



- a company developing evidence-based treatments - specifically for children

# Newsletter #8 - October 2022

## Great progress during Q3 – more to come

### Successful outcome of pharmacokinetic trial (phase II)

The original release included a small typo, that clinical trial 0206 investigating the pharmacokinetics of CT001 in children aged 1-17 undergoing elective surgical procedures, was a phase I study – it was of course a phase II study. We apologise for the mistake. Primary endpoint was successfully met by obtaining pharmacokinetic data in this age group, showing relevant clinical exposure ranges. In addition, secondary objectives of safety, pain assessment, and acceptance of intranasal administration was at an acceptable level (meaning no change to previous safety profile, which is a good).

CT001	<input type="checkbox"/>	<input type="checkbox"/>
Trial-0206	<input type="checkbox"/>	<input type="checkbox"/>

The trial was designed as a non-randomised, open-label study in 25 children needing pre-medication for placement of a peripheral venous catheter for general anaesthesia related to a surgical procedure.

### Start of the important pivotal trial 0205 (September)

First patient was dosed early September 2022 in the important pivotal trial 0205 of lead candidate CT001. The initiation marks that the company is now moving into a different stage with its pivotal study.

Patient recruitment is progressing, and we anticipate to finalise recruitment by the first part of 2023. The trial will investigate the postoperative analgesic efficacy of CT001, in adult participants following impacted mandibular third molar extraction, a randomised, double-blinded, placebo-controlled trial with 220 patients.

CT001	<input type="checkbox"/>	<input type="checkbox"/>
Trial-0205	<input type="checkbox"/>	<input type="checkbox"/>

These important data are needed for the planned modelling and simulation studies of CT001. The data will replace traditional trials through extrapolation of e.g. efficacy from adults to children.

### Company presentation on Nordnet (September)

If you missed the latest company presentation from last month, please visit the link on our company page ([link](#)) – here we gave a short update on the progress we have made, and in particular what we can expect in the future. There are not many late stage biotech companies on the Danish market, we are proud that Cessatech is one of them...

