

Press Release

16 May 2022

Cessatech reports last patient dosed in pharmacokinetic trial in children of lead candidate

CT001 
Trial-0206

- **Clinical trial 0206 will investigate the pharmacokinetics of CT001 in children aged 1-17 undergoing elective surgical procedures.**
- **Primary aim is to obtain pharmacokinetic data from this age group and to demonstrate that CT001 is feasible as premedication in children undergoing a painful procedure.**
- **Topline results are anticipated by the end of Q3 2022**

Cessatech A/S announces that the pharmacokinetic trial (0206) in children has finalised recruitment of all planned patients. The trial is designed as a non-randomised, open-label study in 25 children aged 1-17 years needing premedication for placement of a peripheral venous catheter for general anaesthesia related to a surgical procedure. The analgesic and sedative properties of the CT001 nasal spray is expected to be beneficial in this setting.

The pharmacokinetic data in children are needed for the planned modelling and simulation studies of CT001. Modelling and simulation studies may under the right circumstances replace traditional trials through extrapolation of e.g. efficacy from adults to children and thus a minimum of clinical trials need to be done in children during drug development. In the 0206 trial, pharmacokinetic data for all relevant age groups will be obtained for use in the planned modelling and extrapolation studies.

Comment from Jes Trygved, CEO of Cessatech

We are very pleased with the recruitment of the last patient in this important trial in children. We anticipate having the topline results by the end of Q3 2022. Conducting clinical studies involving children creates particular challenges and it is thanks to the support and hard work of the Cessatech team, the principal investigator, the site staff and in particular the children and parents involved, that we are able to announce today this great achievement of the last patient being dosed in the trial. We continue to work hard to get CT001 available for the treatment of acute pain in children.

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 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.