Press Release
03 June 2024

Cessatech announces superior simulated pain efficacy in children favouring its lead candidate CT001 relative to its active comparators.

- **The simulated pain reduction in NRS in children using CT001 was -87%, compared to -52%, -32% and +10% for sufentanil, ketamine and placebo respectively.**
- **Estimates for the opioid sparing effect of ketamine showed a need for more than double the sufentanil exposure to get the same overall effect seen with the treatment of CT001.**
- **The data supports the earlier reported data from the Dental Study 0205 showing the effectiveness of treatment with CT001. The full simulated data set will be presented at the PAGE conference in Rome 26-28 June.**

On 3 June – Cessatech A/S ("Cessatech" or "the Company") announces the final simulated efficacy data in children with CT001 from the abstract that will be presented at the Population Approach Group Europe (PAGE) conference in Rome Italy, during 26-28 June 2024.

The simulated pain reduction in Numeric Rating Scale (NRS) in children using CT001 was -87% (76%/92%) with a 95% CI for n=37. When using sufentanil alone the change in NRS was -52% (34%/65%) and with ketamine it was -32% (12%/47%), with a +10% (1%/20%) increase for placebo.

The pain relief estimated for CT001 would be difficult to obtain with sufentanil in children and would likely require more than double the sufentanil exposure, while increasing sufentanil or ketamine exposure could lead to side-effects like respiratory depression or hallucinogenic effects. Only 9% of children are expected to require a second dose of CT001.

https://www.page-meeting.org/default.asp?abstract=11064

The simulated data strongly supports the efficacy of CT001 in children and is the substantial part of modelling and simulation Study 0207 and 0208. The data will be important in the regulatory process and later commercialization of CT001.

CT001 is a nasal spray in development for the treatment of acute and procedural pain in children. The development of CT001 in Europe is conducted on the basis of an approved paediatric investigation plan (PIP) from EMA's Paediatric Committee.

Rik Schoemaker, PK/PD modelling senior consultant expert, Occams

"This research has quantified and confirmed the synergistic benefits of combining sufentanil and ketamine in CT001, along with the opioid-sparing effect of ketamine. The modelling supports the proposed posology of CT001 in providing adequate pain relief for children. These findings suggest that adjusting the doses of either ketamine or sufentanil is unlikely to further improve the efficacy profile. We believe that the registration of CT001 as a safe and efficacious non-invasive treatment has the potential to significantly enhance the clinical management of pain in paediatric patients."

Jes Trygved, CEO, Cessatech

"We are very pleased with the final simulated results and the opportunity to present them at the prestigious PAGE conference. The data strongly support our hypothesis that CT001 is very effective in children relative to its active comparators and will be instrumental in our further development. A great effort by the team and CT001 is now one step closer to finalize the clinical program and becoming available to hospitals and the children that really need approved, easy to administer pain relief."

For more information about Cessatech, please contact:

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About Cessatech

Cessatech A/S is a Danish pharmaceutical company committed to developing and commercializing evidence-based and innovative medicines for children for the treatment of paediatric acute pain. Its lead asset (CT001) is an analgesic nasal spray for the treatment of acute and planned painful procedures in children. The advantages include needle-free administration, easy administration, a fast-acting therapeutic effect, and being medically approved for children. CT001 is at its pivotal stage of clinical development, and CT002 is at the early development phase.