Dosing to Effect With Weekly and Monthly Subcutaneous Buprenorphine: Post Hoc Analysis of a Phase 3, Open-label Study

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BACKGROUND

- The safety and effectiveness of buprenorphine in various formulations has been established for the treatment of patients with opioid use disorder (OUD).[1]
- Clinical practice guidelines indicate that the dose and frequency of buprenorphine should be individualized to patients' treatment needs.[2,3]
- CAM2038 is an extended-release injectable buprenorphine available in weekly and monthly formulations with multiple doses.[4]

METHODS

- A post-hoc analysis was conducted to evaluate the impact of CAM2038 dose on OUD treatment outcomes in a 48-week, open-label, flexible-dosing, multi-national Phase 3 study evaluating the long-term safety, tolerability, and efficacy of CAM2038 in adults with moderate to severe OUD (NCT02672111).[4]
- Participants new to treatment at baseline were initiated with CAM2038 weekly and participants on sublingual buprenorphine (SL-BUP) or SL-BUP/naloxone (NX) treatment were transitioned to CAM2038 weekly or monthly at doses corresponding to their prior daily treatment (**Table 1**).[4]
  - The study included flexible CAM2038 doses and individualized dose adjustments were permitted at any time during the treatment phase.[4]
- Urine samples were collected at weekly or monthly visits based on the frequency of CAM2038 injections.[4]
- Opioid withdrawal, as assessed by the Clinical Opiate Withdrawal Scale (COWS), and opioid cravings, as assessed by need-to-use visual analog scale (VAS), were recorded at monthly visits.[4]
  - COWS scores: 5 to 12 (mild); 13 to 24 (moderate); 25 to 36 (moderately severe); >36 (severe).
  - Need-to-use VAS scores: 0 (no need to use since last visit) to 100 (strongest possible need to use since last visit).
- Outcomes were evaluated by dose based on the last dose received prior to assessments. Therefore, sample size is variable between doses, depending on the frequency of each dose administered. Supplemental buprenorphine doses were not included and missing values were not imputed.

Table 1. Dose Conversion for Patients Converting From SL-BUP or SL-BUP/NX to CAM2038 Weekly and Monthly

SL-BUP or SL-BUP/NX	CAM2038 Weekly*	CAM2038 Monthly†
≤6 mg	8 mg	N/A
8–10 mg	16 mg	64 mg
12–16 mg	24 mg	96 mg
18–24 mg	32 mg	128 mg
26–32 mg	N/A	160 mg‡

*Participants were allowed dose adjustments as needed at scheduled visits or with 8 mg CAM2038 supplemental injections at unscheduled visits up to a maximum weekly dose of 40 mg per week.

†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.

‡Dose not available in the United States.

RESULTS

- Most study participants (83.7%; n=190) were converted from SL-BUP or SL-BUP/NX and the minority (16.3%; n=37) were new to treatment.
- In participants converted from SL-BUP or SL-BUP/NX, all available CAM2038 doses were utilized during the study. However, the majority received CAM2038 weekly 24 mg or 32 mg and CAM2038 monthly 96 mg or 128 mg, corresponding to SL-BUP 16 mg to 24 mg daily.
- In participants new to treatment, the majority received CAM2038 weekly 24 mg and CAM2038 monthly 96 mg, corresponding to SL-BUP 16 mg daily.
- Overall, the mean percentage of urine samples negative for illicit opioids was similar across weekly doses of 16 mg, 24 mg, and 32 mg and all monthly doses of CAM2038. CAM2038 weekly doses of 8 mg and 40 mg had 91.5% and 100% of urine samples negative for illicit opioids, possibly reflecting the small sample size (n=31 and n=2) (**Figure 2**).
- Across all doses, opioid withdrawal was well-controlled, with no mean COWS scores greater than 4, indicative of no withdrawal; lower scores were not observed with increasing doses (**Figure 3**).
- Across all doses, opioid cravings were controlled; lower scores were not observed with increasing doses (**Figure 4**).

Figure 1. Highest CAM2038 Dose Reached by Regimen (N=227)

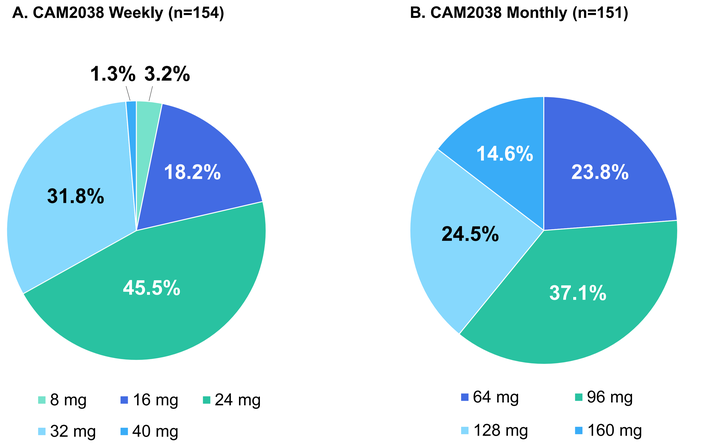


Figure 2. Urine Samples Negative for Illicit Opioids by CAM2038 Dose (N=227)

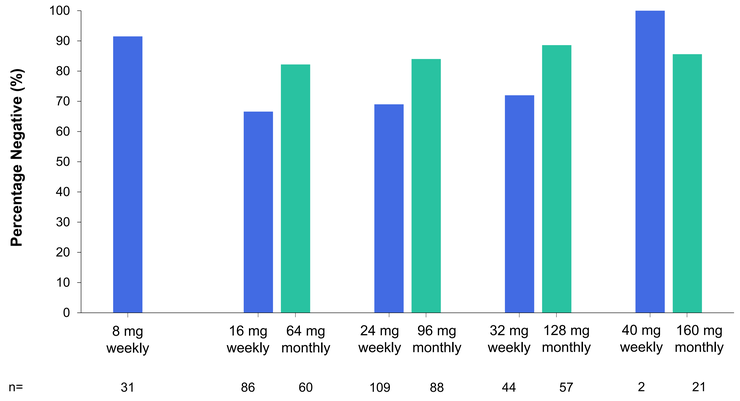


Figure 3. COWS Scores by CAM2038 Dose (N=227)

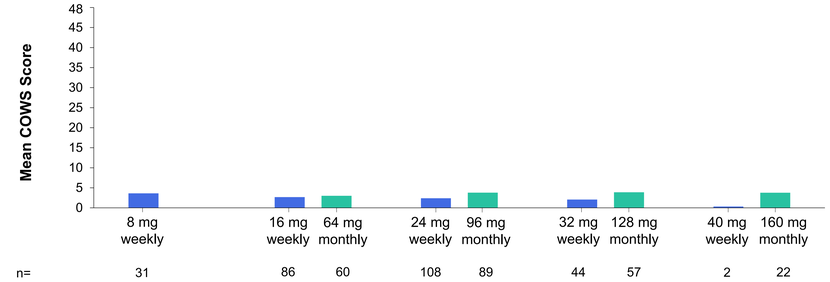
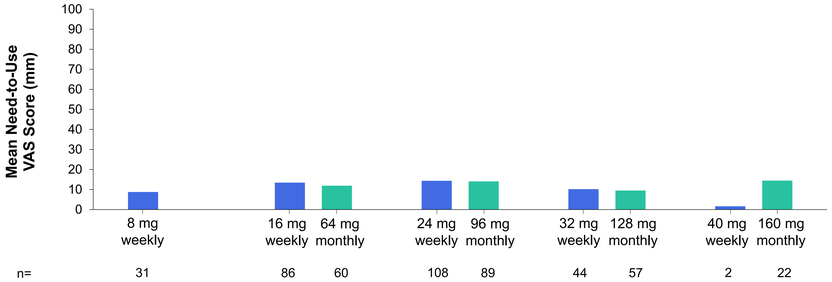


Figure 4. Need-to-Use VAS Scores by CAM2038 Dose (N=227)



CONCLUSIONS

- Treatment with CAM2038 weekly or monthly, administered at individualized doses based on clinical response, resulted in positive outcomes for OUD, including low rates of illicit opioid use and suppression of opioid withdrawal and cravings.
- Participants new to treatment and converted from SL-BUP or SL-BUP/NX responded to all CAM2038 doses and treatment outcomes were similar for CAM2038 weekly and monthly formulations at comparable doses.
- As these are post-hoc analyses, and in some cases, the sample size is limited, more research is needed to evaluate the impact of CAM2038 dose on OUD treatment outcomes.

REFERENCES

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DISCLOSURES

MPF has received consulting/speaking honoraria from Braeburn Inc, consultant fees from Molteni Farmaceutici and Accord Healthcare, and is currently a shareholder of Pinova Therapeutics; GLB is an investigator on NIH-funded studies that have received in-kind donations of medications or digital therapeutics from Alkermes, Braeburn Inc, Camurus AB, CHESS Health, Indivior, and Pear Therapeutics, and has received consultant fees from Braeburn Inc in the past 3 years; EBN and SM are current employees and shareholders of Camurus AB; AF and NRB-K are current employees of Braeburn Inc.

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