Press Release
12 June 2026 - 13.30

Cessatech enters collaboration with University Hospital of Copenhagen, Rigshospitalet, to advance an intravenous formulation of melatonin for post-anaesthesia delirium (CT004) in children

- **CT004 targets post-anaesthetic agitation and emergence delirium, an underserved paediatric condition affecting 25-30% of children, for which no approved treatments are currently available.**

- **A phase II study of 676 children at five sites in Denmark has been initiated and funded by University Hospital of Copenhagen, Rigshospitalet.**

- **Cessatech retains worldwide commercial rights to CT004.**

Copenhagen, Denmark – 12 June 2026 - Cessatech A/S, a late-stage paediatric specialty company developing and commercializing hospital medicines for children, today announced a new collaboration with the University Hospital of Copenhagen, Rigshospitalet, to advance an intravenous melatonin-based therapy for the prevention and management of post-anaesthetic agitation and emergence delirium in children, hereafter named CT004.

Cessatech and the University Hospital of Copenhagen, Rigshospitalet, will jointly outline the regulatory strategy and final development plan, that could lead to regulatory approval of this new treatment option. Under the collaboration agreement, the University Hospital of Copenhagen, Rigshospitalet, initiated a Phase II clinical trial (MELA-PAED) in 2025, as well as a pre-clinical study of the pharmacokinetics of the oral melatonin in preterm pigs. Cessatech retains worldwide commercial rights to CT004.

“Emergence delirium affects a substantial proportion of children recovering from general anaesthesia and can be distressing for both patients, families and healthcare professionals. The MELA-PAED study is designed to investigate whether intravenous melatonin may offer a new approach to addressing this unmet medical need. The results will provide valuable insights into the role of melatonin in paediatric perioperative care,” said Senior Consultant, MD, PhD. **Arash Afshari,** Rigshospitalet, University Hospital of Copenhagen.

“We are extremely pleased with this new asset, and the collaboration is fully aligned with Cessatech’s partnership-driven model and represents an important step in advancing CT004,” said **Jes Trygved, CEO of Cessatech**. “As a specialist company focused on hospital medicines for children, Cessatech is building a leading position in paediatric care management through the development of therapies tailored to the unique needs of children. By combining leading academic expertise with Cessatech’s development and commercialization capabilities, we can progress the program while retaining worldwide commercial rights. As CT001 advances toward commercialisation, CT004 represents another opportunity to expand our portfolio of specialty hospital medicines for children and address a significant unmet need in paediatric care. Going forward we will apart from CT001 focus mainly on CT002 and CT004.”

“While emergence delirium is often transient, it can be highly distressing for children and their families and may complicate recovery following surgery. Melatonin is of particular interest because of its role in regulating the sleep-wake cycle and its favourable safety profile. Through this study, we hope to better

understand whether intravenous melatonin can help support a smoother recovery from anaesthesia and provide a new treatment option for this vulnerable patient population," said Senior Consultant, MD, PhD., **Lars Peter Kloster Andersen**, Zealand University Hospital.

About CT004: Addressing a significant unmet need in paediatric anaesthesia

Many children experience confusion and distress when waking from general anaesthesia, a condition known as emergence delirium. It affects approximately 25-30% of children and up to 40-50% of preschool-aged patients, particularly those undergoing sevoflurane-based anaesthesia. Despite its prevalence, there are currently no approved treatments and no established standard of care for the prevention of this kind of delirium.

Emergence delirium can lead to agitation, crying and disorientation, which may be distressing for both patients and caregivers and can increase the burden on healthcare staff and prolong recovery times.

CT004 is being developed as a targeted treatment to address this gap. It is an intravenous formulation of melatonin - a naturally occurring hormone that regulates sleep - designed to support the body's normal recovery after anaesthesia. Unlike traditional sedatives, CT004 aims to stabilize the sleep-wake cycle without causing deep sedation or respiratory depression.

For more information about Cessatech, please contact

Jes Trygved, CEO
Phone: +45 9387 2309
E-mail: jes.trygved@cessatech.com
www.cessatech.com

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, CT001, is advancing toward near-term commercialization. Cessatech operates a capital-efficient, partnership-driven model, combining a lean, experienced team with best-in-class partners for development, manufacturing and commercial execution across key markets. Headquartered in Hellerup, Denmark, 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.