Press Release

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Proveca and Cessatech plan next regulatory steps for KemSu following CHMP opinion

- **The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has maintained its negative opinion on the Paediatric Use Marketing Authorisation (PUMA) application for CT001/KemSu following the re-examination procedure.**
- **Proveca and Cessatech intend to seek scientific advice from the EMA to better understand and address the remaining gaps identified by the CHMP, with the objective of defining a clear regulatory pathway towards a new submission.**
- **KemSu continues to represent an important potential treatment option for children with moderate to severe acute pain – and both companies remain committed to working closely with the EMA throughout the resubmission.**

Copenhagen, Denmark – 13 November - 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 maintained its negative opinion following the re-examination of 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.

Following the conclusion of the re-examination process, Proveca and Cessatech intend to seek scientific advice from the EMA to gain a clearer understanding of the remaining evidence gaps and the additional data that may be required to support a future resubmission. Both companies remain committed to working constructively with the EMA to define an appropriate regulatory pathway for KemSu. Proveca is Cessatech's commercialisation partner for KemSu and is intended to become the marketing authorisation holder for the product in Europe. In parallel, the U.S. market remains Cessatech's primary strategic focus, representing the company's largest commercial opportunity and a key driver of its future growth.

Jes Trygved, CEO of Cessatech, said:
"While we are naturally very disappointed by the outcome of the re-examination, we are encouraged that the CHMP has removed one of the two original grounds for refusal, leaving a more clearly defined regulatory issue to address. We remain confident in the overall benefit-risk profile of KemSu and its potential to address an important unmet medical need in children. Together with our partner Proveca, our next step will be to seek scientific advice from the EMA to better understand the remaining gaps, and determine how these can best be addressed. We believe this will provide an important foundation for defining a pathway towards resubmission, with our long-term objective unchanged – to make KemSu available to children who need new treatment options for the management of acute pain."

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.

For more information about Cessatech, please contact

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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.