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DNB Healthcare Conference, December 15, 2022

# Science is leading the Way

Sofia Heigis, Chief Commercial Officer

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Oncopeptides is a global biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary Peptide Drug Candidate platform, PDC, to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. Pepaxti® (melphalan flufenamide, also called melflufen) has been granted Marketing Authorization, in the European Union, the EEA-countries Iceland, Lichtenstein and Norway, as well as the UK. Pepaxti is indicated in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation. Melflufen was granted an accelerated approval in the US in February 2021, under the trade name Pepaxto®. The product is currently not marketed in the US, due to regulatory hurdles. On December 7, 2022, the FDA requested a withdrawal of the US marketing authorization for Pepaxto.

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# Science and data driven company passionate to making a difference for patients

## VISION

Bring hope to patients around the world through passionate people, innovative science and transformative medicines

## MISSION

Accelerate the development of next generation Peptide Drug Conjugate therapies to meet the unmet medical needs in haematological diseases



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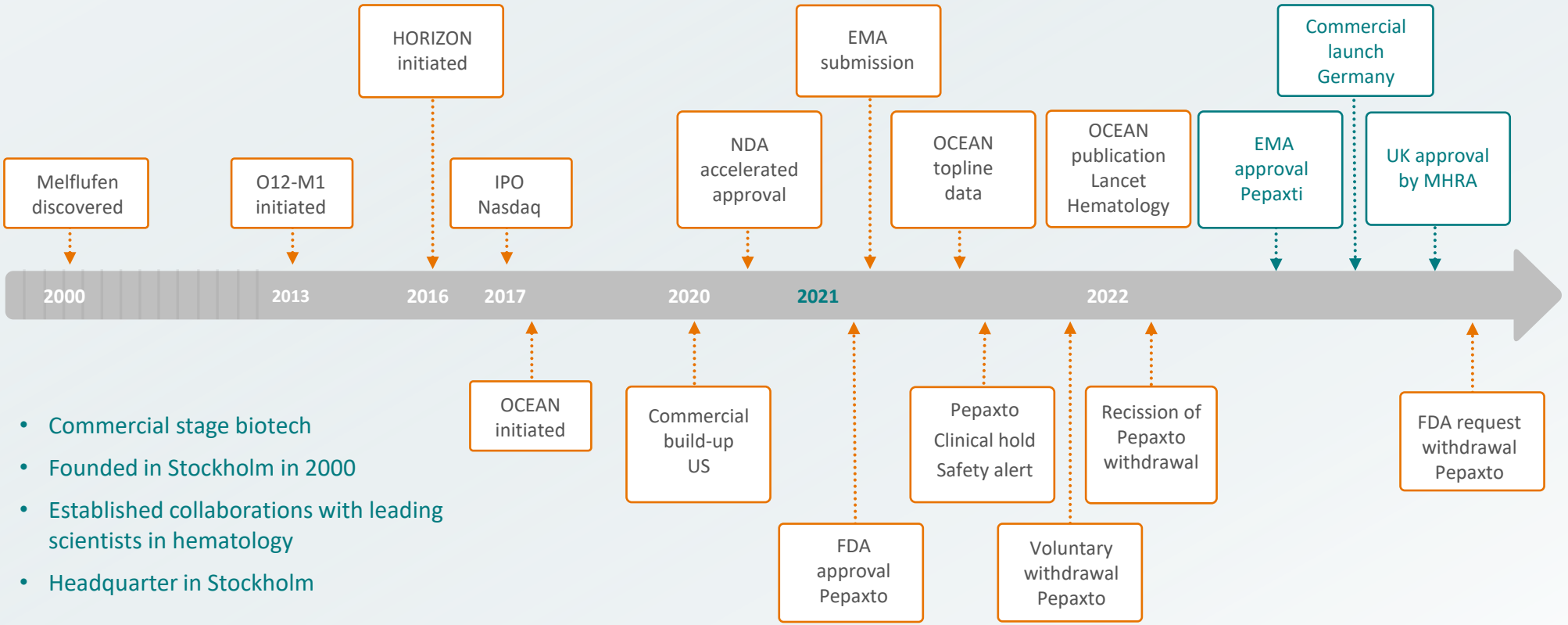
# Journey of innovation




- Commercial stage biotech
- Founded in Stockholm in 2000
- Established collaborations with leading scientists in hematology
- Headquarter in Stockholm



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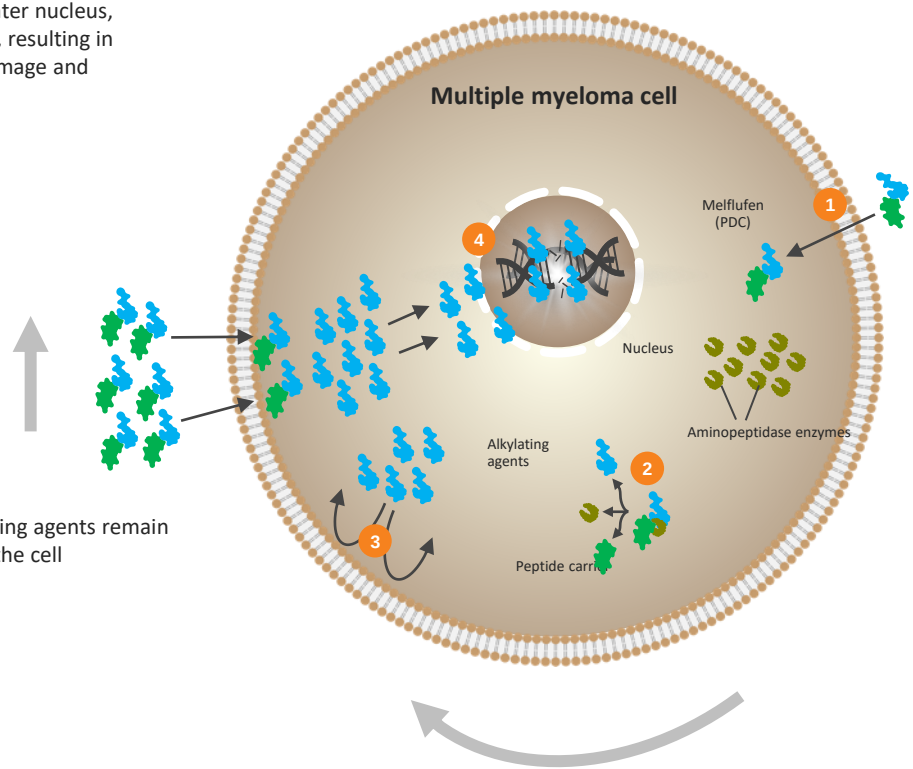
# Company highlights

- Pepaxti granted full approval in EU, Iceland, Lichtenstein, Norway and UK
- Germany first country in Europe to launch Pepaxti
- Market potential in Europe 1.5-2.0 billion SEK
- Data from phase 3 LIGHTHOUSE study further confirms clinical benefit of melflufen
- Type II-variation submission of OCEAN-data to EMA to enable treatment in one earlier line
- FDA requested a voluntary withdrawal of the US marketing authorization for Pepaxto®
- Pre-clinical data presented at 64th American Society of Hematology Meeting, ASH

# Pepaxti is the first & only PDC with an alkylating payload

## Improving the chemotherapy modality

4 Alkylating agents enter nucleus, linking DNA strands, resulting in irreversible DNA damage and apoptosis




1 Melflufen is highly lipophilic and diffuses rapidly and passively across the cell membrane

2 Melflufen is hydrolyzed by aminopeptidases. The drug targets aminopeptidase expression to selectively release potent alkylating agents inside tumor cells

3 Hydrophilic alkylating agents remain entrapped within the cell



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# Pepaxti EMA approval is built on assessment of two clinical trials

HORIZON

**Single-arm trial in multiple myeloma patients with few or no remaining treatment options**

- Current label of Pepaxti in Europe

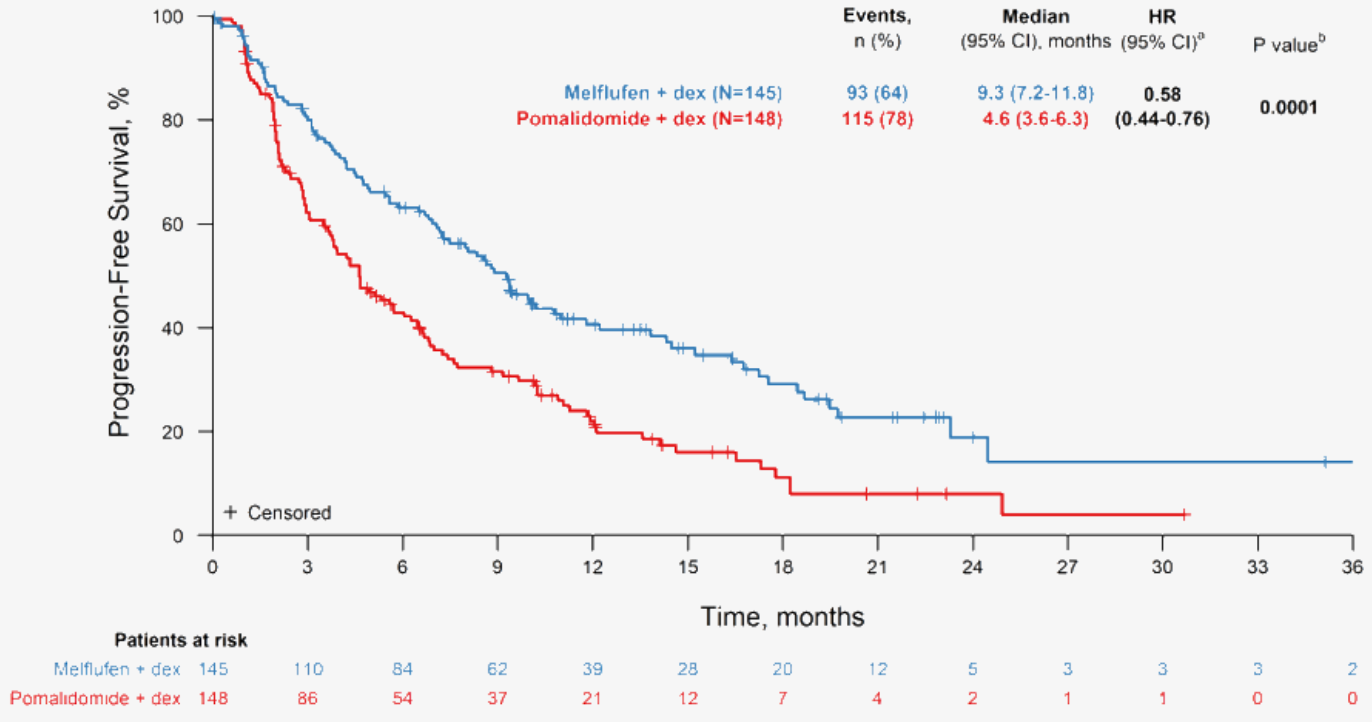
OCEAN

**Direct comparison between PEPAXTI & standard-of-care drug pomalidomide**

- Current confirmatory trial for Pepaxti in Europe
- Pepaxti superior to pomalidomide
- Confirm consistent safety profile
- Highly complex Overall Survival result
- Type II variation based on OCEAN

# PFS in the OCEAN study – recommended population (verified by EMA)

*Post-hoc Analysis* [1,2]




ASCT, autologous stem cell transplant; dex, dexamethasone; melflufen, melphalan flufenamide; PFS, progression-free survival; HR, Hazard Ratio; TTP, time to progression.
[a]Unstratified hazard ratio. [b]Log-rank P value. 1. In House Data. Oncopeptides Pharmaceuticals. DoF ALL-DOF-000055; 2. European Medicines Agency. Assessment Report. https://www.ema.europa.eu/en/documents/assessment-report/pepaxti-epar-public-assessment-report_en.pdf. Accessed August 26, 2022. 



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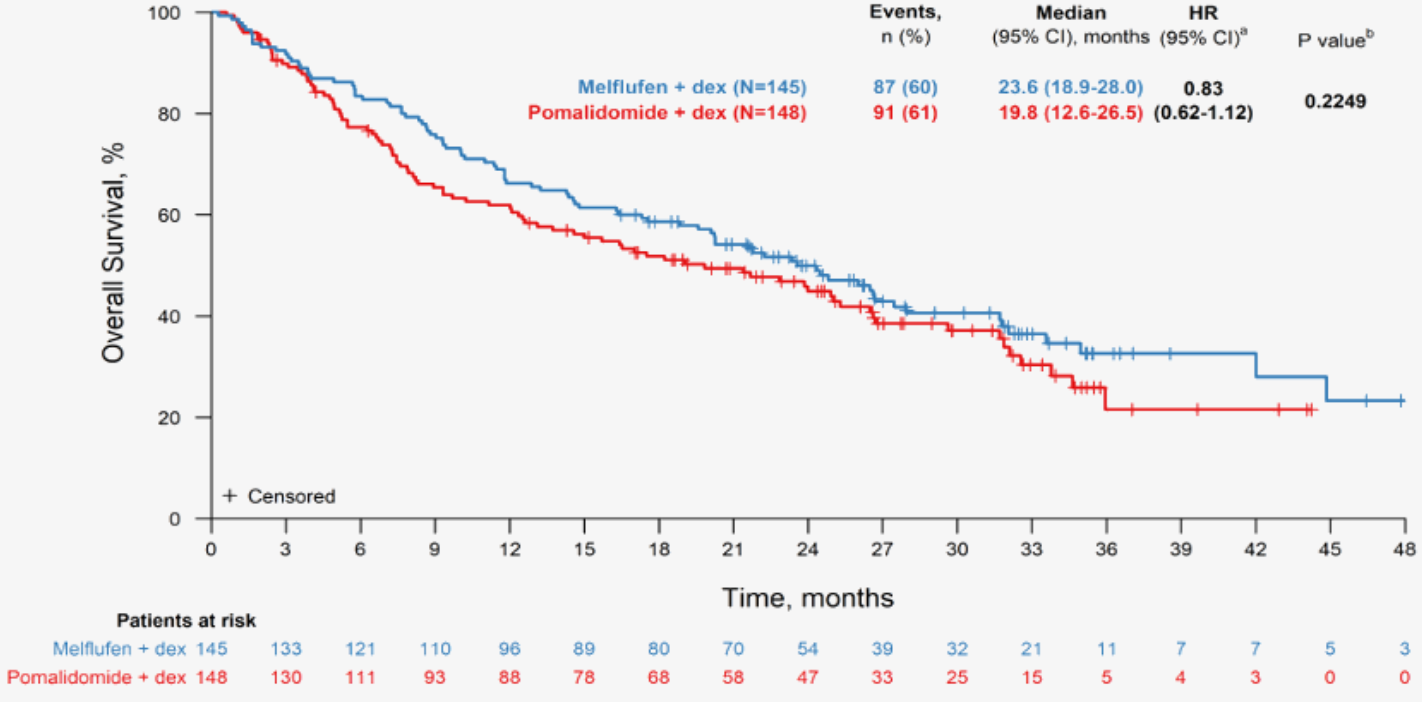
# OS in the OCEAN study – recommended population (verified by EMA)

*Post-hoc Analysis*




*Data cutoff date: 3 Feb 2022*

ASCT, autologous stem cell transplant; dex, dexamethasone; melflufen, melphalan flufenamide; OS, overall survival; HR, Hazard Ratio; TTP, time to progression.
aUnstratified hazard ratio. bLog-rank P value. In House Data. Oncopeptides Pharmaceuticals. DoF ALL-DOF-000055.



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# European approval granted by European Commission

## European Commission approves Oncopeptides' Pepaxti

"The approval of Pepaxti in Europe is foundational for Oncopeptides, and brings excellent news for patients and shareholders," says Jakob. "Despite the introduction of novel therapies, patients with triple class refractory disease have a high unmet medical need, since their treatment options ultimately become exhausted."

**Jakob Lindberg, CEO**

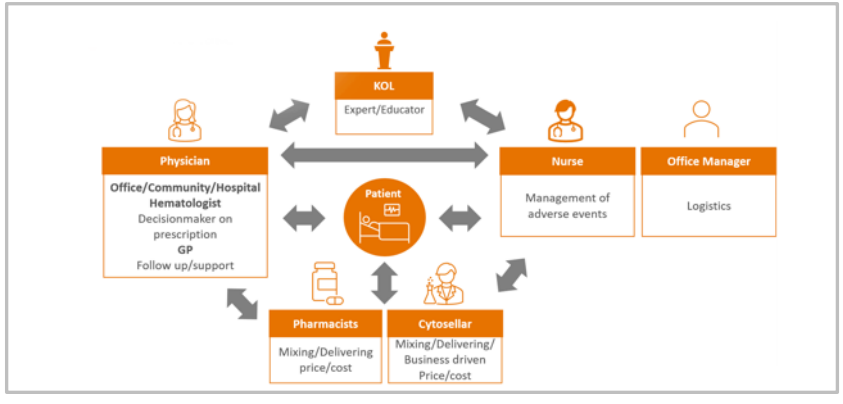
# Commercial launch of Pepaxti started October 2022

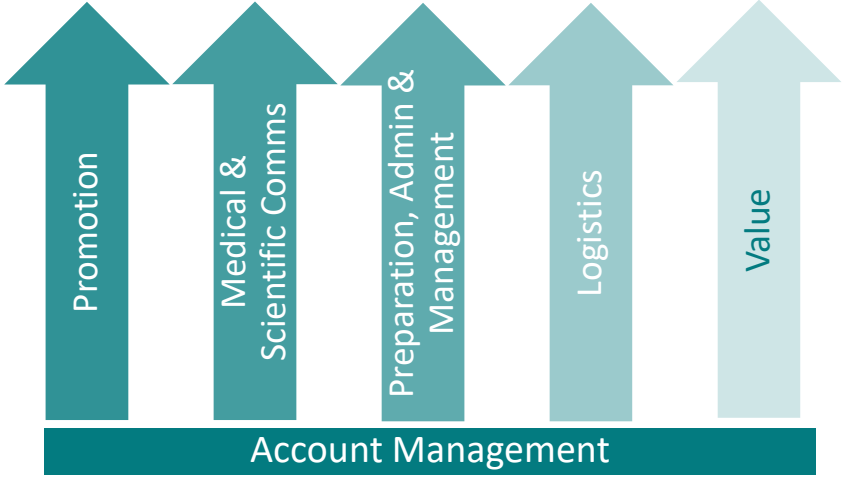
- Germany first market to launch
- Lean organization with in-depth experience
- Focused account activation model
- Broad awareness and engagement plan
- Build team to broaden outreach across Germany
- Provide entry to Austria and Switzerland
- Pave the way for commercialization in Europe

# Account activation key to successful launch

## Traditional Model

- Multiple roles to cover all competences
- Broad approach to support promotional sensitive indications
- Several persons share stakeholder contacts; sales & medical force
- Demands higher degree of F2F access to stakeholders
- Supported & complemented by marketing and Market Access




## Our Focused Model

- Limited number of roles with focus on key competences for Pepaxti
- Targeted and science driven approach to meet high unmet need
- One primary stakeholder contact allows effective execution
- Enables virtual interaction and facilitates customer access
- Complemented by marketing and Market Access



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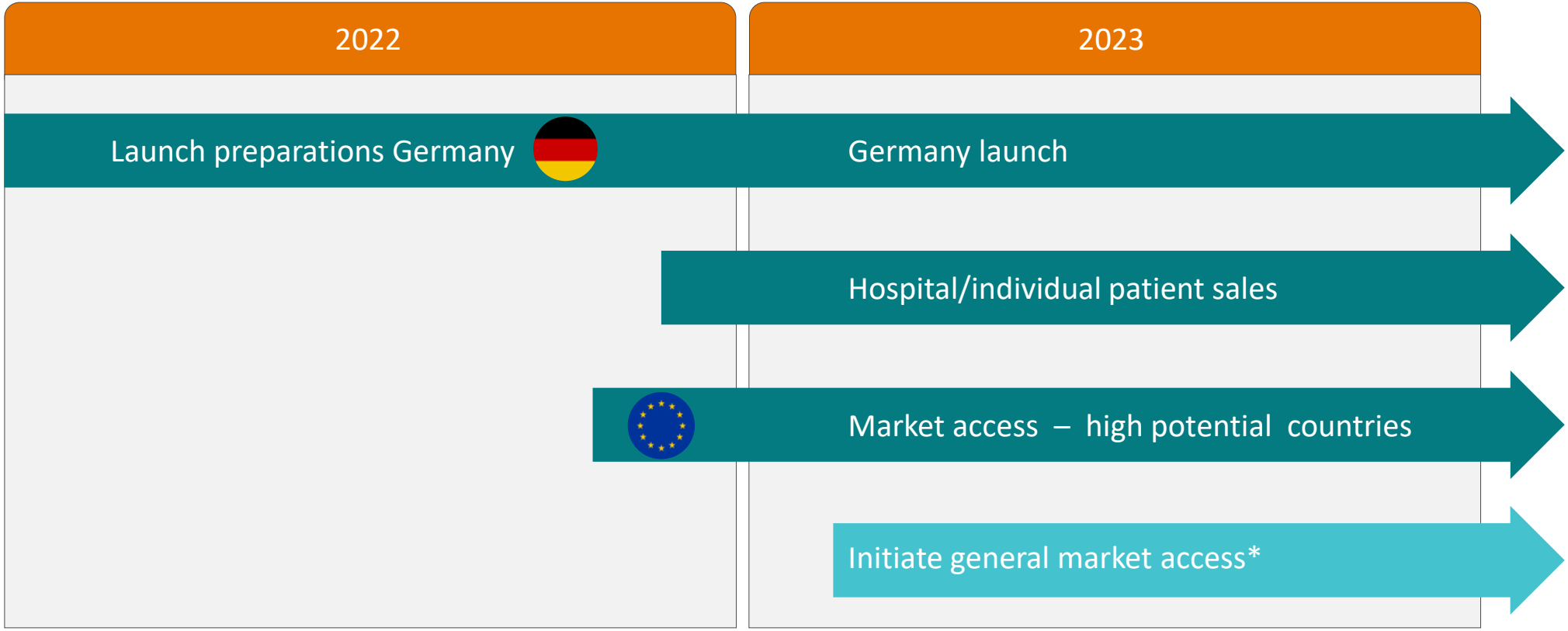
# Roadmap to commercialization in Europe

**Objective:** Maximize value for patients and shareholders by ensuring patients get access to Pepaxti




 * Tentative timeline

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# Growing multiple myeloma market in Europe

**Market drivers**

Incurable disease

Unmet medical need for convenient, efficacious and tolerable options

High adoption of new therapies

Increasing target population in later lines

**European MM market**

**Annual incidence:** ~40.000 patients

**Target population** OCEAN indication: ~17.000 patients

**Annual market potential**

**1.5-2.0 billion SEK***



*Market potential assuming a successful type II variation, and that price negotiations reflect the degree of innovation of the drug and the clinical benefit to the patients.

# NK cell engager rewarded for degree of innovation

**NK cell engaging immunotherapy** with superior penetration and immune cell activation, built on proprietary SPiKEs platform

**Eurostars program** – research consortium with leading scientist from;

- Department of Cancer Immunology at Oslo University Hospital, Norway
- Pharmatest Services Ltd in Turku, Finland
- Oncopeptides with the Royal Institute of Technology, KTH, in Stockholm

**First preclinical data** presented at ASH



Co-funded by the European Union

# Company direction 2023

- Ensure a successful launch of Pepaxti in Germany with own organization
- Advance market access activities for Pepaxti in Europe and optimize launch preparedness
- Explore commercial partnership and broaden geographical footprint
- Enable treatment with Pepaxti in one earlier treatment line pending EMA type II-variation approval
- Make next generation PDC-candidate ready for clinical development



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bringing hope through science