Breakthrough multiplication of blood stem cells

NextCell Pharma AB ("NextCell" or the "company") announces that the FDA has approved a product of multiplied stem cells from umbilical cord blood. It is a breakthrough that could lead to increased interest in saving stem cells for private use, where Cellaviva is the market leader in Scandinavia. Cellaviva is a part of NextCell with offices in Stockholm and Copenhagen.

On April 17, 2023, the US Food and Drug Administration (FDA) approved the first product with expanded stem cells from umbilical cord blood. In the clinical trial that led to the approval, the number of stem cells was expanded an average of 60 times by cell culture.

"Multiplication or expansion of blood-forming stem cells is a significant achievement. The new method opens the door for the use of even smaller collections of cord blood in clinical practice." says Professor Edvard Smith, Medical Director of NextCell Pharma and Cellaviva.

Stem cells from umbilical cord blood have been used in healthcare for the treatment of over 80 different conditions, such as leukaemias, lymphoma and sickle cell anaemia, for more than 30 years. It has also been shown that in regenerative medicine, treatment with stem cells from umbilical cord blood provides clinical benefits for patients. More than 60,000 patients have already been treated with umbilical cord blood.

In addition to the above-mentioned already approved therapies, over 3,000 research studies are currently underway in various fields around the world to discover the full potential of stem cells. Umbilical cord blood is the source of the youngest, most powerful and most readily available stem cells. They can also be easily collected and stored after birth, to be used later in life. Due to the limited blood volume and number of stem cells isolated from umbilical cord blood; critics have pointed out that an average unit of umbilical cord blood is only sufficient for patients weighing up to 40-50 kg. The FDA's groundbreaking decision to approve expanded, also known as multiplied, umbilical cord blood means that this restriction is no longer a concern.

The product approved by the FDA is manufactured by Gamida under the name Omisirge (also known as omidubicel or NiCord).

Link to FDA press release:
https://www.fda.gov/news-events/press-announcements/fda-approves-cell-therapy-patients-blood-cancers-reduce-risk-infection-following-stem-cell

Link to the scientific article about the study:
https://doi.org/10.1182/blood.2021011719

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About NextCell Pharma AB

NextCell is a cell therapy company in clinical phase II. The company has developed a proprietary and patented platform technology to produce mesenchymal stromal cells adapted for allogeneic treatment of various autoimmune and immunological diseases. The drug candidate ProTrans is now being tested for the treatment of type-1 diabetes as well as respiratory complications caused by Sars-CoV-2 infection. The focus is to take ProTrans to market approval for type-1 diabetes via a phase III study. ProTrans is evaluated in two clinical COVID-19 studies, in Sweden and Canada. NextCell is working on completing its own GMP facility for the manufacture of ProTrans. The GMP facility is expected to be ready for manufacturing smaller quantities of ProTrans in 2023. NextCell also owns 8.5% of FamicordTX, a start-up company in CAR-T and oncology, and 100% of Cellaviva, Scandinavia's largest stem cell bank for family savings of stem cells from umbilical cord blood and umbilical cord tissue with permission from the Swedish Health and Social Care Inspectorate (IVO).