Quality of Life in Adult Outpatients with Opioid Use Disorder Treated with Long-Acting Subcutaneous Injection Buprenorphine Depot (CAM2038): Results from an Open-Label Multicenter Clinical Trial

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Background

- Long-acting weekly and monthly buprenorphine injection, CAM2038, for treatment of opioid use disorder (OUD) may improve outcomes by reducing the burden of daily dosing and supporting medication adherence. Given the implications of the depot modality on how patient monitoring and follow-up may be conducted, there has been interest in how to evaluate relapse risk and treatment success on an ongoing basis[1].

Methods

- CAM2038 was evaluated in a Phase 3, 48-week, open-label, flexible dosing study of participants with a current or past history of moderate to severe OUD, currently treated with sublingual buprenorphine (SL BPN) or seeking to initiate BPN (with no BPN treatment for ≥60 days)[2]. This study is a post-hoc analysis of the relationships between QOL and treatment response.
- Participants from the full-exposure safety population, with no missing toxicology samples, and QOL scores recorded between months 7 and 12 (inclusive) were included for analysis.
- Relapse rate was defined as % of months with positive illicit opioid assessments (urine toxicology and self-report), and participants were categorized as either:
  - High Responders ("High"): 0-50% relapse rate
  - Low Responders ("Low"): 51-100% relapse rate
- QOL was evaluated monthly via EQ-5D-5L: a self-report instrument with demonstrated validity in OUD[3,4]. Its descriptive system measures 5 domains (Mobility, Self-Care, Usual Activities, Pain / Discomfort, and Anxiety / Depression) on a scale of 1-5 (higher values = more impairment). It includes a visual analogue scale (VAS, 1-100, higher values indicating higher QOL). Index scores representing overall QOL were derived from descriptive items with a USA reference value set.
- The impact of relapse rate on QOL was assessed descriptively. Due to the EQ-5D-5L being implemented after the trial began, the analysis was limited to data collected after week 20.

Results

- N=156 participants in the full-exposure safety population (out of 228 enrolled, 68%) were included for analysis (**Table 1**).
- From these 156 participants, 883 EQ-5D-5L surveys were collected for 6 months (between months 7 and 12).

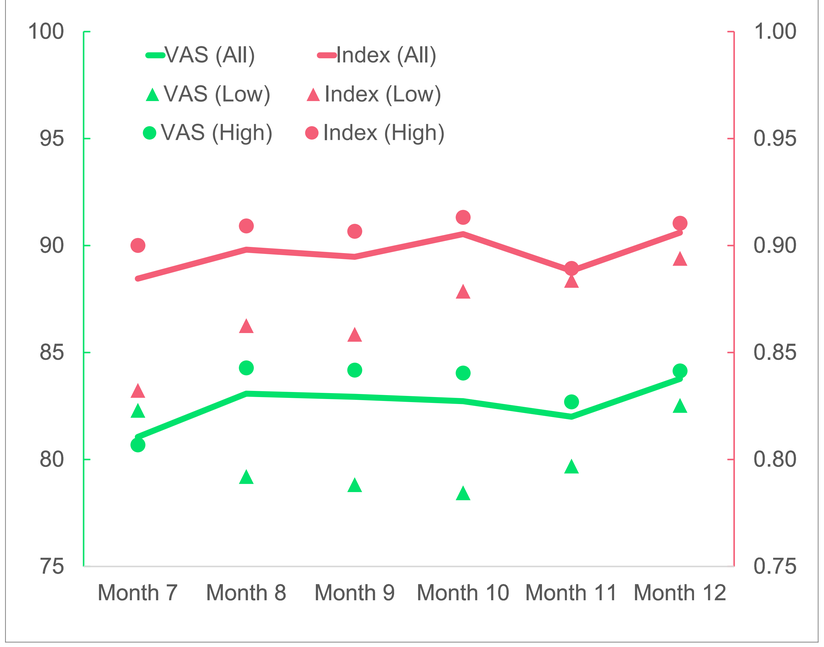
Table 1. Demographics and Baseline Characteristics

	N = 156
Median Age	41 (±9.9)
Sex, Male	95 (61%)
White vs Black/African American*	138 (88%) vs 14 (9%)
Employed vs Unemployed*	82 (53%) vs 68 (44%)
Arrest/Conviction History	--
None	88 (56%)
Previously Arrested	34 (22%)
Misdemeanor Conviction	18 (12%)
Felony Conviction	16 (10%)
Substance Abuse History	--
OUD diagnosis (DSM-5)**	134 (86%)
Heroin as primary opioid of use	92 (59%)
Converted from SL BPN vs Naïve	128 (82%) vs 28 (18%)

*The remaining proportion is "Other"; **19 converted from SL BPN had a history of OUD

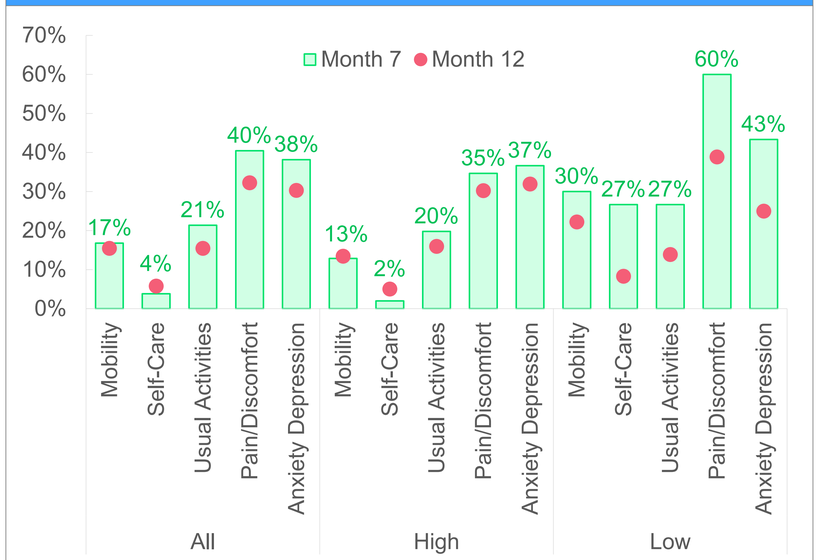
- Overall, EQ-5D VAS and Index scores were stable from month 7 to 12, but with a slight increase in both (**Figure 1**).

Figure 1. EQ-5D VAS and Index Score Trends



- High and low responder groups converged on similar values by Month 12, but high responders had nominally better QOL on both scales and resided at higher QOL levels for longer.
- The mean change in EQ-5D-5L VAS scores in the month preceding a relapse was -2% (±3%).
- EQ-5D domains were analyzed for changes in the proportion of participants with any problem (i.e., domains scored 2-5,**Table 2**).

Figure 2. Proportions of Patients with "Any Problem"



- Improvements from Month 7 to 12 in all domains - except Self-Care - were observed overall.
- Low responders began with worse domain scores accrued larger improvements versus high responders.

Conclusions

- All participants treated with CAM2038 demonstrated stability and nominal increases in QOL from Month 7 to 12.
- Transient reductions in overall QOL were observed in the month prior to a relapse, which preliminarily supports use of the EQ-5D-5L in assessing relapse risk.
- Key limitations include lack of baseline QOL observation, lack of a comparator arm, and exclusion of discontinued participants.

References / Disclosures

[1] Drug Des Devel Ther 2017;11:2493–2505. [2] US NLM. NCT02672111. [3] Health Qual Life Outcomes. 2018;16:106. [4] Qual Life Res. 2013;22(7):1717-27. The original abstract submission reported results based on an interim analysis. This poster reports an analysis of the final trial data-set. This research was supported by Braeburn and Camurus AB. MF received consulting fees from Braeburn but was not compensated for his role in this study. JAC is an employee of EPI-Q, Inc., which received payment from Braeburn and Camurus AB to develop, conduct, and report this study. MAR is a paid consultant to Camurus AB. FT and RJ are employees of Camurus AB. SK and NBK are employees of Braeburn.

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