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June 27, 2022

Company Update

CHMP issues a positive opinion recommending full approval of Pepaxti in EU for patients with TCR Multiple Myeloma

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Oncopeptides is a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary peptide-drug conjugate (PDC) platform to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. The first drug coming from the PDC platform, Pepaxto® (INN melphalan flufenamide), also called melflufen was granted accelerated approval in the U.S., on February 26, 2021, in combination with dexamethasone, for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Oncopeptides voluntarily withdrew the drug from the U.S. market on October 22, 2021, due to worse overall survival data in the phase 3 OCEAN study. The study was a post-approval requirement under the accelerated approval program. Oncopeptides is developing several new compounds based on the PDC platform. Melflufen is not approved by any other registration authorities.

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Participants

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Introduction

Oncopeptides – a science and data driven company
Passionate to make 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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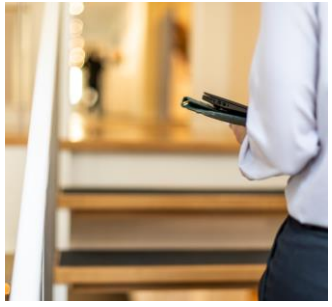
CHMP recommends full approval of Pepaxti

- CHMP recommends a full approval of Pepaxti in EU for patients with triple class refractory multiple myeloma
- Formal marketing authorization of Pepaxti granted by the European Commission within 60 days
- Marketing authorization will be valid in all EU member states, and in the European Economic Area (EEA) countries
- No post-marketing commitments



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Pepaxti label in EU

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 therapy, 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.**

Basis for marketing authorization application

Positive opinion is based on data from the phase 2 HORIZON study and is supported by data from the randomized controlled phase 3 OCEAN study

Phase 3 OCEAN study was utilized by EMA as a confirmatory study

Efficacy results in indicated population

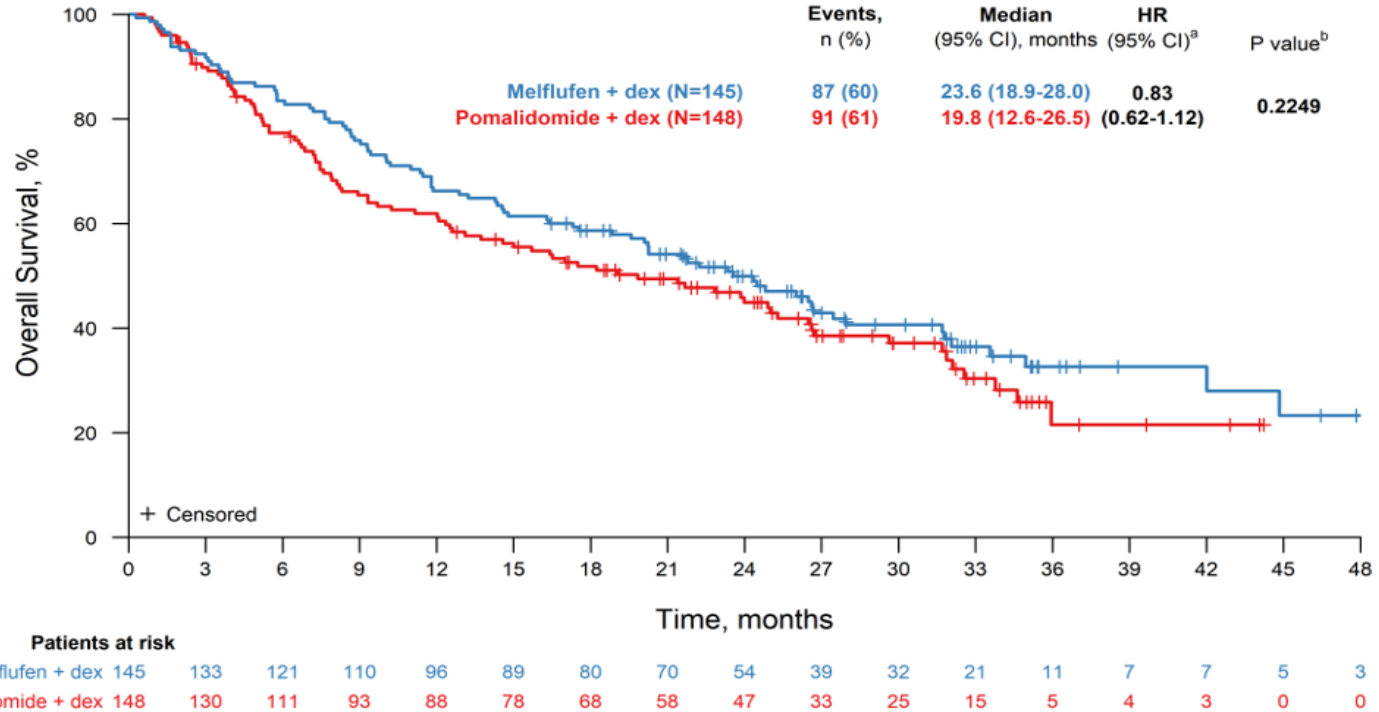
Response (n=52)	HORIZON study (assessed by investigator)
Overall response rate (ORR), 95% CI	28.8% (17.1%, 43.1%)
Duration of response (DOR), 95 % CI (months)	7.6 (3.0-12.3)
Time to response (TTR) (months)	2.3 (1.0-10.5)

"The overall survival result in the OCEAN study constitutes a case of true survival heterogeneity which is reflected in the indication statement in accordance EMA guidelines"

Klaas Bakker, MD, PhD, Executive Vice President and Chief Medical Officer.

OS in OCEAN Demonstrates True Heterogeneity in patients with TTP of <36 months from ASCT

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.
[a]Unstratified hazard ratio. [b]Log-rank P value.
In House Data. Oncopeptides Pharmaceuticals. DoF ALL-DOF-000055.

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No toxicological safety signals

EMA confirms that there are no toxicological safety signal(s) and that there is a positive benefit risk profile in the indicated patient population

For patients with a prior autologous stem cell transplantation, the time between transplantation and disease progression should be at least 3 years

The non-transplanted, often older patient population, which represents the largest group of RRMM patients, particularly benefits from treatment with Pepaxti

High unmet medical need

"The recommendation for full approval of Pepaxti by EMA is really good news for patients with triple class refractory disease, where the unmet medical need remains high and treatment options often are exhausted,"

Pieter Sonneveld, professor of Hematology at the Erasmus University Medical Center in Rotterdam, the Netherlands and principal investigator of the OCEAN study.

What happened in 2021/ 2022?

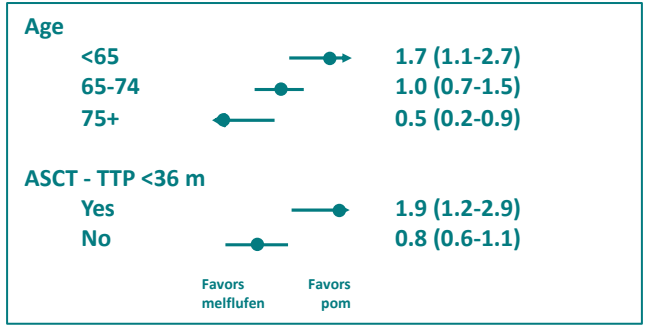
- Primary end-point of superior PFS met in confirmatory phase III trial OCEAN
- ITT OS HR was 1.1 with significant heterogeneity

True heterogeneity?

EMA position

- Information value of 1.1 dubious
- No toxicological safety signal
- FDA and EMA guidelines identical

OS Hazard ratio



Observed heterogeneity?

Initial FDA position

- OS HR of 1.1 is informative
- Safety alert and clinical hold

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Regulatory next steps

EMA submission of type II variation in Q4 2022 to enable earlier lines of treatment for Pepaxti

FDA interactions intensified to potentially resolve current regulatory situation in alignment with EMA conclusions and achieve a clear path forward also for US patients.

Commercialization

Advance market access activities after an approval by the European Commission, to pave the way for a successful launch of Pepaxti

Launch Pepaxti in Germany and Austria in Q4 and make Pepaxti available in Switzerland, supported by a small, dedicated organization, targeting haematology specialists

Various commercialization options are evaluated, to optimize patient access across Europe, and maximize shareholder value

Financing options considered

Additional financing options are considered to capture the opportunities with the upcoming EU-approval. This may include new share issues and other public or private financing options.

The Company has an EIB loan facility, and is currently in negotiations, to update tranche definitions to reflect the current regulatory situation

R&D focus and pipeline

Haematological diseases with unmet need – focus for drug development

Multiple Myeloma

- Annual incidence ~85,000 people (EU+US)
- Annual deaths ~45,000
- 5-year survival rate 55-60%
- Drug resistance and exhausted treatment options

Melflufen

R&D Pipeline

Lymphoma

- Annual incidence ~225,000 (EU+US)
- Annual deaths ~75,000
- 5-year survival 65-75%
- Comorbidity a major challenge in elderly

R&D Pipeline

Acute Myeloid Leukemia

- Annual incidence ~40,000 (EU+US)
- Annual deaths ~38,000
- 5-year survival 25-30%
- Resistance, comorbidity and high relapse in elderly

R&D Pipeline

Capture global market opportunities

Rapidly Growing Market

Haematological malignancies:
€70 billion by 2029 at CAGR of 9.8%

Global MM: €29 billion by 2026,
at CAGR of 6.0 %

Global lymphoma: €12 billion by 2026
at CAGR of 8.3%

Global AML: €23 billion by 2026
at CAGR of 10.0%

Market drivers

Rising prevalence of haematological cancers

Increasing geriatric population

More patients in later line therapies

High adoption of new therapies

Combination therapies needed

Our PDCs are superior to standard of care alkylators and are built on a proprietary peptide drug conjugate technology with limited competition

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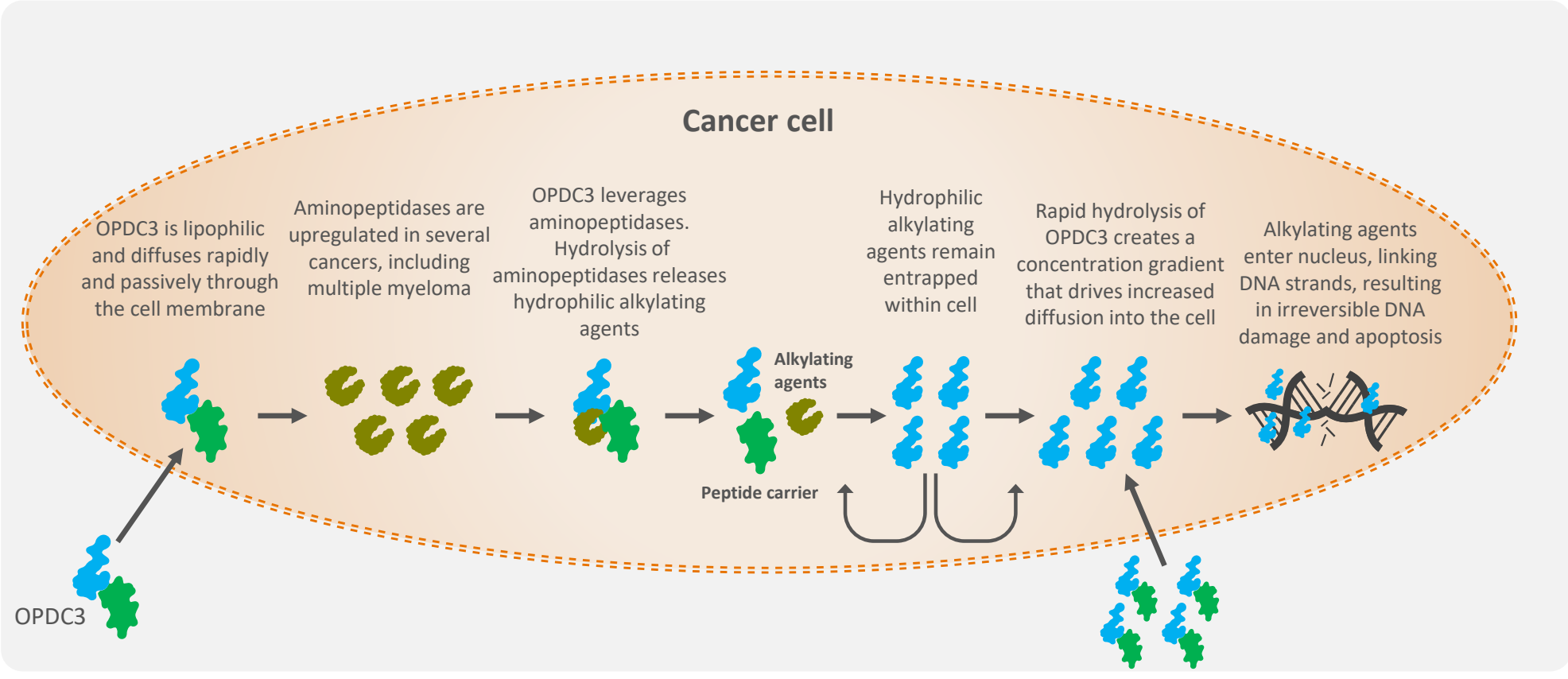
OPDC3 designed to address unmet need in haematological cancers



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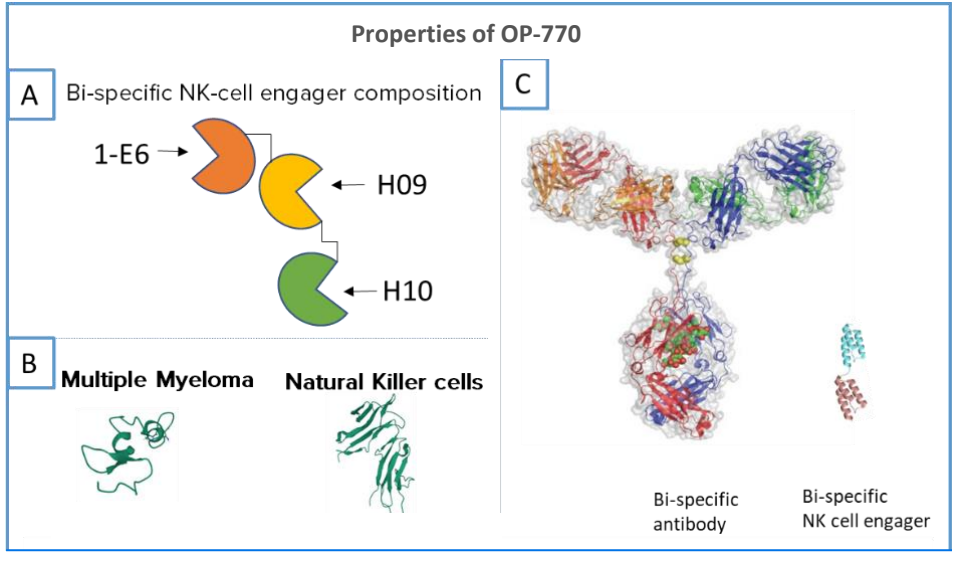
SPiKE platform: NK-cell engager with best-in-class pre-clinical data

- Affibody modules bind activating NK-cell receptor
- A SPiKE containing <u>one</u> affibody domain binding the myeloma cell and <u>two</u> affibody domains binding two different paratopes activate NK cell and mediate myeloma target dependent killing of myeloma cells
- Several myeloma targets affinity maturated



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Conclusions and near-term priorities

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Conclusions

- CHMP recommends a full approval of Pepaxti in EU for patients with triple class refractory multiple myeloma
- Formal marketing authorization of Pepaxti by the European Commission expected within 60 days
- Marketing authorization will be valid in all EU member states, and in the European Economic Area countries
- Commercial launch of Pepaxti in Q4 2022
- EMA submission of type II variation in Q4 2022 to enable earlier lines of treatment for Pepaxti
- FDA interactions intensified to potentially resolve current regulatory situation in alignment with EMA conclusions

Near term priorities

- Partnership discussions
  - Value creating business model to bring melflufen to patients in the EU and US
- Launch in Europe
  - Team on the ground preparing to launch in Germany and Austria, and make the drug available for patients in Switzerland in Q4 2022
- FDA interactions
  - Resolve current regulatory situation in alignment with full EMA approval
- Type II variation based on OCEAN study submitted to EMA in Q4 2022
  - Submission may enable a melflufen MM label for earlier lines of therapy
- Accelerate publication and scientific communication vis-à-vis myeloma community
  - Publications in Q3 and Q4 will support submission and commercialization

Q&A

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bringing hope through science