

Novel treatment of paediatric pain

- **Strong niche product protected by regulatory data protection**

Biotech and Health Care



Value proposition/USP

Novel and improved treatment of acute procedural pain in children with a nasal spray developed exclusively to paediatric patients

- **Attractive clinical profile, incl.**
 - fast onset-of-action,
 - no use of needles
 - easy to implement in clinical care
- **A very significant market opportunity based on acknowledged medical need**
- **The product development is characterised by short time to market, relatively low risk and a modest budget**
- **Regulatory data protection (Paediatric-Use-Marketing Authorisation) in Europe**

Business Opportunity/Objective/commercial perspectives

More than 10 million children in Europe are each year exposed to acute procedural pain, *i.e.* pain inflicted due to a medical procedure at the hospital, in the emergency room or ambulances. No convenient and well-documented product is available to treat acute procedural pain in the paediatric population, and there is a significant medical need for a safe, efficacious product approved by the authorities.

We have invented a novel treatment designed to meet the significant shortcomings of the existing treatment. We intend to finalise the development with the aim of obtaining a regulatory approval in Europe and potentially other markets. Subsequent marketing of the product will be performed by an established company with the necessary geographical presence and marketing expertise. The product represents an attractive business opportunity with a significant sales potential based on preliminary estimates.

Technology description/technology Summary

The nasal spray contains a fixed combination of two well-know analgesics and features a needle-free administration with fast onset of clinical effect within 10-15 min after dosing and a good safety profile, as demonstrated by a clinical study already conducted. All of these features are highly desirable in the treatment of acute pain in children, and constitutes a significant improvement compared to the current situation characterised by the frequent use of poorly documented medicinal products in children.

Development phase/current state

The maturity level of the overall project corresponds to TRL 6/TRL 7. The nasal spray has been investigated in a clinical trial in 50 paediatric patients with encouraging results in respect to efficacy as well as safety. Moreover, the product was well accepted by the patients. The remaining development, including the overall strategy is currently discussed with the European Medicines Agency and we expect to reach an agreement with the authorities on the paediatric development plan by Q4, 2017.

The inventors

Dr. Steen Henneberg,
Chief Physician,
Dr. Bettina Nygaard Nielsen,
Clinical pharmacist,
Department of Anaesthesiology,
The Juliane Marie Centre,
Copenhagen University Hospital,
Rigshospitalet

Contact information

lars.noergaard@childtreat.dk;
Phone: +45 2612 5010

louise.meinert@adm.ku.dk;
Phone: +45 3533 0334

Intellectual property rights: All rights belong to Copenhagen University Hospital, Rigshospitalet.