

## Newsletter

Lund October 6, 2023

# Scandinavian ChemoTech's Clinical Development and Medical Affairs Newsletter for Tumour Specific Electroporation™ - TSE

*ChemoTech's Chief Medical Officer, Suhail Mufti, provides an update on the clinical development and strategy of Medical Affairs.*

The purpose of this newsletter is to provide investors and the public with regular updates and insights into the progress, achievements, and advancements of our TSE technology. We aim to foster transparency and share key milestones, patient success stories, and important clinical trial updates in the further development of TSE.

Our goal is to keep our stakeholders informed and engaged in our mission to advance oncology treatment options with this innovative medical device. For the TSE technology, one of our long-term goals is to develop a portfolio of therapeutic strategies to boost the efficacy of immunotherapy for cancer.

## Clinical Development and Medical Affairs Strategy Overview

Our patented TSE-technology is a newer paradigm in the treatment of solid tumours which potentiates chemotherapy, radiotherapy, and immunotherapy; immunomodulates the tumour, inducing immune-mediate cell death, and can potentially be imparted by a minimally invasive laparoscopic/robotic approach.

## TSE technology's goals – A Target Product Profile (TPP) statement

Apart from continued validation of the beneficial effects in superficial tumours and palliative care settings, the clinical development of TSE is focused on earlier and curative lines of cancer treatment in combination with other therapies, especially immunotherapy.

## Achievements

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|--------|---|
| ⇒ 2015 | ChemoTech launched TSE  |
| ⇒ 2016 | TSE first publication<br>NOC in India   |
| ⇒ 2018 | First clinical trial in Malaysia is initiated   |
| ⇒ 2021 | CE mark under MDD<br>PMCF at AIIMS Jodhpur with immune biomarker analysis   |
| ⇒ 2022 | Two pancreatic cancer cases treated with 50% mass reduction<br>ISO 13485 received<br>Registration in Malaysia and Ukraine |
| ⇒ 2023 | Multicentre study for validating immune effect and combinations   |

### Upcoming

- Singapore postponed to 2024
- Australia Q1 2024
- New CE mark under MDR 2027

View attachment for further information.

### Clinical Trial Progress

- ❖ University Hospital in Jodhpur India, non-sponsored trials (externally financed):
  - The ongoing clinical trial is expected to be completed in Q2 2024. There was a delay in patient inclusion since the criteria set to using TSE was as a last line treatment, this gave the patients a very short survival time and no possible chance of even surviving the duration of the study. The protocol has now been revised to also include patients with recurring tumours, where TSE will be used as first line treatment. This will be up at the next ethics committee meeting.
  - A protocol on breast cancer has been shared.
  - Ongoing discussions regarding pilot studies for deeper seated tumours such as pancreatic cancer (expected to initiate Q1 2024).
  - For the cases performed routinely, i.e., outside the clinical trial, a write-up for a case series publication has been initiated and is expected to be published in Q4 2023.
- ❖ Pancreatic study protocol for TSE in combination with immunotherapy has been shared with King Faisal Hospital, Rwanda
- ❖ Protocol for breast cancer clinical validation study has been shared with investigator at Kakamega General Hospital, Kenya. Discussions are ongoing with the regulatory authorities to include TSE in the payment system in Kenya.
- ❖ Clinical Study Data from Malaysia has been received and will be published in Q4 2023.
- ❖ First real-world data analysis report on multiple indications and histopathology will be available in Q4 2024.
- ❖ Ukraine - Pancreatic cancer update  
Regrettably, but anticipated, the second pancreatic cancer patient also passed away after nearly nine months. These patients received TSE treatment via open surgery. In both cases, post-treatment CT scans revealed a remarkable reduction of the tumour mass by more than 50%. Notably, there was a significant improvement in pain levels and overall quality of life.

Immunohistochemistry analysis for Tumour Infiltrating Lymphocytes (TILs) indicated a transformation from 'Cold' tumours to 'Hot' tumours in both patients. There is substantial evidence to suggest that converting 'Cold' tumours to 'Hot' makes them more responsive to immunotherapy, radiotherapy, and chemotherapy.

Even though the overall survival for both patients was nearly 9 months, this positive experience with a single TSE treatment underscores the necessity for multiple applications of TSE in the management of pancreatic cancer, especially in conjunction with other systemic therapies. Recognizing this need, ChemoTech has initiated a

development project for laparoscopic TSE treatments, which is scheduled to enter clinical trials in the first quarter of 2024.

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#### **Scandinavian ChemoTech AB (publ)**

ChemoTech is a Swedish medical technology company based in Lund that has developed a patented technology platform to offer cancer patients access to a new treatment alternative, Tumour Specific Electroporation™ (TSE), available for treatment of both humans and animals. There are a large number of cancer patients whose tumours for various reasons cannot be treated by conventional methods but where TSE can be a solution. Therefore, the company continuously evaluates new opportunities and areas of application for the technology. ChemoTech's shares (CMOTEC B) are listed on Nasdaq First North Growth Market in Stockholm and Redeye AB is the company's Certified Adviser. Read more at: [www.chemotech.se](http://www.chemotech.se).