Press Release
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Favourable data from the Registry Safety Study

First major milestone reached: Data from the Registry Safety Study (0203) indicates a favourable safety-profile for Cessatech's lead product CT001

Cessatech A/S announces positive, top line data from a retrospective, non-interventional study – also referred to as the Registry Safety Study (0203). The database counts 2286 painful medical procedures, performed as a part of routine clinical care at the Astrid Lindgren Children's Hospital, Karolinska Hospital, Stockholm, Sweden. The Registry Safety Study includes data from 328 children that had the combination of sufentanil, and s-ketamine administered nasally for 700 medical procedures for prevention of acute pain.

The primary outcome of the Registry Safety Study has been to investigate adverse events, including serious adverse events for the combination of sufentanil and s-ketamine when administered as a part of routine clinical care. **No serious adverse events were reported** for the use of sufentanil and s-ketamine in combination, confirming a favourable safety profile for this combination. For the development of CT001 it has been important to address the risk of serious respiratory adverse events which is an uncommon but feared adverse event when administering strong analgesics for treatment of pain in children. The Registry Safety Study indicates a favourable safety profile for the CT001, containing a 'fixed and ready to use' combination of sufentanil and ketamine. Furthermore, the doses reported in the Registry Safety Study support the choice of dose level that is planned for the upcoming clinical trials with CT001. The free combination of nasal sufentanil and s-ketamine provided adequate analgesia for the vast majority of the painful procedures in the database.

The Registry Safety Study delivers supportive safety data to the already published data from a phase II study with 50 children and will together with the additional four clinical studies form the full package as agreed with the EMA for the final marketing approval.

Background and study details

- Nasal administration of drugs has become increasingly popular in especially children for a number of reasons: needle-and pain free administration, rapid absorption through the nasal mucosa directly to the systemic circulation means rapid onset effect of suitable drugs.
- In this retrospective, non-interventional registry study, the main objective was to evaluate the safety and tolerability of sufentanil and s-ketamine used in the free combination for prevention of acute pain in children 1-17 years old undergoing painful medical procedures as a part of routine clinical care - during a time period of more than 10 years.
- In the Registry Safety Study, the free combination of sufentanil solution for injection and s-ketamine solution for injection were administered as nasal drops or with a spray device according to the patient's weight.

PIP plan and PUMA/EMA approval

Cessatech's approved PIP consists of four (4) additional short clinical trials and two (2) computer-based modelling-simulation studies, which will be conducted during 2021-2023. After completing the approved PIP and filing for regulatory approval, Cessatech will be able to provide sufficient data to demonstrate the efficiency and safety of its lead asset CT001, which will be the basis of a paediatric-use marketing authorisation (PUMA) by the EMA and the reward of ten years of market exclusivity in Europe**.** It is Cessatech's ambition to have its nasal spray (CT001) ready for launch on the market in 2024.

Comment from Stefan Lundeberg, MD, PhD – Senior Consultant, Paediatric Pain Treatment Service, Karolinska University Hospital

We have used intranasal analgesia for painful medical procedures in children for many years. Nasal administration is convenient and can be done without needles which is a great advantage working with children. Our experience with combining the analgesic and sedative effects of low dose sufentanil and s-ketamine is that we in most cases obtain sufficient analgesia and safety is good. We are glad that the Registry Safety Study confirms our clinical experience.

Comment from Jes Trygved, CEO of Cessatech

It is rare that we have structured results and data on so many children (328), and over such a long period which is why I think the results of a favourable safety profile is very confirming and encouraging for the future of CT001. Data will later be further disseminated. A big thanks to the team for their efforts over the years, much work has been put into this study. The fact that we have not seen any serious adverse events reported is extremely strong and a very important aspect in the pain management of children. We are on track and one big step closer on our journey. VideoLink

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This information is information that Cessatech is obliged to publish in accordance to the EU Market Abuse Regulation. The information was provided by the contact person set out above for publication on 4 March 2021.

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.