Press Release
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Cessatech announces positive top-line results from its final CT001 Study 0202

- **The primary endpoint of responder analysis, of pain relief (pain score ≤4/10), was met and reported by 54% of patients after 15 minutes and by 88% after 30 minutes.**
- **Overall pain reduction was 75% after 30 minutes, and 86% after 60 minutes.**
- **No drug related unexpected adverse effects, and they were all transient and of mild to moderate intensity.**

On 28 May – Cessatech A/S ("Cessatech" or "the Company") announces top-line results from its Paediatric Study 0202, an open-label trial in the development program of CT001 an intranasal, needle-free analgesic for acute paediatric pain. The study demonstrated a rapid, clinically meaningful reduction in pain scores and confirms a favourable safety and tolerability profile for CT001. These positive data mark a key milestone towards regulatory submission in Europe and reinforce Cessatech's commitment to delivering innovative, child-friendly pain treatments. The company and its partner, Proveca, will accordingly initiate the EMA process for submission later this year.

In April of 2025 the Company announced the completion of patient recruitment of the final study, Paediatric Study 0202 in the development program of CT001. Study 0202 is the final required clinical study that will evaluate the safety and efficacy profile for CT001 in 152 children with moderate to severe pain due to an injury in the emergency departments. The primary endpoint was patients with pain intensity (≤4) measured at 15 minutes and 30 minutes. Pain intensity ≤4 was reported at 54% at 15 minutes and 88% after 30 minutes. The quick onset and level of pain reduction is very encouraging and in line with previous presented data simulated from study 0208.

There were no drug related unexpected adverse effects, and they were all transient and of mild to moderate intensity. There were no obvious differences across age groups. CT001 has been very well perceived by the children involved, the parents and physicians involved in the study.

CT001 is a nasal spray under development for treatment of acute pain in children. The development of CT001 in Europe is done in line with an endorsed paediatric investigation plan (PIP) by EMA's Paediatric Committee. UK based company Proveca has exclusive rights to market and sell CT001 outside North American and will take the lead in the regulatory submission and later commercialization.

Dr Stuart Hartshorn, Chief Investigator of Study 0202
"The study data are, of course, important, but what really stood out were the moments we saw at the bedside," said Dr Stuart Hartshorn, Chief Investigator of Study 0202. "The response from children and their families often said more than any statistic: within minutes, children were visibly more settled, parents looked reassured, and you could see the relief on everyone's faces. Seeing your patient sit up, smile, and start engaging again so quickly made it clear this needle-free treatment isn't just effective, it makes a real difference when comfort and reassurance are most needed."

Martin Juhl, CSO, Cessatech
"It is truly encouraging to see CT001 perform so effectively in the demanding environment of emergency departments across Europe. The efficacy demonstrated in Study 0202 is compelling: not only did we observe a median overall pain reduction of 75% at 30 minutes, but the responder rates were also very strong. For instance, 95% of children in Study 0202 experienced at least a 30% reduction in pain, after 30 minutes, which is highly consistent with the 93% predicted by our unified adult-paediatric model. Furthermore, 86% in Study 0202 achieved at least a 50% pain reduction, closely mirroring the 84% predicted by the same modelling. Critically, these positive efficacy results are coupled with a benign safety profile, with all AEs being transient and of mild to moderate intensity. This combination of robust, clinically meaningful pain relief and favourable safety is a remarkable outcome and strongly supports CT001's potential for paediatric acute pain."

Jes Trygved, CEO, Cessatech
"We are extremely pleased with this milestone in our final study for the development of CT001 in paediatric patients, especially as it requires significant effort to recruit so many children and to secure the trust and consent of their parents," said Jes Trygved, CEO of Cessatech A/S. "The results clearly demonstrate that CT001 can make a meaningful difference for children who need rapid, needle-free pain relief during acute medical procedures. With this positive outcome, we are one step closer to bringing an innovative, child-friendly analgesic to children, caregivers and healthcare professionals worldwide."

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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.