Press Release
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This press release is intended for investors only.

The Marketing Authorisation Application (MAA) for CT001 is submitted to the European Medicines Agency (EMA) for acute pain management in children

- **Proveca has submitted a Paediatric Use Marketing Authorisation (PUMA) application for CT001 (ketamine/sufentanil nasal spray) to the EMA**
- **The validation process has been completed**
- **The review process will now be initiated and potential approval expected in 2026**

Copenhagen, Denmark - 14 August 2025 - Cessatech A/S ("Cessatech") and Proveca Ltd ("Proveca") today announce that the European Medicines Agency (EMA) has validated the Marketing Authorisation Application (MAA) for CT001 (a prescription only medicine), confirming that the submission is complete and that the formal scientific review has started. This event marks a significant milestone in Proveca's and Cessatech's mission to bring an innovative treatment candidate to paediatric patients in Europe.

CT001 is being developed for acute pain management in children aged 1-17 years with the goal of addressing a clear unmet medical need where current options are limited and inconsistent in meeting patient and caregiver expectations. If approved, CT001 has the potential to become the first and only nasal treatment specifically designed for the management of moderate to severe acute pain in children aged 1-17 years. PUMA is a type of application to the EMA to get a medicine approved specifically for use in children, across the EU.

Comments from Proveca CEO, Simon Bryson
"We are very pleased to have submitted this PUMA application to the EMA for this innovative, new medicine to manage acute pain in children aged 1-17. Proveca and Cessatech signed the exclusive licensing agreement less than 12 months ago, and in this time the team have successfully completed the CMC and clinical programmes and prepared the marketing authorisation dossier for EU registration. This is a significant milestone, and we look forward to bringing this new treatment to paediatric patients."

Comments from Cessatech CEO, Jes Trygved
"The EMA application of the CT001 MAA is a proud moment for the team and all of our partners. It reflects years of rigorous clinical development and close collaboration with investigators, regulators and advisors. We believe CT001 can make a meaningful difference for patients facing acute pain, an area where the unmet need remains high. It is amazing that we can submit the application just a few months after the top-line results of the last study, with thanks also to Proveca for their immense effort."

Proveca and Cessatech extend their sincere appreciation to all participants, investigators, study-site teams and the parents and families who took part in the clinical programmes. Their commitment and trust have been essential in advancing this potential therapy toward patients in need. Following validation, the EMA's Committee for Medicinal Products for Human Use (CHMP) has initiated its assessment of CT001. While the outcome of regulatory reviews cannot be guaranteed, both Cessatech and Proveca look forward to a potential EMA approval, pending a positive benefit–risk assessment.

About CT001

CT001 is a fixed-dose combination analgesic nasal spray (ketamine and sufentanil) for acute pain management in children age 1-17, in two strengths. The development program included studies both in children and adults, designed with a focus to evaluate the medicine's efficacy, safety and usability in children.

About Proveca

Proveca Ltd is a UK-founded pharmaceutical company, with technical and commercial operations globally. The company specialises in the development, licensing and commercialisation of evidence-based medicines to address the unmet medical needs of children, with a current paediatric product portfolio within the neurology, cardiovascular, gastroenterology and immunology therapeutic areas.

About Cessatech

Cessatech A/S is a Danish pharmaceutical company committed to developing and commercialising 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 pain management in children. Another key asset of Cessatech is CT002, which is at the early development phase, for sedative procedures.

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