Press Release
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Cessatech reports successful outcome of bioavailability trial 0204 with CT001

Topline results of clinical trial 0204 investigating the absolute bioavailability of CT001 showed clinical relevant exposures following nasal administration. Primary aim of the trial was to investigate drug-exposure following nasal administration of CT001 relative to the IV injection of the approved drug counterparts.

Cessatech A/S announces topline results of its Phase 1 bioavailability trial (0204) with CT001 in healthy adults (NCT04807335).

In this randomised, three-treatment, three-period, single dose crossover trial 15 healthy subjects were allocated to treatment with CT001, IV ketamine, and IV sufentanil at three different dosing visits. The objective of the trial was to investigate the absorption of CT001 across nasal mucosa (also known as bioavailability) compared to marketed intravenous solutions of the two analgesic drugs composing CT001. Additionally, the safety and tolerability of CT001 was assessed during the trial.

Approximately 40% of sufentanil and 50% of ketamine was absorbed into the systemic circulation when administered via the nasal spray as compared to intravenous infusions in the subjects, meeting the objective of the trial. The reported side effects were of mild severity and CT001 was assessed to be safe and well tolerated in the trial. The most common side effects reported for CT001 was headache.

Comment from Mads Werner, MD, PhD, DMSc, Principal Investigator
The main results of the trial demonstrated clinical relevant exposure to CT001 when administered via a nasal spray as compared to intravenous infusions, underscoring the potential of CT001 in clinical practice.

Comment from Jes Trygved, CEO of Cessatech
We are very happy with the results of trial 0204 - these positive data together with the coming data from our pharmacokinetic trial in children (0206) are key to the CT001 paediatric development plan. With these data we are now one step closer to our ultimate goal of making this product available to patients. Thanks to the trial participants, the staff at the clinic, and the team for making this possible.

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This disclosure contains information that Cessatech is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 8 March 2022

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 at its pivotal stage of clinical development.