



# XNK THERAPEUTICS

Company presentation

*May 2022*

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# Investment highlights

1.

*A unique, proprietary autologous NK-cell based platform built on world-leading research on NK-cells at Karolinska Institutet in Stockholm*

2.

*The platform has ideal properties for targeting cancer across a wide range of indications in mono- and combination therapy*

3.

*First-in-human phase I study showing very good safety data and promising efficacy data for the leading investigational drug product*

4.

*Phase II study ongoing in patients with Multiple myeloma in combination with Sanofi's anti-CD38 antibody Sarclisa (isatuximab)*

5.

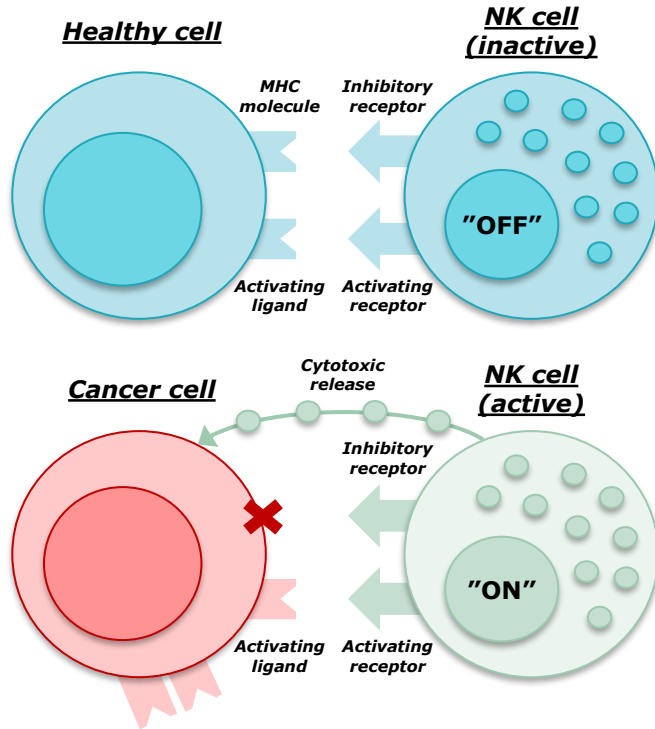
*A potential USD multi-billion white space market opportunity in the US and in Multiple myeloma alone*

6.

*Strong momentum in business development - recently signed collaboration agreements with Sanofi and MD Anderson*

# Natural killer (NK) cells

- Natural ability to kill cancer cells



- Discovered at Karolinska Institutet in 1975
- Play a major role in the host-rejection of cancer cells
- Triggered by the lack of major histocompatibility complex (MHC) receptors, often lost by cancer cells, and/or by overexpression of activating ligands
- NK cells release cytotoxic granules containing perforin and granzymes, killing the cancer cells

# Autologous & allogeneic NK cell therapies

- There is a place for both methods on the NK cell therapy market

## Allogeneic cell therapy

**"Off-the-shelf" availability**

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**Possibility to select optimal donor**

## Autologous cell therapy

**Applicable in early line treatment or MRD**

**No need for immunosuppressive conditioning**

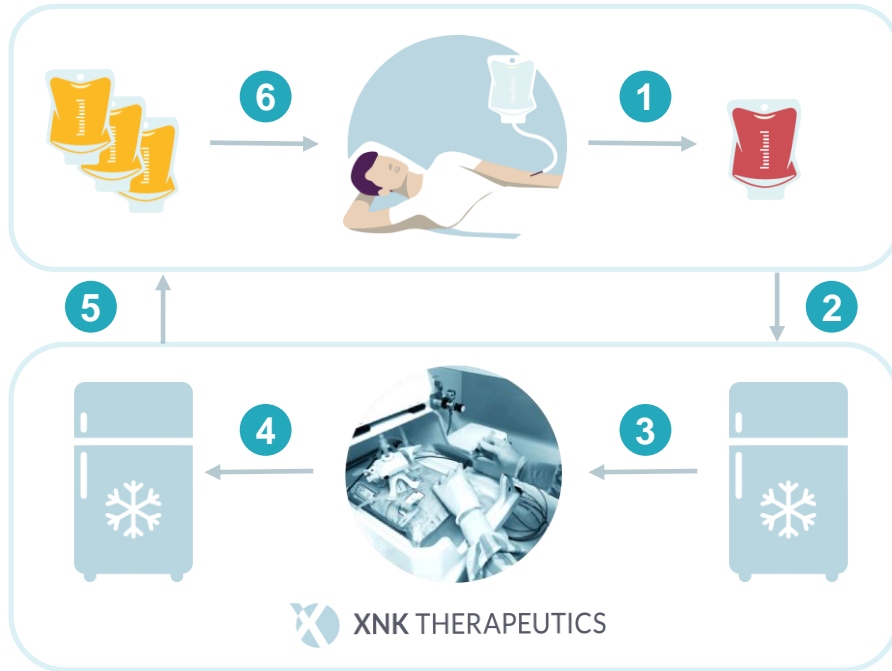
**Longer *in vivo* endurance**

**Favorable safety profile**

**Repetitive dosing feasible**

# Our technology

- Step-by-step overview of the platform



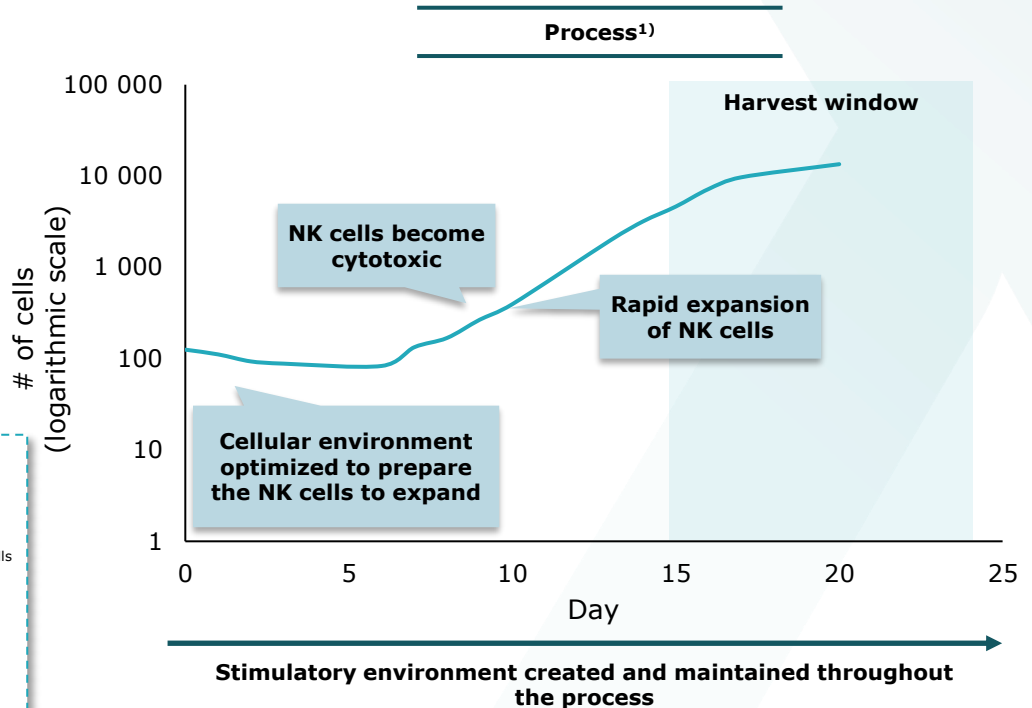
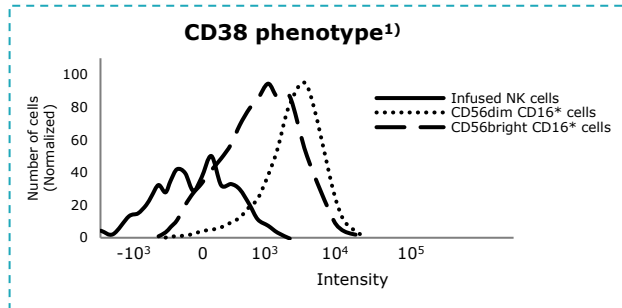
- 1 Blood sample from the patient
- 2 Blood sample cryopreserved and transported to XNK's laboratory
- 3 Expansion and activation of NK cells
- 4 The activated NK cells cryopreserved, with stability of >10 years
- 5 Product transported cryopreserved
- 6 The activated NK cells are thawed and infused bedside without need for further processing, with repetitive dosing possible

# Our technology

- Unique platform enabling the expansion and activation of NK cells

## Activation and expansion

- Feeder cell free system
- Start from frozen materials
- Cellular environment optimized in the beginning of the process to prepare the NK cells for expansion
- *Ex-vivo* expansion, in the absence of tumour cells restores NK cells cytotoxicity around day 10
- NK cell fold expansion typically around 400-500 times

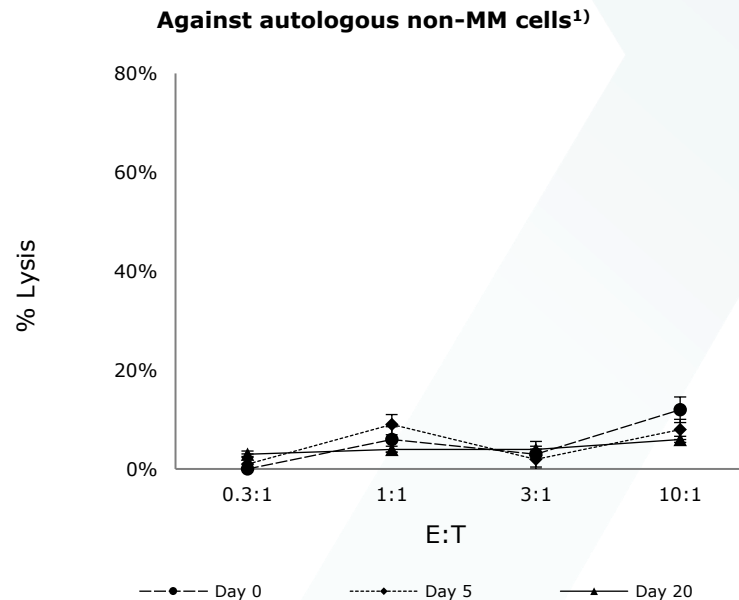
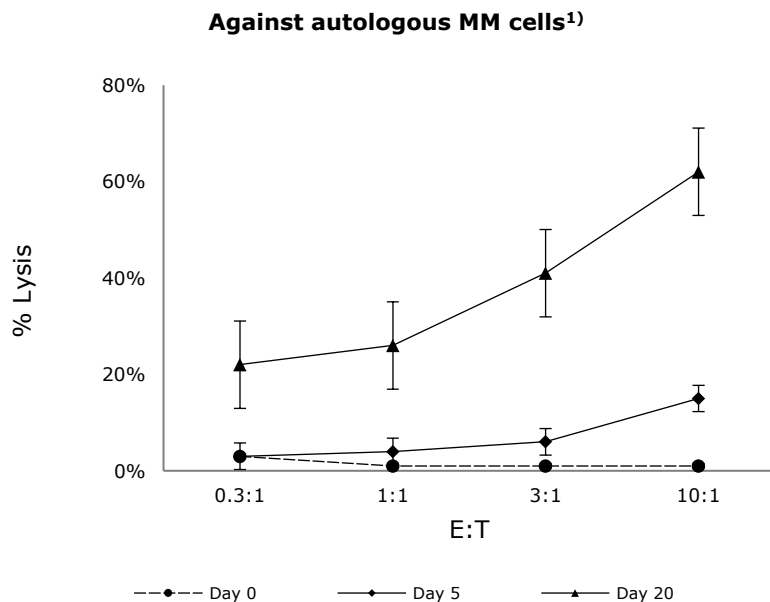


1) Approximate illustration, for exact underlying clinical data, see data on file

# Expanded NK cells show cytotoxic effect

- Specifically targeted against autologous MM cells




## Significant cytotoxicity against autologous MM cells







# Patents and market exclusivity

- Patents cover platform technology as well as method of treatment

Patent family	Patent area	Submission of application	Patent term	Geographies
P63055	<ul style="list-style-type: none"> <li>Method of large-scale expansion and activation of NK cells and NK-like T cells</li> </ul>	2010 (granted)	2030	
P63107	<ul style="list-style-type: none"> <li>Expanded NK cells and method of treatment</li> </ul>	2015 (granted)	2027	
P68961	<ul style="list-style-type: none"> <li>Anti-viral agents for use in preventing herpes virus reactivation,</li> <li>NK cells and/or NK-like T cells for use in treating a malignant disease</li> <li>Pharmaceutical compositions and kits</li> </ul>	2019 (pending)	2038	
<i>New patent application</i>	<ul style="list-style-type: none"> <li>Parts of new updated process</li> </ul>	<i>2021 (pending)</i>	<i>2041</i>	<i>Pending application</i>

**XNK Therapeutics has been granted orphan drug designation in Europe and the US**

Orphan drug designation	Market exclusivity	Geographies
ODD US	+7 years from launch	
ODD EU	+10 years from launch	

# Scalable technology

- Potential to target wide range of indications including both solid and blood cancers

## Favourable conditions



Minimal residual disease (MRD) situation, enabling efficient NK-cell dependent responses



Antibody acting through antibody-dependent cell-mediated cytotoxicity (ADCC)



Platform

Multiple myeloma

Other cancer indications



**Multiple myeloma**

A cancer of the plasma cells, a type of white blood cell that normally produces antibodies



**Acute myeloid leukemia**

A cancer of the myeloid line of blood cells that starts in the bone marrow



**Amyloidosis**

A plasma cell disorder closely related to myeloma and other blood cancers with limited available treatment



**Glioblastoma**

An aggressive brain cancer with limited treatments and a high degree of recurrence



**Hepatocellular carcinoma**

The most common type of primary liver cancer, occurs most often in people with chronic liver diseases



**Non-small-cell lung cancer**

The most common type of lung cancer with no available treatment that cures the cancer



**Other cancers**

The technology platform could potentially be suitable for treatment of a wide range of other cancers

**Blood cancers**

**Solid tumours**

# First-in-human phase I trial

- Monotherapy

## Phase I study (ACP-001) completed

### Description

First-in-human Phase I clinical trial in newly diagnosed MM as consolidation treatment after autologous stem cell transplantation

### Patient population

6 patients recruited at Karolinska University Hospital Huddinge

### Primary endpoint

Safety and tolerability

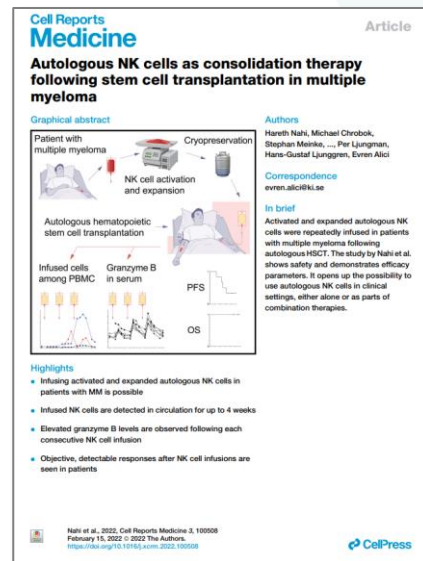
### Secondary endpoint

Effect on serum Ig levels (M-component serum free light chains)

### Exploratory endpoints

Exploratory analyses of peripheral blood mononuclear cell (PBMC) and plasma proteins

## Published in Cell Reports Medicine



**The ACP-001 study was published in Cell Reports Medicine in February 2022**

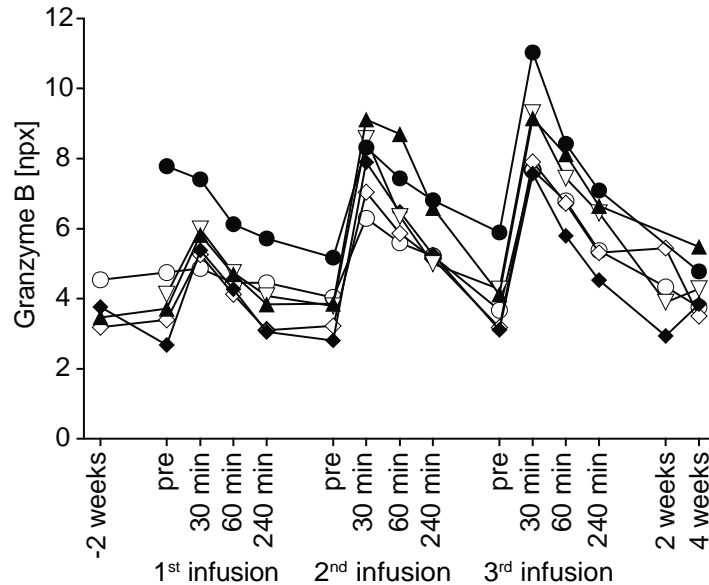
# Very good safety profile

## Safety

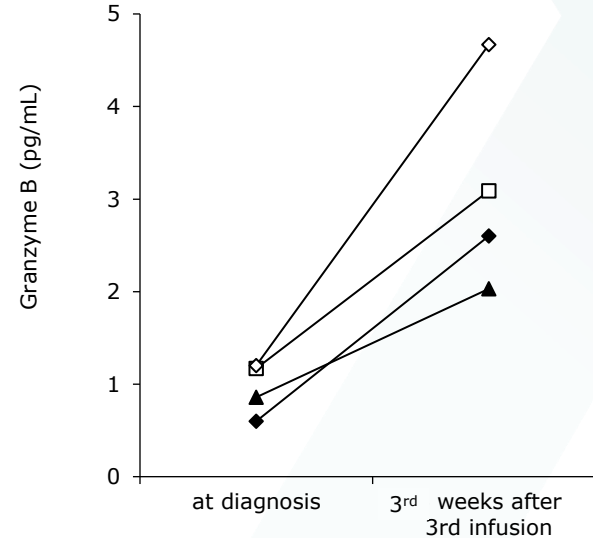
- No SAEs
- Majority of AEs Grade 1 (mild)
- Majority of AEs unlikely to be related
- The most frequently reported AEs, reported in two or more patients (n), were:
  - shingles (n=4)
  - upper respiratory infection (n=4)
  - lumbago (n=3)
  - diarrhea (n=2)
  - headache (n=2)
  - paraesthesia (n=2)

# Increased Granzyme B as a surrogate biomarker

## Serum (blood plasma)



## Bone marrow



# Phase II combination trial ongoing

- First of its kind study in collaboration with Sanofi, Karolinska Institutet & Hospital

## Phase II study (ISA-HC-NK) initiated in Q2 2021

### Description

- XNK Therapeutics' lead candidate in combination with isatuximab (anti-CD38 monoclonal antibody - mAb) to:
  - amplify tumour cell recognition and killing via ADCC
  - decrease mAb-related side effects
- NK cells express low levels of CD38, implying that a combination with anti-CD38 monoclonal antibodies could be beneficial as the NK cells themselves will not be targeted

### Patient population

- 60 patients to be recruited at Karolinska University Hospital Huddinge

### Primary endpoint

- Overall response rate including minimal residual disease

### Secondary endpoint

- Time to progression / progression free survival
- Duration of response
- Overall survival
- Safety

### Exploratory endpoint

- Evaluate the activity and function of PBMCs
- Evaluate serum cytokine and chemokine levels



*Production facility in Huddinge*

# Production for clinical trials

- In-house GMP-facility under construction, enabling expanded production capacity

## Production

- Current production for clinical trials at the production unit at Karolinska Cancer Center (KCC) Vecura
- GMP-facility, including QC and R&D, currently undergoing validation enabling full control
  - Production of initially 100 batches per year which, could be expanded upon need
  - Enables efficient planning of production in the US for future clinical studies
- Competitive productions costs due to streamlined, feeder free production process, and no gene modification of NK cells



Zahra Rajabkhani, Senior Scientist from XNK Therapeutics

# Strong momentum in business development

- Signed collaboration agreements with MD Anderson Cancer Center and Sanofi/KI

## Ph II study in collaboration with Sanofi & KI

- XNK Therapeutics is conducting a joint Phase II clinical study to treat patients with multiple myeloma using XNK's leading drug candidate in combination with Sanofi's anti-CD38 antibody Sarclisa (isatuximab)
- XNK and Sanofi are both collaborative partners within NextGenNK Competence Center coordinated by Karolinska Institutet
- The study (ISA-HC-NK) compares XNK's leading drug candidate combined with isatuximab vs isatuximab as a consolidation treatment following autologous stem cell transplantation in patients with newly diagnosed multiple myeloma

## PoC study in collaboration with MD Anderson

- XNK Therapeutics has entered into an agreement with the University of Texas MD Anderson Cancer Center to perform a proof of concept study in acute myeloid leukemia (AML) patients
- The objective of the study is to determine feasibility of expansion and activation of NK cells from blood samples of patients with AML using XNK's proprietary platform
- The goal is to establish patient selection criteria for a clinical trial to be conducted at MD Anderson Cancer Center using XNK's platform and, ultimately, to develop novel therapeutic approaches for AML patients

***XNK Therapeutics currently has ongoing discussions with global pharmaceutical companies regarding the development of new indications using XNK's proprietary platform***



# SEK 132 million raised to accelerate growth

- Lead by Flerie Invest

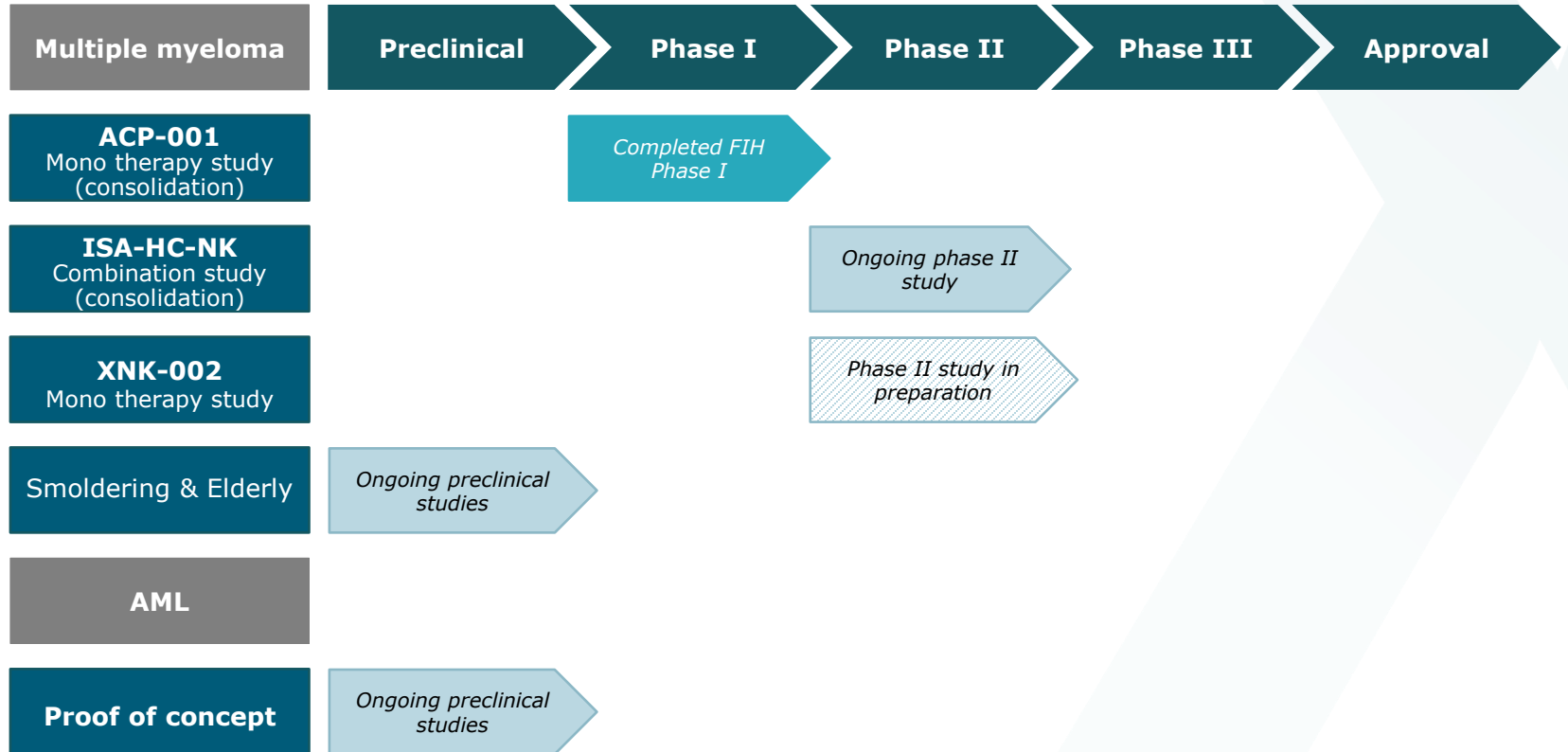
## Transaction

- Private placement of SEK 132 million
- Lead by Flerie Invest AB
  - Placing 100 Msek
  - Ted Fjällman, partner at Flerie Invest joins the board of directors
  - Owning NorthX, who offer services and support in the development and manufacturing of biologics used in vaccines, gene therapy and other advanced applications
- Existing and new investors

## Flerie Invest

- European biotech and pharma investor managing a portfolio of more than 20 companies in the US, UK, Sweden and other countries.
- The portfolio companies are engaged in a wide range of areas including immuno-oncology, metabolic diseases and biologics development and manufacturing.
- The present investment focus is on drug development and tools for drug development.
- The company was founded in 2010 by Thomas Eldered, who also co-founded and built Recipharm to be one of the top five pharmaceutical contract manufacturers globally.
- Flerie Invest is based in Stockholm and London.

# Current development status



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**XNK THERAPEUTICS**

*Individualized NK Cell Therapies*