Press Release
4 February 2025 – 11.30

Cessatech receives positive Notified Body opinion under MDR for CT001

- **CT001 receives positive opinion during the Medical Device Regulation (MDR) approval process.**
- **Confirms that CT001 meets the General Safety and Performance Requirements of the MDR.**
- **An important milestone for Cessatech's EMA filing, planned for later this year – and highlights Cessatech's commitment to quality and evidence-based treatments.**

On 4 February – Cessatech A/S ("Cessatech" or "the Company") announces that the Company has received a positive Notified Body Opinion under Article 117 of the Medical Devices Regulation (EU) 2017/745 (MDR) for its lead asset CT001. The technical documentation for CT001 was reviewed in accordance with Annex I of Regulation (EU) 2017/745. The assessment has been performed for the purpose of an initial application – and the objectives of this assessment were found to have been met. Technical documentation for the device is considered adequate to support compliance with the General Safety and Performance Requirements of the MDR.

The MDR opinion ensures medical devices with a drug component are safe and effective. The EMA reviews the drug part, while a Notified Body evaluates the device. Together, they ensure the product meets EU efficacy and safety standards.

Martin Juhl, CSO, Cessatech
We are very proud to have received this positive opinion from the Notified Body. It is a testament to the team's dedication to scientific rigor and quality in meeting MDR requirements. We are pleased that the quality of our technical documentation and approach has been recognized through this positive opinion. As a side note, this marks the first time a company has used the Interactive Online Review Process through the selected Notified Body organization for Article 117, which underscores our commitment to innovation and improved efficiency.

Jes Trygved, CEO, Cessatech
The MDR assessment is a major achievement for the Company and is an integrated part of the EMA approval process of CT001. We are now one important step closer to getting CT001 approved in Europe for children aged 1-17 years old, together with our commercial partner Proveca. Since the introduction of the MDR process in 2021, it is estimated that some +3,000 certificates and opinions have been completed in Europe, while there is still a large backlog of some 3-4000 pending – it is an amazing effort that we completed our assessment within the estimated timeframe. Thanks to all for an amazing effort.

For more information about Cessatech, please contact:
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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.