Press Release
22 December 2023

Cessatech announces positive topline data from study 0205 with its lead candidate CT001 for the treatment of pain in children supporting further advancement of CT001

- **The study a double-blinded, randomised, placebo-controlled in adults demonstrated that CT001 was superior to the placebo and ketamine control arms and at par to the sufentanil control arm.**
- **CT001 was safe and well tolerated and with response analysis confirming prior observations in children and with a 50% opioid sparring effect of ketamine.**
- **The 0205 data demonstrated significant reduction in pain scale, and although superiority was not achieved for the sufentanil control arm in adults the co-primary endpoint of preliminary modelled exposure-response data substantiates that CT001 is superior in children.**
- **Exposure-response analysis supports prior observation in children in study 0201 and 0206 and supports advancement of CT001 in the planned 0202 study.**

22 December - Cessatech A/S ("Cessatech" or "the Company") today announced topline results from the double-blind, randomised, placebo-controlled 0205 study that investigated efficacy, safety, and tolerability of CT001 as postoperative analgesic treatment in adults, following impacted mandibular third molar extraction. CT001 has a significant potential to reduce pain in children as demonstrated with data from the study 0205 translated into children using the planned PKPD modelling and simulation. Although CT001 was not superior to sufentanil due to the low exposure of CT001 in adults, the co-primary endpoint of preliminary modelled exposure-response data substantiates that CT001 is superior in children.

Blood sampling from adult participants in study 0205 reveal a difference in drug exposure and thereby effect of sufentanil and ketamine in CT001 participants, compared to what previously has been seen in children from study 0201 and study 0206. The difference is considered due to a different absorption in adults compared to children, highlighting that children cannot be viewed as small adults.

The results from the preliminary modelling and simulation into children data showed that a single dose of CT001 significantly reduced pain (SPID55) compared to the other arms, due to the higher exposure seen in children in study 0201 and 0206 compared to both adult studies 0204 and 0205. Data from study 0205 provided clear evidence that ketamine can significantly reduce the need for opioids. Specifically, it showed that the presence of ketamine allows for approximately a 50% reduction in the amount of sufentanil exposure needed to achieve a certain level of pain relief.

The double-blind, randomised, placebo-controlled 0205 study investigated efficacy, safety, and tolerability of CT001 as postoperative analgesic treatment in adults, following impacted mandibular third molar extraction. The results of study 0205, in the first of two primary endpoints CT001 (-13.59, 95% CI -16.58, -10.60) showed a statistically significant pain reduction compared to both placebo (-1.00, 95% CI -4.11, 2.10) and ketamine (-5.90, 95% CI -8.90, -2.90) and was on par with sufentanil (-17.20, 95% CI -20.19, -14.21) as measured as the sum of pain intensity differences (SPID) at 55 min.

Paediatric Investigation Plan (PIP) of CT001
The development of CT001 in Europe is done in line with the endorsed Paediatric Investigation Plan (PIP) by EMA's Paediatric Committee, which is a combination of both clinical trials and modelling and simulation data from adults into children. The results of study 0205 were intended to provide evidence that efficacy in adults can be translated into children and therefore forms an integrated part of the full dataset to enable a submission and potential approval of CT001.

Mads Werner, MD, PhD, DMSc, Principal Investigator of study 0205
"*The outcomes of the study are encouraging, proving that CT001 is well tolerated and efficacious in adults. Modelling the data into children's characteristics, a heightened pain relief is evidenced, indicating that CT001 has the potential for approval in paediatric acute care. We are delighted to have conducted the 0205 study at a single clinical centre. The inflow of patients from the referring dental clinics has worked well and has been optimised during the last six study months. It is, of course, always extra rewarding knowing that the study has provided positive simulated results for CT001 in children, and we look forward to communicating more details about the study at scientific meetings.*"

Jes Trygved, CEO, Cessatech
We are very excited about these results which demonstrated that CT001 is superior to both sufentanil and ketamine when simulated into children due to a much higher exposure compared to adults. Although CT001 did not show superiority to sufentanil in adults, we are very encouraged with the exposure and simulation data that support the prior findings in children and allows us to move forward with CT001 as planned. This is important news for children and hospital nurses and doctors as it indicates that we in the future can offer efficient and non-invasive treatment for acute pain in children. We plan to share the data at upcoming scientific meetings and will also submit the study for publication. We are now focusing on initiation of the 0202 study and the US launch which is expected to take place during 1H of 2024.

For more information about Cessatech, please contact:
Jes Trygved, CEO
Phone: +45 9387 2309
E-mail: jes.trygved@cessatech.com
www.cessatech.com

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.