Press Release
24 March 2021

Cessatech reports first subject dosed in bioavailability trial of lead product candidate

Clinical trial 0204 in healthy volunteers will investigate the absolute bioavailability of CT001. Primary aim of trial is to demonstrate drug-exposure following nasal administration of CT001 relative to the IV injection of approved drug counterparts

Cessatech A/S announces that the 12-subject bioavailability trial (0204) has been initiated according to plan and will include adult healthy volunteers in a randomized three-treatment, three-period, single dose crossover design with a wash-out period of minimum 5 days and maximum 3 weeks. The study will investigate the absorption of CT001 nasal spray across nasal mucosa (also known as bioavailability) compared to marketed intravenous solutions of the two analgesic drugs in a standardised set-up with healthy volunteers.

The paediatric investigation plan (PIP) for CT001 nasal spray has been approved by the European Medicines Agency in November 2019 and trial 0204 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 and we have put a lot of efforts into the preparation and execution of this trial. Despite the COVID10 conditions, we anticipate finalizing the recruitment earlier than anticipated which is a strong sign for our new organization. A special thanks to the principal investigator and the site teams for their great effort.

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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 expected to enter late stage clinical development in 2021.