Cessatech - positive topline data from Study 0205 - Q&A session

Selected top 10 investor questions

On 4 January – Cessatech A/S ("Cessatech" or "the Company") releases a short Question and Answers (Q&A) overview, based all the positive feedback and questions from the release of topline data from study 0205

1. Can the Company elaborate on the exposure data and levels in children compared to adults?	A: The exposure observed in children in both the 0201 and 0206 study showed a 2 times higher exposure of both sufentanil and ketamine compared to adults in both the 0204 and 0205 studies at similar weight-adjusted dosing, highlighting that children are not just small adults.
2. The simulated data done in children, are these the completed 0207 and 0208 studies?	A: Not completely, but much work has been done to be able to compare the adults data from study 0205 into the modelled and simulated data in children. This will obviously make the remaining part of study 0207 and 0208 easier.
3. Can the Company explain the reduction in pain compared to placebo, in layman's terms?	A: Descriptive statistics for CT001 from the study showed a pain reduction of approximately 40% at 30 minutes compared to baseline, while placebo showed an approximate 1-2% reduction at 30 minutes.
4. Has the Company had any discussions with EMA regarding the 0205 data and process?	A: A discussion with the EMA requires advanced planning and cannot be arranged with short notice. However, the Company has engaged with regulatory experts concerning the data and the strategic approach.
5. Did you see any sedation effect in the 0205 data?	A: As the exposure in adults were 2 times lower than in children, the sedative effect previously observed in children, was only observed in a few subjects in 0205.
6. Was the dose in the sufentanil arm the same as given for CT001?	A: The sufentanil dose in CT001 and the sufentanil arms were the same, while the exposure measured in blood samples from the CT001 arm was three times lower, compared the exposure in the sufentanil arm. Despite lower exposure, a similar pain reduction was observed, due to the presence of ketamine in CT001.
7. When will secondary endpoints be communicated	A: Secondary endpoints included mainly safety and tolerability, use of rescue medication, and analysis of various efficacy results at different timepoints. These will be communicated later in more detail.
8. What does it mean that the adult data of CT001 was not superior to sufentanil?	A: The treatment effect of CT001 was not statistically significantly better than sufentanil, but on par with sufentanil. The sufentanil exposure in the sufentanil arm was 3 times higher than the sufentanil exposure in CT001, resulting in similar clinically relevant pain reduction in both arms.
9. Can you elaborate on the opioid sparing effect	A: Across the 4 main treatment arms and the 12 supportive arms in the study there was a robust finding, that the presence of ketamine reduced the amount of sufentanil exposure needed with 50% to achieve the same pain reduction as observed for sufentanil only.
10. Can you be more specific on the anticipated US launch and EU partnerships?	A: The Company will soon give a more detailed update on the planned launch of CT001 in the US and other ongoing plans regarding partnerships.