Press Release
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Cessatech reports Regulatory Green Light for trial 0205, the pivotal trial for CT001 - first patient expected shortly

- **Trial 0205, the pivotal trial, will investigate the postoperative analgesic efficacy of CT001, in adult participants following impacted mandibular third molar extraction, a randomised, double-blind placebo controlled trial with 220 patients.**
- **Regulatory green light and approval is finally in place, a process that has taken much too long by the authorities.**
- **Patient recruitment will be initiated very soon, and we anticipate to finalise recruitment by early 2023.**

Cessatech A/S announces that the pivotal trial 0205 has obtained regulatory approval and thereby green light by the authorities and is now ready to initiate patient recruitment. The trial will investigate the postoperative analgesic efficacy of CT001, in adult participants following impacted mandibular third molar extraction, a randomised, double-blind placebo controlled trial with 220 patients.

The paediatric investigation plan (PIP) for CT001 nasal spray has been approved by the European Medicines Agency and trial 0205 is a part of the clinical development plan for treatment of acute pain in children.

Comment from Jes Trygved, CEO of Cessatech
We are very pleased with finally being able to initiate this important trial, and the company is now moving into a different stage with its pivotal study - great work and effort by all the people involved in the preparation of this trial. Unfortunately, it has taken much too long a time and we are disappointed that the approval process, in particular with the Ethical Committee, is so cumbersome and not in favour of an innovative company and industry. CT001 is getting closer to the market and its potential patients and the period ahead will be extremely interesting.

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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 and planned painful procedures in children. The advantages include needle-free administration, being easy to administer, a fast-acting therapeutic effect, and being medically approved for children.