Press Release
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Proveca intends to request a re-examination of CHMP opinion for CT001/KemSu

- **The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a negative opinion on the Paediatric Use Marketing Authorisation (PUMA) application for CT001/KemSu (intranasal sufentanil/ketamine).**
- **Proveca intends to request a re-examination of the CHMP opinion in accordance with EMA procedures.**
- **Proveca and Cessatech remain committed to working closely with the EMA throughout the re-examination process.**
- **CT001/KemSu continues to represent an important potential treatment option for children with moderate to severe acute pain**

Copenhagen, Denmark - 24 July 2026 - Cessatech A/S, a late-stage paediatric specialty pharmaceutical company developing and commercialising hospital medicines for children, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on Proveca's application for a Paediatric Use Marketing Authorisation (PUMA) for CT001/KemSu, a fixed-dose ketamine/sufentanil nasal spray for the treatment of acute pain in children aged 1-17 years.

In accordance with established EMA procedures, Proveca intends to request a re-examination of the CHMP opinion. Both companies will continue to engage constructively with the EMA throughout the re-examination process to address the points raised by the CHMP and support the continued assessment of KemSu formally known as CT001. Proveca is Cessatech's commercialisation partner for KemSu and is intended to become the marketing authorisation holder for the product in Europe.

Jes Trygved, CEO of Cessatech, said:
"While we are naturally disappointed by today's opinion, we remain confident in the overall benefit-risk profile of KemSu and in the comprehensive data supporting the application. Together with our partner Proveca, we intend to request a re-examination of the CHMP opinion and will continue to work constructively with the EMA, with the objective of making KemSu available to children who need new treatment options for the management of acute pain. The re-examination process is expected to take several months."

About KemSu/CT001
KemSu is a fixed-dose combination nasal spray developed specifically for the treatment of acute pain in children aged 1-17 years. KemSu has been designed to provide needle-free analgesia and addresses a significant unmet need in paediatric acute pain management. KemSu has been evaluated in a comprehensive clinical development programme supporting its efficacy, safety and usability in children.

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About Cessatech

Cessatech is a pivotal-stage paediatric biotech company developing first-in-class specialty hospital medicines for children, focused on high-impact unmet needs in acute and emergency care. The company's lead program, KemSu/CT001, is advancing towards commercialization subject to regulatory approval by the EMA. Cessatech operates a capital-efficient, partnership-driven model, combining an experienced team with best-in-class partners for development, manufacturing and commercial execution across key markets. Cessatech is led by a seasoned leadership team with a strong track record in drug development and product launches in Europe, the US and Asia.