

Oncopeptides – Science is Leading the Way

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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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Oncopeptides in brief

Oncopeptides in brief



Basics

- Founded in 2000
- Listed on Nasdaq Stockholm
- Collaborations with leading research institutes



Discovery and IND generation

- Targeted therapies for hematological diseases
- Proprietary peptide drug conjugate platform (PDC)
- Several PDC's in pipeline



Commercialization

- Pepaxto approved in the US - currently not marketed
- EMA process on track – CHMP Q2
- Germany first country to launch

Highlights 2022

- EMA review process of melflufen in Europe is proceeding as expected, includes HORIZON and OCEAN data sets
- Focus on R&D has advanced preclinical portfolio with next generation PDC's including a NK cell engager platform
- Rescission of the voluntary withdrawal of Pepaxto in the US was announced on January 21
- Phase 3 OCEAN study was published in Lancet Haematology on January 13, data have been shared with regulatory authorities





Regulatory update

EMA review process of melflufen in Europe on track

- EMA review process of melflufen in Europe is proceeding as expected
- Scientific Advisory Group meeting with EMA on May 11
- CHMP opinion anticipated in Q2, and an EC decision in Q3, 2022
- EMA application based on pivotal HORIZON-study, now includes OCEAN as a confirmatory study

Phase 3 OCEAN data published

“Results from OCEAN provide evidence that melflufen, with its novel mechanism of action, plus dexamethasone, can improve progression-free survival for patients with lenalidomide-refractory relapsed or refractory multiple myeloma who have received two to four previous lines of therapy.

The results also suggest that treatment with melflufen should be carefully tailored on the basis of a patient's previous medical history.”

Source: The Lancet Haematology, MD Fredrik H Schjesvold, et.al

THE LANCET Haematology

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Melflufen or pomalidomide plus dexamethasone for patients with multiple myeloma refractory to lenalidomide (OCEAN): a randomised, head-to-head, open-label, phase 3 study

Fredrik H Schjesvold, MD   Prof Meletios-Athanasios Dimopoulos, MD

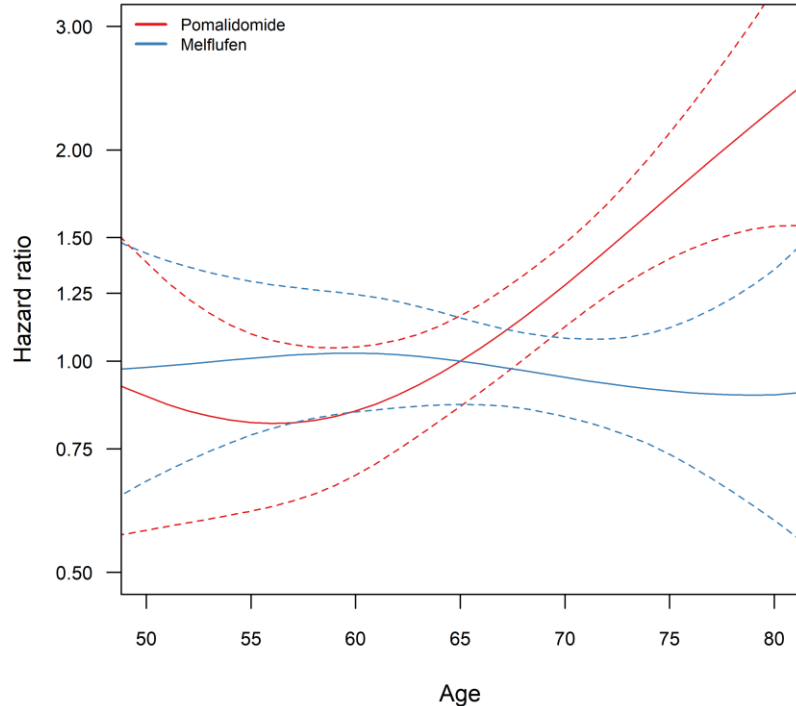
Sosana Delimpasi, MD • Pawel Robak, MD • Daniel Coriu, MD •

Wojciech Legiec, MD • et al. [Show all authors](#) • [Show footnotes](#)

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Overall survival in phase 3 OCEAN study



- Need to study pre-specified subgroups to understand survival in OCEAN given the variability in OS result in pomalidomide + dexamethasone arm (not reflected by PFS)
- As a function of age, the benefit-risk profile of pomalidomide + dexamethasone changes and consequently the relative benefit-risk profile of melflufen + dexamethasone
- This also counts for gender and ASCT status

Understanding OCEAN is key

- Phase 3 head-to-head study melflufen vs pomalidomide
- OCEAN met primary endpoint of PFS
- Heterogenous survival data
 - OS HR of 1.104 favoring pomalidomide
 - No toxicological safety signals

Pre-specified Age Group	Hazard Ratio	95% Confidence Interval
<65 years (n=181)	1.71	1.09-2.69
65-74 years (n=238)	1.03	0.71-1.50
≥75 years (n=76)	0.46	0.23-0.92

Market access paves way for commercialization

- More than 70 patients included in Early Access Program in Europe
- Market access preparations in Germany initiated
- If approved, we will be ready for a commercial launch before end of Q3
- Potential partners identified to broaden patient access and market penetration

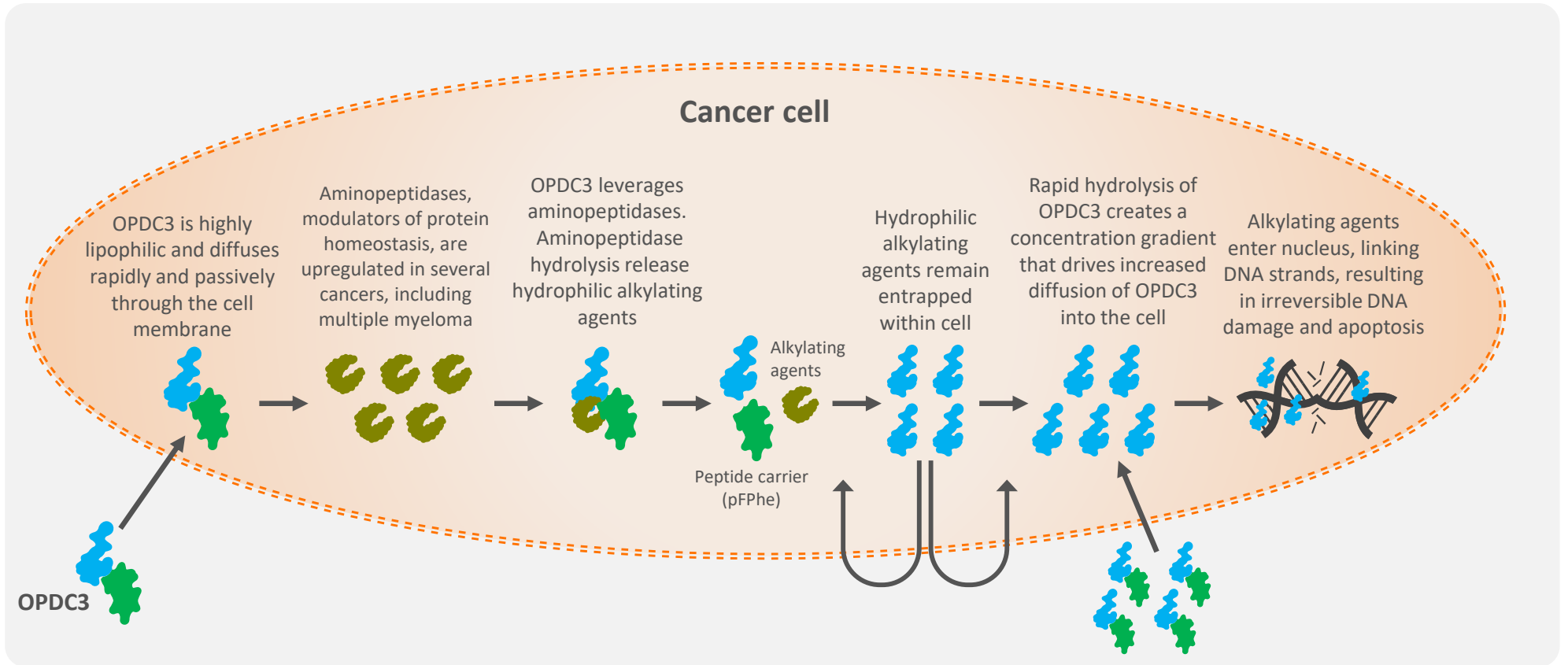
Approved product in the US – not marketed

- Voluntary withdrawal of Pepaxto in the US has been rescinded, based on further review and analyses of the heterogenous overall survival data from phase 3 OCEAN study and other relevant trials
- Pepaxto is not marketed in the US at this time, we have a dialogue with the FDA to reach a mutual understanding and interpretation of OCEAN data. We cannot speculate on the timetable and outcome
- We are committed to provide US patients continued access to melflufen via the Individual Patient Expanded Access Investigational Drug Application (IND) process if deemed appropriate by physician



Preclinical development

OPDC3 – the next generation PDC's





Q&A



oncopeptides

bringing hope through science