

Press Release

30 April 2025 – 15.45

Cessatech announces that recruitment has completed in the Paediatric Study 0202, and now the EMA submission process can be initiated for CT001



- 150 paediatric patients have been recruited in Study 0202 as planned
- Study 0202 is the final required clinical study that will evaluate the safety and efficacy profile for CT001 in children
- Top-line results are expected within the next 3-6 weeks
- The EMA submission process can now be initiated, for submission later this year

On 30 April – Cessatech A/S (“Cessatech” or “the Company”) announces that it has completed the patient recruitment of its 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 150 children, with top-line results expected soon. The company and its partner will initiate the EMA process for submission later this year.

CT001 is a nasal spray under development for treatment of acute and procedural 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.

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 including getting the consent from parents that their child can participate. In some age-groups this has been a bit challenging, but fortunately we know that CT001 has been well tolerated in the study and therefore there has also many satisfied parents. This is a fantastic achievement and great effort by the team, and we look forward to presenting the data soon – and more importantly also initiate the EMA submission process for potential approval. The clinical program has now been finalised for CT001, and we are one step closer of having CT001 available to hospitals and the children that really need approved, easy to administer, pain relief – hopefully in 2026.”

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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.