Press Release
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MAR Release

Cessatech reports successful outcome of pharmacokinetic trial in children of lead candidate

- **Clinical trial 0206 investigated the pharmacokinetics of CT001 in children aged 1-17 undergoing elective surgical procedures.**
- **Primary endpoint was successfully met by obtaining pharmacokinetic data in this age group, showing relevant clinical exposure ranges.**
- **Secondary objectives of safety, pain assessment, and acceptance of intranasal administration was at an acceptable level**

Cessatech A/S announces positive topline outcome of its Phase 2 pharmacokinetics trial with CT001 in children, which met the primary endpoint of the trial. The trial was designed as a non-randomised, open-label study carried out in 25 children aged 1-17 years who needed premedication for placement of a peripheral venous catheter for general anaesthesia related to a surgical procedure.

The primary endpoint was successfully met by obtaining pharmacokinetic data in children, showing relevant clinical exposure ranges in all age groups. The pharmacokinetic data in children are needed for the planned modelling and simulation studies of CT001 (study 0207 and 0208). 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.

The reported side effects were mainly of mild intensity and CT001 was considered to be safe and well tolerated in the trial. The most common side effects reported for CT001 were nausea and vomiting. There was a high acceptance rate of CT001 intranasal administration with 25 patients that received at least one dose all responded yes for acceptance, except for one who did not provide response.

Comment from Jes Trygved, CEO of Cessatech
We are very happy with the results of trial 0206 - these positive data together with the data from our bioavailability trial in adults (0204) 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. Conducting clinical studies involving children creates particular challenges and therefore a great effort from all, in particular the trial participants both children and parents involved, the staff and investigator at the hospital, and the team for making this possible. 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 pivotal stage 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.