at baseline	4.7 (8.1)	27.1 (15.3)	8.3 (12.7)
Desire to use VAS at baseline	11.7 (24.2)	74.8 (24.8)	22.0 (33.7)
Need to use VAS at baseline	11.7 (23.8)	76.3 (24.9)	22.3 (33.8)

Unless otherwise noted, data is presented as n (%).
[a]Percent is <100 because some participants qualified due to a history of OUD at screening.
COWS, clinical opiate withdrawal scale; DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; OUD, opioid use disorder; SD, standard deviation; SL BPN, sublingual buprenorphine; SOWS, subjective opiate withdrawal scale (0–64); VAS, visual analog scale (0–100 mm).

- For participants converted from SL BPN, median scores at 12 months were 7.0 ("extremely important") for all items on the survey for the importance of various characteristics regarding treatment with BPN, including ease of travel, daily adherence, privacy, lack of need for daily medication or regular trips to pharmacy, accidental pediatric exposure, and access to medications by others (**Figure 1**)

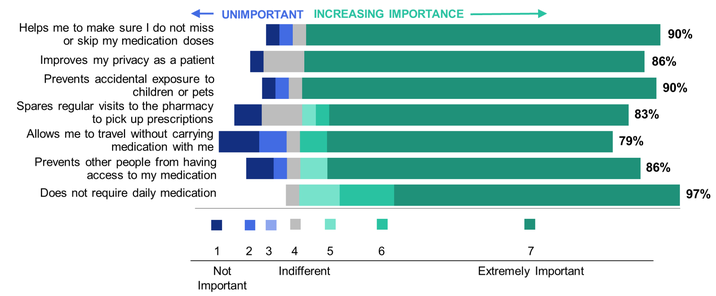
Figure 1: Characteristics of BPN treatment that are important to participants converted from SL BPN, month 12 (n = 133)



Data shown is percentage of participants who responded with that rating. The total percentage of patients who responded 5, 6, or 7 for each item is shown to the right. For the item "helps me not miss or skip medication dose," n = 132.
BPN, buprenorphine; SL BPN, sublingual buprenorphine.

- For new-to-treatment participants, median scores for all items at 6 and 12 months were 7.0 (**Figure 2**), except for a median score of 6.5 for "prevents others access to my medication" at month 6 (data not shown)

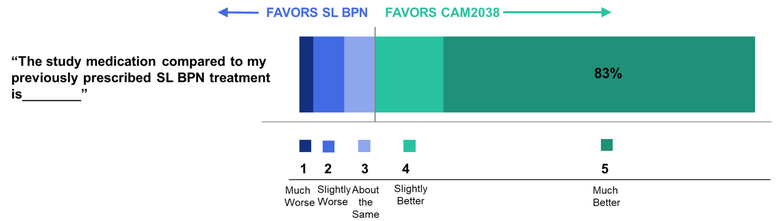
Figure 2: Characteristics of BPN treatment that are important to participants new to treatment, month 12 (n = 29)



Data shown is percentage of participants who responded with that rating. The total percentage of patients who responded 5, 6, or 7 for each item is shown to the right. BPN, buprenorphine.

- At month 12, of the 133 responding participants who converted from SL BPN, 91 (68.4%) participants responded treatment with CAM2038 was "much better" than their previous treatment, 20 (15.0%) answered that it was "slightly better," 9 (6.8%) responded CAM2038 was "slightly worse," and 4 (3.0%) responded CAM2038 was "much worse" (**Figure 3**)

Figure 3: Patient satisfaction with CAM2038 compared with previously prescribed SL BPN treatment (n = 133)



Data presented is percent of participants who responded with that rating. The total percentage of patients who responded 4 or 5 is shown to the right. SL BPN, sublingual buprenorphine.

CONCLUSIONS

- CAM2038 weekly and monthly was associated with high retention rates and low levels of continued illicit opioid use throughout the study period for participants converted from treatment with SL BPN, as supported by prior data[5]
- Study participants generally reported high levels of satisfaction with the individualized treatment provided by weekly and monthly CAM2038 subcutaneous injections
- In both groups, participants identified ease of travel, daily adherence, privacy, lack of need for daily medication or regular trips to pharmacy, accidental pediatric exposure, and access to medication by others as important characteristics of BPN treatment
- More than 80% of patients converted from treatment with SL BPN reported that CAM2038 was slightly or much better than their previous SL BPN treatment

REFERENCES

1. National Institute on Drug Abuse, "Overdose Death Rates". Accessed at https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates on 10/16/2018; 2. Barry, DT, et al. *J Gen Intern Med*. 2007;22(2):242-5; 3. Trujols, J, et al. *Patient Prefer Adherence*. 2014;8:107-17; 4. Carlson, MJ, et al. *Psychiatr Serv*. 2001;52(9):1230-6; 5. Walsh, SL, et al. *JAMA Psychiatry*. 2017;74(9):894-902.

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DISCLOSURES

GLB's institution has received grant support from NIDA, Braeburn, and Reckitt-Benckiser/Indivior. GLB has received study drug-in kind from Reckitt-Benckiser/Indivior; has received travel support from Braeburn, Alkermes, and Indivior; and is on the advisory boards of Braeburn, BioDelivery Sciences International, and Camurus. AB is on the speaker's bureaus of Bio.Delivery Sciences International and Alkermes; and is a member of Alkermes's Antagonist Awareness Network Initiative. MPF has served as a consultant for Braeburn, Knight Pharmaceuticals, and BioDelivery Sciences International; has received speaking honoraria from Indivior Pharmaceuticals and BioDelivery Sciences International; has served on an advisory board for Kaleo Pharmaceuticals; and has received research funding from Braeburn. NRB-K and SK are Braeburn employees. FT is a Camurus employee.

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