Cessatech – EMA initial KemSu/CT001 opinion Q&A and next steps

10 investor questions

On 3 August – Cessatech A/S ("Cessatech" or "the Company") releases a short Question and Answers (Q&A) overview, based on the questions and comments from investors related to the Refusal of the marketing authorisation for KemSu (sufentanil/ketamine) – dated 23 July 2026

1. What is the key efficacy message to EMA/CHMP?

A: The efficacy package links adult head-to-head data with paediatric PK/PD modelling and validates it in Study 0202; the core point is that 0208 and 0202 reach the same conclusion.

2. Who agrees the paediatric study setup - PDCO or CHMP?

A: For children, EMA's Paediatric Committee (PDCO) agreed the PIP and study package; CHMP evaluates the application. The programme followed the agreed PIP, a re-examination should focus dialogue on how the endorsed PIP supports approval.

3. Did adult Study 0205 show that KemSu works?

A: Adult study 0205 showed KemSu and intranasal sufentanil had analgesic effects of similar magnitude. Conventional superiority was not shown for KemSu vs sufentanil, but exposure-adjusted data support ketamine's analgesic and opioid-exposure-sparing contribution.

4. Why bridge from adults to children instead of another comparator trial?

A: Children and adults are different, and a paediatric head-to-head comparator trial would be difficult to justify ethically and practically. The PIP used modelling to bridge adult exposure–response into children. The modelling outcome was presented at the PAGE conference in Rome, June 2024 - Link

5. What did the paediatric PK/PD model predict?

A: Children showed higher intranasal exposure than adults, and the PDC 01-0208 model predicted a median 80.5% pain reduction at 30 minutes across all paediatric age groups.

6. Did Study 0202 validate the prediction?

A: Yes. Study 0202 observed a median 75.0% pain reduction at 30 minutes across all paediatric age groups, close to the 80.5% predicted, and met its endpoint: 88% (134/152) reached pain score ≤4 within 30 minutes, 54% at 15 minutes. Median reduction was 85.7% at 60 minutes.

7. How close were the 0208 and 0202 responder rates?

A: At the Society for Pediatric Pain Medicine's Annual Meeting in Denver earlier this year (Link) the following responder data was presented: The PDC 01-0208 simulation predicted 84% responders at 30 minutes (≥50% pain reduction); Study 0202 observed 86.2% on the comparable definition.

8. Why is off-label intranasal fentanyl not enough?

A: It is used in Europe because approved alternatives are limited, but it is not approved for children, and it is difficult to dose consistently and requires specialist expertise; KemSu was studied in normal emergency units in different countries and at multiple sites.

9. What is the safety concern with sufentanil alone?

A: Paediatric patients receiving sufentanil monotherapy require 2-3x higher exposure to reach the analgesic effect of KemSu and thus have a lower respiratory safety margin. In Study 0203, a statistically significantly higher proportion of sufentanil monotherapy patients received naloxone, also when adjusting for dose, year, age and indication, and two SAEs occurred only in the sufentanil arm.

10. How do we address hospital-use/device concerns?

A: KemSu is hospital-only, reducing misuse concerns versus home use. If needed, volume can be reduced further, and we have additional options to consider and discuss, while preserving the simple administration hospitals prefer.

Proveca has appealed for re-examination, and we then have up to 2 months to submit our case.
The EMA will then review within 60 days, and potentially a new oral explanation meeting (OEM) will be scheduled, likely end of this year.