

Press Release

20 August

Cessatech reports first patient dosed in pharmacokinetic trial in children of lead product candidate

CT001 
Trial-0206 

Clinical trial 0206 will investigate the pharmacokinetics in children aged 1-17 undergoing elective surgical procedures. Primary aim of this trial is to obtain pharmacokinetic data from this age group and to demonstrate that CT001 nasal spray is feasible as premedication in children undergoing anaesthesia.

Cessatech A/S announces that the pharmacokinetic trial (0206) in children has been initiated according to plan and that the first patient has been dosed. The trial is designed as a non-randomized, 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. Patients participating in the trial will receive CT001 nasal spray as premedication before placement of a peripheral venous catheter. 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.

The paediatric investigation plan (PIP) for CT001 nasal spray has been approved by the European Medicines Agency in November 2019 and trial 0206 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 the initiation of this important trial in children. We have put a lot of effort into the preparation and execution of this trial and anticipate having the study completed by the end of this year. A special thanks to the principal investigator and the site teams for their effort which requires more when dealing with children. 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. CT001 is expected to enter late stage clinical development in 2021.