**Apceth Initiates Phase II Clinical Trial for Pioneering Engineered Cell Therapy to Treat Gastrointestinal Cancer**

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**Successfully Completed Phase I Clinical Study and Regulatory Approval Enable World’s First Genetically-Engineered Cell Therapy to Enter Phase II**

**Munich, Germany, March 26, 2015 / B3C newswire / --**[apceth](http://www.apceth.com/), a global leader in engineered cell therapies, today announced the successful completion of the Phase I and initiation of the Phase II part of its ongoing monocentric Phase I/II clinical trial TREAT-ME 1 with the engineered cell therapeutic product [Agenmestencel-T](http://www.apceth.com/clinical-development/agenmestencel/), at the Klinikum Grosshadern in Munich.  To the company’s knowledge, this is the first time that a genetically engineered Mesenchymal Stem Cell (MSC) treatment has successfully completed a Phase I clinical trial and been approved to initiate a Phase II trial.  The first patient in the Phase II trial has already been treated.

apceth’s proprietary Agenmestencel-T next-generation MSC therapy is based on cells harvested from the patient's own (autologous) bone marrow, which are processed, genetically modified, and re-infused into the patient. The cells specifically target tumors or metastases, and, upon reaching the target tissue, the cytotoxic gene product is selectively activated, increasing local efficacy with reduced systemic toxicity.

“apceth is pioneering a transformative approach to cell-based therapies and we see this trial start as an important validation of both the safety and therapeutic potential of our technology,” said Dr. Christine Günther, Chief Executive Officer of apceth. “apceth’s progress to date supports our larger objective of expressing any therapeutic gene directly in tumors, with future applications planned for other indications including lung diseases and inflammation. We also expect to initiate a Phase I/II trial for the allogeneic off-the-shelf version of Agenmestencel-T (Agenmestencel-L) in Q4 2015.”

apceth has initiated the Phase II part of the trial using the high-dose treatment regime as evaluated in the  Phase I trial. The open label study will include ten advanced gastrointestinal cancer patients and will evaluate the safety and tolerability of Agenmestencel-T and its efficacy based on RECIST criteria, with the aim to establish proof of concept of this novel technology in late-stage cancer patients. In parallel, six patients will be treated prior to tumor resection surgery, without subsequent ganciclovir administration, and tumor biopsies will be analyzed for presence of the genetically modified MSCs.

The completed Phase I trial included six patients suffering from advanced-stage gastrointestinal adenocarcinomas (3 colorectal, 2 pancreatic, and 1 cholangiocellular carcinoma). Top-line data analysis confirmed the infusion of the engineered cells and the treatment was safe and tolerable. apceth anticipates presenting the full data from the Phase I trial later in 2015.

**About**[**Agenmestencel-T**](http://www.apceth.com/clinical-development/agenmestencel/)Agenmestencel-T is apceth’s first-in-man, first-in-class, next generation autologous cell therapy product of genetically modified mesenchymal stem cells for the targeted treatment of advanced, recurrent or metastatic cancer. The cells are isolated from the patient’s bone marrow (autologous), multiplied in cell culture and genetically modified with apceth’s proprietary SIN vector.

**About**[**apceth**](http://www.apceth.com/)apceth is a pioneering clinical-stage biopharmaceutical company expanding its pipeline of next-generation cell-based therapeutics. Our modular platform technology is based on genetically-modified MSCs, and the lead program Agenmestencel is a first-in-man, genetically-modified MSC for the treatment of cancer. In addition, we are developing new cell therapy candidates for the treatment of lung diseases and inflammation.

Based in Munich, we provide our know-how, expertise and GMP-certified facilities to industry and academic partners around the world.

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