Individualised dosing of long-acting injectable buprenorphine (CAM2038) in Phase 3 studies

P02

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Introduction

- Medications for opioid use disorder (OUD) are the standard of care, combining pharmacotherapy with psychosocial support to reduce cravings, suppress withdrawal symptoms and improve treatment retention[1–3]
- Buprenorphine (BPN), a partial μ-opioid receptor agonist, is widely used for treatment of OUD based on robust evidence demonstrating clinical efficacy similar to methadone[1–5]
- Clinical guidelines emphasise dose titration to clinical effect sufficient to suppress withdrawal symptoms and reduce non-prescribed opioid use[2,3]
- Compared with daily OUD therapies, long-acting injectable BPN (LAIB) formulations can reduce treatment burden[6,7]
- CAM2038 is a LAIB available for weekly (q1w) and monthly (q4w) administration, with a range of doses across both regimens to enable flexible and individualised dose titration[8]

Objective

- To evaluate dosing patterns of CAM2038, including supplemental dosing and regimen transitions, across two Phase 3 studies

Methods

- The CAM2038 clinical programme included two Phase 3 studies with flexible dose titration and capacity for supplemental dosing[9,10]
  - HS-14-499 (NCT02672111; **Figure 1**) was a 48-week, open-label safety study conducted in the USA, the UK, Hungary, Denmark, Sweden, Germany and Australia,[9] encompassing heroin-predominant settings in Europe and Australia and fentanyl-dominated settings in the USA[11–13]
  - DEBUT (ACTRN12618001759280; **Figure 2**) was a 24-week, randomised, open-label, active-comparator study that primarily assessed patient-reported outcomes and was conducted in Australia,[10] a heroin-predominant setting[12]
- Both studies enrolled adults with OUD
  - Eligible participants included those actively seeking BPN treatment and those already receiving sublingual (SL) BPN or BPN/naloxone (NX)
  - In DEBUT, participants receiving methadone were also eligible after switching to SL BPN according to local practice
- Both studies allowed flexible dosing of CAM2038, enabling dose titration based on clinical need and suppression of withdrawal symptoms
  - In HS-14-499, participants could switch between q1w and q4w regimens and receive supplemental doses of 8 mg up to 40 mg for q1w or two additional doses per week for q4w up to 160 mg
  - In DEBUT, participants could switch between q1w and q4w regimens and receive supplemental doses of 8 mg up to 32 mg for q1w or 160 mg per month for q4w
- For each study, dose utilisation across the available range and supplemental dosing extent and timing were assessed, with regimen switching evaluated in HS-14-499 and dosing intervals in DEBUT

Figure 1. HS-14-499 trial design[9]

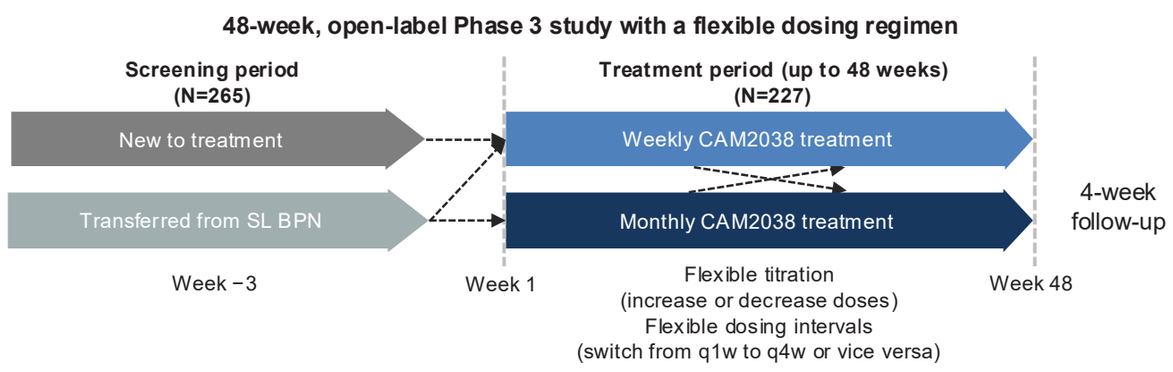
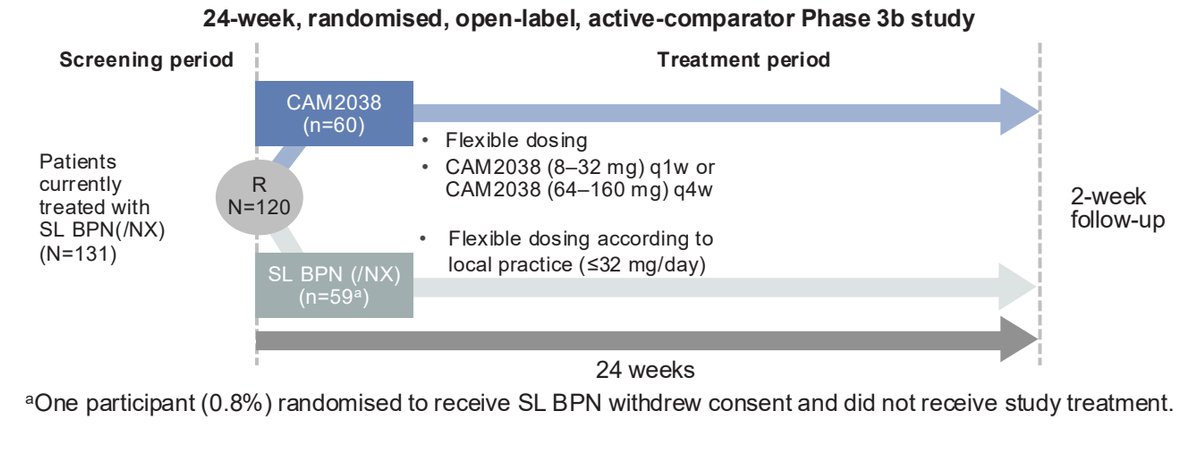


Figure 2. DEBUT trial design[10]



[a]One participant (0.8%) randomised to receive SL BPN withdrew consent and did not receive study treatment.

Results

Highest dose reached

- In HS-14-499, the most common highest q1w dose reached (n=154) was 24 mg (45.5%; 70/154), followed by 32 mg (31.8%; 49/154), 16 mg (18.2%; 28/154) and 8 mg (3.2%; 5/154)
  - For q4w dosing (n=151), the most common highest dose reached was 96 mg (37.1%; 56/151), followed by 128 mg (24.5%; 37/151), 64 mg (23.8%; 36/151) and 160 mg (14.6%; 22/151) (**Figure 3**)
- In DEBUT, the most common highest q1w dose reached (n=29) was 32 mg (41.4%; 12/29), followed by 24 mg (24.1%; 7/29) and 16 mg and 8 mg equally (17.2%; 5/29 each)
  - All participants received at least one q4w dose (n=60); the most common highest dose reached was 128 mg (36.7%; 22/60), followed by 96 mg (26.7%; 16/60), 160 mg (21.7%; 13/60) and 64 mg (15.0%; 9/60) (**Figure 3**)

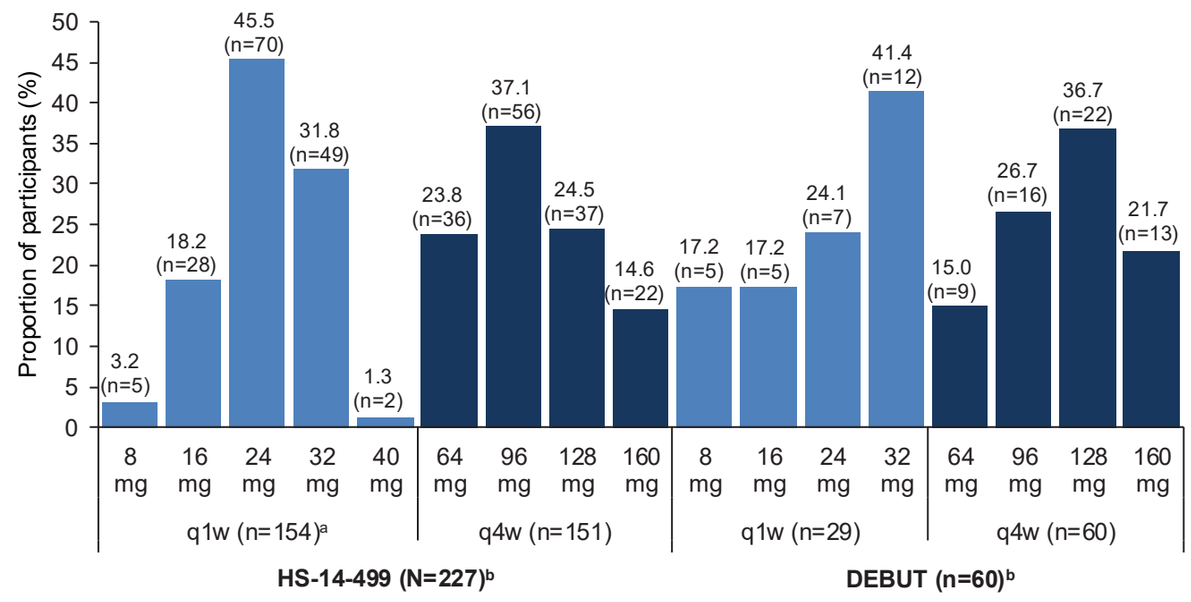
Supplemental dosing

- In HS-14-499, 96 participants (42.3%) received at least one supplemental dose
  - Supplement dosing was less common among participants who were new to treatment (13.5%; n=5) than those who transferred from SL BPN at entry (47.9%; n=91)
- In DEBUT, supplemental dosing was minimal; during the first 4 weeks, five participants receiving CAM2038 q1w and nine receiving CAM2038 q4w received 1–3 supplemental doses (**Figure 4**)
  - Supplemental dosing declined over time, with only isolated cases after Week 12 and none after Week 20

Regimen transition in HS-14-499

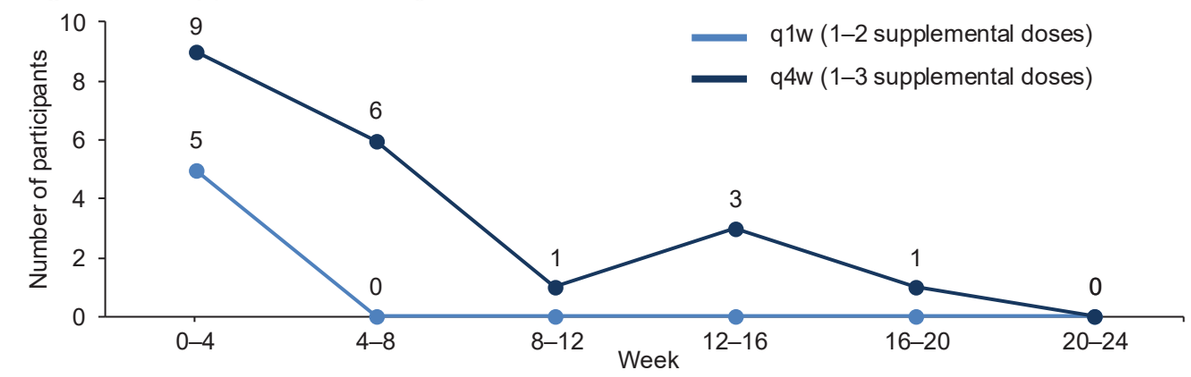
- Most injections involved no regimen transition (97.0%); 1.7% represented q1w to q4w transitions and 1.3% q4w to q1w transitions
- At the participant level, 65.6% (149/227) continued receiving their initial regimen throughout, 33.0% (75/227) had ≥1 q1w to q4w transition and 25.6% (58/227) had ≥1 q4w to q1w transition
- Among participants transitioning from q1w to q4w dosing, the most common last q1w dose was 24 mg (45.1%), followed by 16 mg (31.7%) and 32 mg (22.0%)
  - Median time to first transition was 64 days (range 22–275); this was notably longer in participants new to treatment than in those who transferred from SL BPN at entry (92 vs 57 days)
- Among participants transitioning from q4w to q1w dosing, the most common last q4w dose before transition was 64 mg (35.9%), followed by 96 mg (31.3%), 128 mg (23.4%) and 160 mg (9.4%)

Figure 3. Highest dose reached by participants in HS-14-499 and DEBUT



[a]Based on the investigator's clinical judgement, participants could receive additional 8 mg q1w doses on Days 5–7, up to a maximum dose of 40 mg during Week 1; [b]Some participants were present in both the q1w and q4w regimen groups.

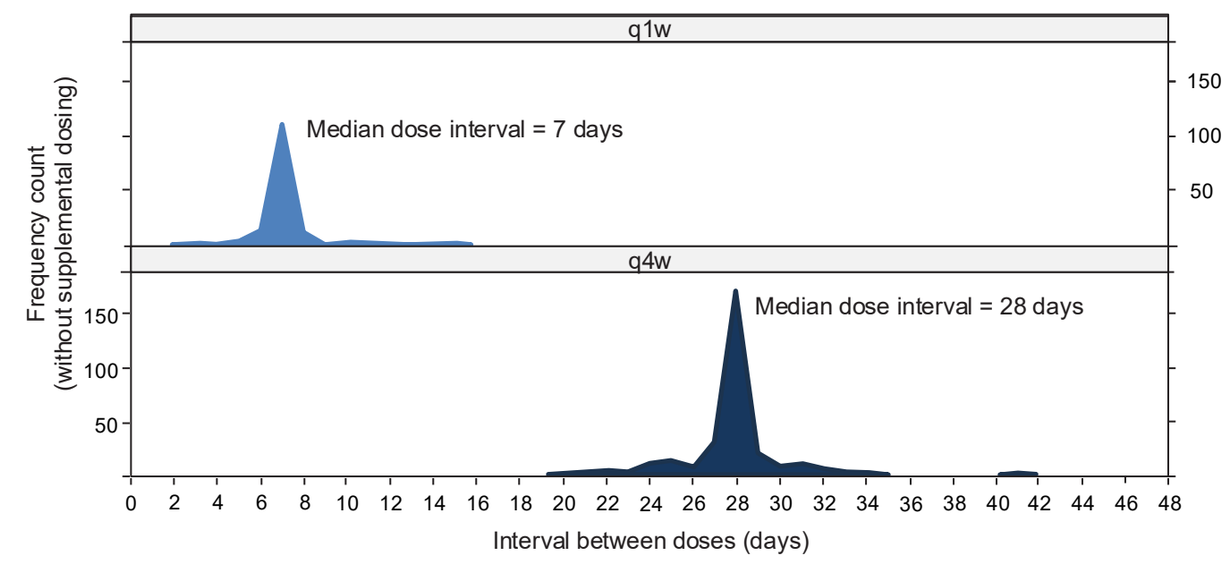
Figure 4. Supplemental dosing over time in DEBUT



Dosing intervals in DEBUT

- Median dosing intervals were 7 days for q1w dosing and 28 days for q4w dosing, matching their respective intervals (**Figure 5**) and indicating that participants received injections on a highly regular schedule with little deviation

Figure 5. Frequency of dosing intervals in DEBUT



Conclusions

- Across HS-14-499 and DEBUT, the full CAM2038 dose range was used, with most participants stabilising on 24 or 32 mg for q1w dosing and 96 or 128 mg for q4w dosing, corresponding to conventional SL BPN maintenance doses[8]
- Supplemental dosing was minimal and mainly occurred during early dose titration
- CAM2038 regimen flexibility supports dose titration to clinical effect and personalised treatment to optimise outcomes, aligned with clinical guidelines and real-world practice[2,3,14–17]
- Further evaluation is needed to determine whether individualised dosing improves outcomes relative to fixed-dose approaches

Abbreviations: **BPN:** buprenorphine; **LAIB:** long-acting injectable buprenorphine; **NX:** naloxone; **OUD:** opioid use disorder; **q1w:** weekly; **q4w:** monthly; **R:** randomised; **SL:** sublingual.

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