



NextCell Pharma receives wholesale distribution authorisation

NextCell Pharma AB ("NextCell") today announces that the company has been granted license for wholesale of cell based investigational medicinal products. The company was inspected earlier this summer by the Swedish Medical Products Agency. The permission is required for NextCell to acquire, stock and distribute investigational drugs in the planned clinical trial of ProTrans™ for treatment of diabetes.

CEO Mathias Svahn says "This license is a good next step towards the start of our first clinical trial with ProTrans™ for the treatment of patients with Type 1 diabetes".

About the clinical trial:

The study is divided into two parts: The first part is a three-step dose escalation with three patients in each, a total of 9 patients. The second part is randomized, double-blind, placebo-controlled study where 10 patients receive ProTrans and 5 patients receive placebo, a total of 15 patients. Primary safety endpoint is safety at 3 months and primary efficacy endpoint is change in insulin production after 1 year.

The study sponsor of the proposed clinical trial related to the wholesale distribution is NextCell and the principal investigator is Professor Per-Ola Carlsson, who works at Uppsala University and the Academic Hospital in Uppsala. The study will be conducted together with Karolinska Trial Alliance (KTA), which holds great expertise in performing cell therapy clinical trials. Treatments are scheduled to take place at the KTA Phase I unit located at Karolinska University Hospital in Huddinge. Ulf Smith MD, PhD, Professor and Director, Lundberg Laboratory for Diabetes Research, Sahlgrenska Academy and Sahlgrenska University Hospital, Gothenburg; Anders Fasth MD, PhD, Professor of Pediatric Immunology, Sahlgrenska Academy and Chief Physician at Drottning Silvias Children's Hospital, University of Gothenburg; and Åke Lernmark PhD, Professor and Principal Investigator in Diabetes and Coeliac, MAS, Lund University; will together make up the Data Safety Monitoring Board with Ulf Smith as Chairman.

This information is the information that NextCell Pharma AB is required to disclose under the EU Market Abuse Regulation. The information was provided by the above contact person for publication on September 21st, 2017.

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About Pharma AB:

Stem cells are expected to change the way how many of today's life-threatening diseases are treated. NextCell Pharma AB develops ProTrans™, a drug candidate consisting of stem cells for the primary treatment of autoimmune and inflammatory diseases as well as for use in kidney transplants. ProTrans™ consists of selected stem cells derived from the umbilical cord tissue with NextCell Pharma AB's proprietary method. In addition, the company has a service called Cellaviva, Sweden's first and only IVO-approved stem cell bank for the family-saving of stem cells from umbilical cord blood and umbilical cord tissue.

NextCell Pharma AB
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