Press Release
25 October 2023

Cessatech announces that the Paediatric Committee has agreed to a 50% reduction of the required number of patients in the final study of its nasal spray for the treatment of acute pain in children

- **The European Paediatric Committee (PDCO) has agreed to a 50% reduction in the number of children required in the final safety study (0202) of CT001 for the treatment of acute and procedural pain in children**
- **New safety data from both adult and paediatric studies has been presented to PDCO and based on this information, the PDCO agreed to the proposed reduction in number of children**
- **With this PDCO opinion, study 0202 will have a much shorter recruitment period and at less costs that previously anticipated. The study is now approved by the competent authorities in Spain and UK**

On 25 October – Cessatech A/S ("Cessatech" or "the Company") announce that EMA's Paediatric Committee (PDCO) has agreed to reduce the number of required children in the final clinical study with CT001 from 300 to 150 children. Study 0202 is the final required clinical study that will evaluate the safety profile for CT001 in children. The company presented new data from both adult and paediatric studies to PDCO and with this additional information, the PDCO agreed to the proposed changes to the clinical development program for CT001. The significant reduction of children means that study 0202 can be completed faster and at a significant lower cost than previously assumed. The study is now approved by the competent authorities in Spain and UK where the study will recruit. The company expects the study to start during Q1 2024.

CT001 is a nasal spray under development for treatment of acute and procedural pain in children. The development of CT001 in Europe is done in line with an approved paediatric investigation plan (PIP) by EMA's Paediatric Committee.

Helle Sickmann Bendixen, Head of Clinical Development, Cessatech
"We have now completed 4 clinical studies with 375 patients being exposed to CT001 without any safety and tolerability concerns. The agreement from EMA's Paediatric Committee also acknowledges that we seem to have sufficient safety information and can reduce the number of required children for study 0202. We are of course delighted about this opportunity because it means that we will be closer to completing the development of CT001. We are excited to soon start the study activities at several clinical sites in UK and Spain."

Jes Trygved, CEO, Cessatech
We are very pleased with the acknowledgement from PDCO and that we can now initiate the study with a much lower number of children. A great effort by the team and the sites involved. With the agreement from

EMA's Paediatric Committee, CT001 is now one step closer to finalize the clinical program and becoming available to hospitals and the children that really need approved, easy to administer pain relief."

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About Cessatech

Cessatech A/S is a Danish pharmaceutical company committed to developing and commercializing 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, easy administration, a fast-acting therapeutic effect, and being medically approved for children. CT001 is at its pivotal stage of clinical development, and CT002 is at the early development phase.