

NextCell publishes opinion piece with ISCT

NextCell Pharma AB ("NextCell" or "Company") published an opinion piece on particulates in cell and gene therapy products with the International Society for Cell and Gene Therapy's Process Development, Manufacturing and Analytics Committee last week in the journal *Cytotherapy*.

NextCell Pharma AB is a cell therapy company working in the development and commercialization of the mesenchymal stromal cell therapy product, ProTrans. This product, with its proprietary platform technology, is in clinical development for the treatment of autoimmune conditions, such as type I diabetes and inflammatory conditions such as viral pneumonia.

NextCell's CEO, Mathias Svahn and CSO, Lindsay Davies are active members of the International Society for Cell and Gene Therapy (ISCT), the leading global society for the development and commercialization of advanced therapeutics. Dr Davies is a member of both the ISCT Commercialization Committee and Process Development, Manufacturing and Analytics Committee and an ISCT mentor for early stage professionals entering the cell therapy space. The Process Development, Manufacturing and Analytics working group brings together scientists and cell and gene therapy companies, in all stages of commercial development, to discuss current issues in the advanced therapy arena and lead forward thinking in these novel and evolving areas of clinical development.

"It has been great to work with such a diverse and knowledgeable group of scientists and business developers from across the globe to discuss ways of addressing and supporting cell and gene therapy development. The NextCell team is committed to actively participating in advancing knowledge and understanding, promoting regulatory change and thereby ensure wider accessibility of safe cell and gene therapies for patients", says Dr Davies.

Last week Lindsay Davies and the Process Development, Manufacturing and Analytics Committee published an opinion piece in the journal *Cytotherapy*. The piece entitled, "Particulates are everywhere, but are they harmful in cell and gene therapies?" addresses the potential issue of evaluating particulate matter in cell and gene therapy products, and the need for regulations to differentiate this distinct class of drugs from other, more traditional pharmaceutical products.

The published article can be accessed, for free, at <https://authors.elsevier.com/a/1fpxZ5DBIBTE%7EZ> until November 16th, 2022.

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About NextCell Pharma AB:

NextCell is a phase II cell therapy company with the drug candidate ProTrans for the treatment of type 1 diabetes. The focus is to take ProTrans to market approval via a Phase III study. ProTrans is in addition to diabetes, used in two clinical trials for Covid-19, in Örebro and Montreal (Canada). The company is in the processes of establishing its own GMP facility for production of ProTrans. The GMP facility is expected to be ready for production of smaller quantities of ProTrans in 2023. NextCell furthermore owns 8,5% in FamicordTX, a CAR-T start-up in oncology and 100 % of Cellaviva, Scandinavia's largest stem cell bank for family saving stem cells from umbilical cord blood and umbilical cord tissue with permission from the Swedish Health and Social Care Inspectorate (IVO).