SmartCella

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SmartCella initiates Phase I/IIa clinical study with Extroducer® for targeted delivery of chemotherapy in pancreatic cancer

SmartCella Holding AB ("SmartCella") today announces that the first patient has been treated in nEXT-GEM, a clinical combination study evaluating the Extroducer® platform for targeted delivery of chemotherapy directly to the tumor in patients with non-metastatic, inoperable locally advanced pancreatic cancer (LAPC).

The study is conducted in collaboration between SmartWise Sweden AB, a subsidiary of SmartCella, and Karolinska University Hospital in Solna.

Pancreatic cancer is one of the most difficult cancers to treat. In Sweden, approximately 1,700 patients are diagnosed with pancreatic cancer each year. According to data from the Swedish Cancer Society, around 87 percent of those affected die from the disease within five years, and pancreatic cancer is expected to become the second deadliest form of cancer by 2030. Systemic chemotherapy is often insufficient, as the drugs fail to reach the tumor at therapeutically effective concentrations while causing side effects in organs other than the pancreas.

The Extroducer® is SmartCella's endovascular delivery platform, designed for minimally invasive, localized delivery of therapies and cells to hard-to-reach organs, tumors, and tissues. Developed at Karolinska Institutet and FDA 510(k)-cleared for use in peripheral (including abdominal) tissues, the platform enables catheter-based delivery using arteries and veins as natural access routes for localized injection of therapeutic agents into target tissue.

The study is being conducted at Karolinska University Hospital in Solna and is the first clinical trial in Europe in which the Extroducer® platform is used in humans. The principal investigator is Maximilian Kordes, MD, PhD, oncologist at the Phase 1 Unit at the Center for Clinical Cancer Studies in Solna. The responsible interventional radiologists are Jan Engström, MD, and Peter Kihlström, MD. nEXT-GEM is a prospective, non-randomized, open-label pilot dose-escalation study evaluating the safety and efficacy of the Extroducer® platform for peri-/intratumoral administration of the chemotherapy agent Gemcitabine. The study will enroll a total of nine patients across two cohorts. The starting dose will be 200 mg Gemcitabine, with possible escalation to 400 mg based on recommendations from an independent Data Safety Monitoring Board (DSMB). Each participant will undergo four treatment sessions and a total of 13 study visits over approximately nine months. The total study duration is estimated at approximately 27 months.

Niklas Prager, CEO at SmartCella, comments: “Pancreatic cancer is a diagnosis where we have historically had too little to offer. When surgery is not an option and the body can no longer tolerate systemic treatment with all its side effects, the alternatives are often exhausted. The Extroducer® gives us the tool to deliver treatment directly to the tumor using minimally invasive technology, something that has not previously been possible. Seeing the first patient treated in a clinical study is a milestone for us, and I am convinced that this can make a real difference in the future treatment of pancreatic cancer and other hard-to-reach tumors.”

Maximilian Kordes, MD, PhD continues: “Patients with inoperable advanced pancreatic cancer currently have limited treatment options and a significant unmet medical need. In nEXT-GEM, we are investigating a new approach to deliver a higher concentration of Gemcitabine directly to the tumor while reducing the systemic side effects that can affect the body as a whole. Treating the first patient in the study is an important milestone toward potentially offering this patient population a new treatment option in the future.”

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About SmartCella

SmartCella is a global drug delivery company pioneering innovative delivery solutions for targeted therapies. The main technology, the Extroducer®, is a modality-agnostic endovascular delivery device designed for localized delivery of drugs and cells to hard-to-reach organs, tumors, and tissues. The Extroducer® is FDA 510(k)-cleared for use in peripheral (including abdominal) tissues to inject diagnostic and therapeutic solutions into the perivascular space. It is currently in clinical investigation for additional indications. SmartCella commercializes the Extroducer® through non-exclusive licensing agreements with global biotech and pharma companies, enabling broad application across all development phases. The company also offers a proprietary stem cell platform for the delivery of mRNA therapeutics, featuring a proof-of-concept program focused on Osteoarthritis.

Founded in 2014, SmartCella is built on world-class research from Sweden's Karolinska Institutet.

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