XNK THERAPEUTICS
Individualized NK Cell Therapies

XNK Therapeutics receives US orphan drug status for NK cell-based immunotherapy in multiple myeloma

November 4, 2020

XNK Therapeutics AB ("XNK") today announced it has received Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA) for its leading investigational drug candidate in the treatment of multiple myeloma (MM).

Receiving ODD status from the FDA for the treatment of multiple myeloma is a critical next step for the development of XNK's leading investigational drug candidate. XNK has already received ODD status in the EU.

"Obtaining an ODD by the FDA is a significant milestone for XNK and our goal of taking the present drug candidate to the next level," said Johan Liwing, CEO of XNK Therapeutics. "This is the starting point for us to expand clinical development into the most important market globally for cancer treatment."

XNK has already completed its first-in-human Phase I/II clinical trial (ACP-001) in multiple myeloma at the Karolinska University Hospital in Stockholm, Sweden, showing a very good safety profile, and promising efficacy data. The company is continuing the clinical development in multiple myeloma in Europe and plans to initiate a Phase II clinical trial in the near future.

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About XNK Therapeutics AB
XNK Therapeutics is a clinical stage, immunotherapy company focusing its efforts on preventing and treating cancer by developing novel NK cell-based therapies. The company has established a leadership position in the clinical development and manufacture of autologous NK cell-based products using its proprietary technology platform. The company's platform technology and leading investigational drug candidate have ideal properties for targeting cancers, including settings where allogeneic cell products are not readily applicable. It is foreseen that the product will bring a critical component to tomorrow's cancer treatment strategies. XNK Therapeutics is headquartered in Stockholm, Sweden. For more info, please visit www.xnktherapeutics.com.

About XNK Therapeutics's technology platform
The platform has ideal properties to produce autologous NK cell-based drug candidates for targeting malignant diseases across a wide range of indications in mono- and combination therapy. It encompasses a unique closed manufacturing system for development of the NK cell-based products. The process includes a selective expansion and activation of NK cells

from peripheral blood of patients with cancer. The product is produced in less than three weeks. It is delivered to the clinic upon need, where the product is thawed and infused into the patient without any further processing. The product has demonstrated an up to 10-year stability in liquid nitrogen. The assets of XNK Therapeutics are protected by patents in the US, Europe and certain other jurisdictions. Additional patent applications have been filed.

About Our Therapy

The leading drug candidate from XNK Therapeutics' technology platform was previously clinically tested in a first-in-human Phase I/II clinical trial (ACP-001). The study was performed at the Karolinska University Hospital, Stockholm, Sweden in a setting of consolidation treatment following high dose stem cell transplantation in patients newly diagnosed with multiple myeloma. The study was an open, single-arm, triple escalating dose/patient clinical trial with the primary objective of studying the product's safety and tolerability. In the study, the therapy showed a very good safety profile, and promising efficacy data. XNK Therapeutics is continuing its clinical development in multiple myeloma and plans to initiate a Phase II clinical trial in the near future.

About multiple myeloma

Multiple myeloma, the company's first target, is the third most frequent hematological malignancy worldwide. Multiple myeloma treatment has improved over the last two decades with the development and introduction of new agents leading to more effective treatments. Still, it remains a fatal disease in the majority of cases.