

Press Release

5 September 2022

Cessatech reports first patient dosed in pivotal trial of lead product candidate



- First patient has been dosed in pivotal trial of lead candidate CT001
- The pivotal trial, trial 0205, 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.
- Patient recruitment has now started, and we anticipate to finalise recruitment by the first part of 2023.

Cessatech A/S announces that the pivotal trial 0205 has now been initiated with the dosing of the first patient. 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 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 the initiation of 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 and initiation of this trial. 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. CT001 is in late stage clinical development.