Press Release
12 September 2023

Cessatech announces agreement with the European Medicines Agency on a Paediatric Investigational Plan for its second asset CT002 for medical procedural sedation in children

- **The Paediatric Committee (PDCO) under The European Medicines Agency (EMA) has agreed to the Paediatric Investigational Plan (PIP) for CT002**
- **CT002 is the second asset in Cessatech's pipeline that has secured a PIP aimed at ensuring the necessary data to support a future authorisation for use in children**
- **CT002 is developed to address the unmet medical need of a non-invasive sedative procedure for children undergoing MRI scanning or other procedures requiring sedation**

On 12 September - Cessatech A/S ("Cessatech" or "the Company") announces that EMA's Paediatric Committee (PDCO) has agreed to the Paediatric Investigational Plan (PIP) for CT002 for procedural sedation. CT002 is the second asset in Cessatech's pipeline that has been selected for development.

Cessatech A/S has had discussions with EMA's Paediatric Committee and aligned the development plan for CT002. This includes both non-clinical, clinical discussions and quality aspects to ensure the necessary data are obtained to support a potential future authorisation of CT002 in children. The Paediatric Investigational Plan includes two clinical studies, a quality-related study and a modelling and simulation study. No pre-clinical studies are required. The development program will ensure that children in the future may be offered an easy to administer, non-invasive nasal spray for medical procedural sedation.

The **advantages of an agreed Paediatric Investigational Plan (PIP) for CT002** with the objective of market exclusivity of a PUMA authorization, are a significantly reduced risk profile, much shorter development timelines and especially much lower development costs compared to a full development program of a new molecular entity. Once the agreed studies have been performed, the efficacy and safety will be evaluated - and a PUMA/MA authorization may be granted.

CT002 will be tested in children **undergoing MRI scanning**, which often requires a full anaesthetic procedure, involving an intravenous (IV) sedative-hypnotic agent. The intravenous process is a very unpleasant experience for the child, the parents and to the physicians involved. CT002 is a non-invasive nasal spray designed to overcome this hurdle with a good sedative profile. It is estimated that there are more than +30 million paediatric medical procedures annually in Europe alone, that would normally require a form of sedation.

The approval of the CT002 PIP development program is in line with our previous communicated strategy to build a differentiated franchise within sedative and acute pain management for children. This second PIP agreement with the European Medicines Agency validates Cessatech's ability to develop innovative solutions for children. The actual initiation of the CT002 development program and related development costs and timelines will be linked to the commercial partnerships.

Jes Trygved, CEO, Cessatech
"We are very excited that EMA has agreed to the paediatric investigational plan for CT002 and look forward to progressing further with this second asset in Cessatech's pipeline. Diagnostic imaging procedures in the paediatric population are increasing and so is the number of examinations where sedation or general anaesthesia is needed. Having discussed CT002 with several experts in the field there is no doubt that CT002 may serve the unmet medical need for a safe and easy to administer drug for procedural sedation in children. With the positive opinion from EMA's PDCO for CT002, we have aligned expectations for a potential paediatric-use marketing authorization for the European market. We continue to work towards our purpose of rethinking child treatments"

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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.