

Article about Gene and Cell Therapy

Professor Edvard Smith, CMO NextCell Pharma AB ("NextCell" or the "Company") has written a review article in the Swedish Medical Journal (Läkartidningen) entitled "Gene therapy now comes in many medical specialties", together with Associate Professor Pontus Blomberg, Director of Operations; both at the Department of Laboratory Medicine, Karolinska Institutet; Karolinska Centre for Cell Therapy, Karolinska University Hospital, Stockholm.

The main message of the article is that the development of gene therapy has been rapid, and more and more preparations are reaching patients and in many different types of diseases. The number of market-approved gene therapy drugs has more than doubled in the last 3 years, and in some disease groups a significant proportion of patients are likely to be successfully treated.

<https://lakartidningen.se/klinik-och-vetenskap-1/artiklar-1/klinisk-oversikt/2021/06/genterapi-kommer-nu-inom-manga-medicinska-specialiteter/>

Karolinska University Hospital in Huddinge and Karolinska Institutet's leading research groups in gene and cell therapy are the main reason why NextCell has chosen to locate all operations to the Novum building and the company is now in the process of building a manufacturing facility in the same house. Both Professor Smith's research group and Vecura, where Associate Professor Blomberg is director of operations, are in the same house. Karolinska Center for Cell Therapy (KCC) is a core facility at Karolinska University Hospital, established to meet the need for manufacturing of Advanced Therapy Drugs (ATMP) for clinical trials as well as the management of cells and tissue for human use, primarily for researchers at Stockholm County Council and KI. Vecura is a manufacturing unit within KCC.

NextCell's drug candidate, ProTrans, is an ATMP with genetically unmodified cells. The mesenchymal stromal cells in ProTrans have the ability to balance an immune system in imbalance which is the cause of autoimmune diseases and hyperinflammation.

"Gene therapy and, in particular, the combination of gene and cell therapy are extremely exciting. It is almost 15 years since I wrote my doctoral thesis on the subject, but it is only in recent years that it has really taken off. A success that is important for all stakeholders in the field," says Dr. Mathias Svahn, CEO NextCell.

As described in the article in Läkartidningen, medicines included in the concept of advanced therapy medicinal product (ATMP) are classified as:

- Gene therapy (including genetically modified cells) excluding oligonucleotides, which are classified as chemicals.
- Cell therapy where a cell has been manipulated by, for example, cultivation or used for a new purpose, such as a blood stem cell that forms muscle cells (so-called non-homologous use).
- Tissue engineering products, such as transplantation with cultured cells in case of burns.

- Extracellular vesicles containing therapeutic genomes and DNA vaccines against endocellular components such as cancer cells and combination drugs containing ATMP.

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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.