

Advisory meeting with the European Medicines Agency

NextCell Pharma AB (“NextCell” or “the Company”) announces that a scientific advisory meeting with the European Medicines Agency (EMA) has been held regarding ProTrans and the path forward to a possible market approval. The focus was the design of the phase III study ProTrans-3, which NextCell intends to submit an application for later this year.

Preparations for ProTrans-3 are progressing according to plan and the advisory meeting with EMA’s Scientific Advisory Working Party (SAWP) is an important milestone. The intended trial Principal Investigator, Professor Per-Ola Carlsson, participated in the meeting together with Professor Edvard Smith, CMO, Dr. Lindsay Davies, CSO, Dr. Mathias Svahn, CEO and regulatory experts hired by the company.

NextCell and SAWP agree on primary endpoints. Guidelines for clinical trials in type-1 diabetes suggest co-primary endpoints and two years follow up on the patient. The effect will be measured as the patient’s own insulin production and need for exogenous insulin after 12 months.

“We are very pleased with the meeting and appreciate the answers given by SAWP. The updated study design is more robust and can be used as a registration-based study”, says Mathias Svahn, CEO of NextCell.

In addition to NextCell's clinical development, they have together with SAWP identified supplementary preclinical studies with the aim of describing the mechanism of action in detail, which helps NextCell to further refine the therapeutic effect.

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About NextCell Pharma AB

NextCell is a Phase II cell therapy company with the lead candidate ProTrans™, for the treatment of type-1 diabetes. Focus is to take ProTrans™ to market approval via a phase III study. Furthermore, NextCell operates Cellaviva, Scandinavia's largest stem cell bank for family-saving of stem cells from umbilical cord blood and umbilical cord tissue with permission from the Health and Social Care Inspectorate. FNCA Sweden AB is appointed Certified Adviser, +46(0)8-528 00 399, info@fnca.se.