

Oncopeptides corporate presentation

Redeye growth day 2021, June 2, 2021

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Disclaimer

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On 26 February 2021, the U.S. Food and Drug Administration (“FDA”) approved PEPAXTO® (melphalan flufenamide, also known as melflufen), in combination with dexamethasone, for the 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. This indication has been granted under accelerated approval based upon data from the HORIZON study. Melflufen is not approved by any other registration authorities.

Melflufen is an abbreviated form of the international non-proprietary name (INN) melphalan flufenamide

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Oncopeptides at a glance

Fully integrated biotech company with first product launched in March



Innovative drug discovery

- Targeted therapies for hematological diseases
- Drug candidates from peptide drug conjugate platform (PDC)



Comprehensive clinical development program

- Initial focus on \$ 19 B Multiple Myeloma market
- Broad supportive MM clinical program, entering into new indications
- Positive phase 3 OCEAN data presented May 25



First commercial launch in the U.S.

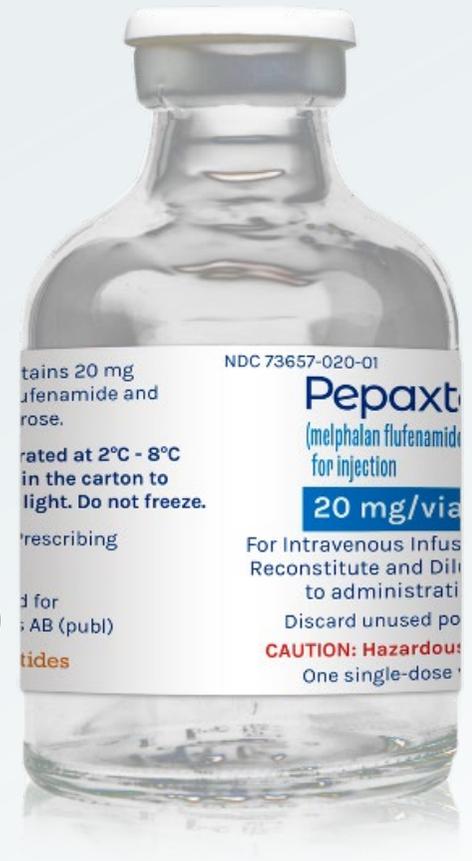


- PEPAXTO launched by own sales force in the US mid-March
- EMA submission April 16

PEPAXTO granted accelerated approval on February 26 by FDA

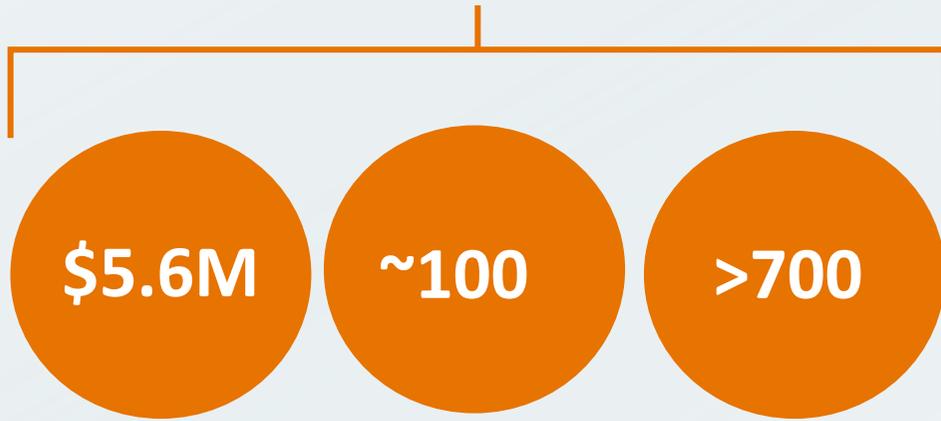
Offers hope to RRMM patients with high unmet needs

- Initial label targets patients with relapsed or refractory multiple myeloma
 - whose disease is refractory to at least;
 - one proteasome inhibitor,
 - one immuno-modulatory agent
 - one CD38-directed antibody,
 - who have received at least four prior lines of therapy
- FDA approval based on a sub population of the HORIZON study (n=97) with high unmet medical of which 41% had extramedullary disease (EMD)
- Commercial drug available to patients beginning from March 15



PEPAXTO off to a strong start first six weeks

Revenue Metrics



Net sales in first 6 weeks

of accounts using product

of 20 mg vials shipped

Field Team Metrics



Top tier customers

Customer awareness

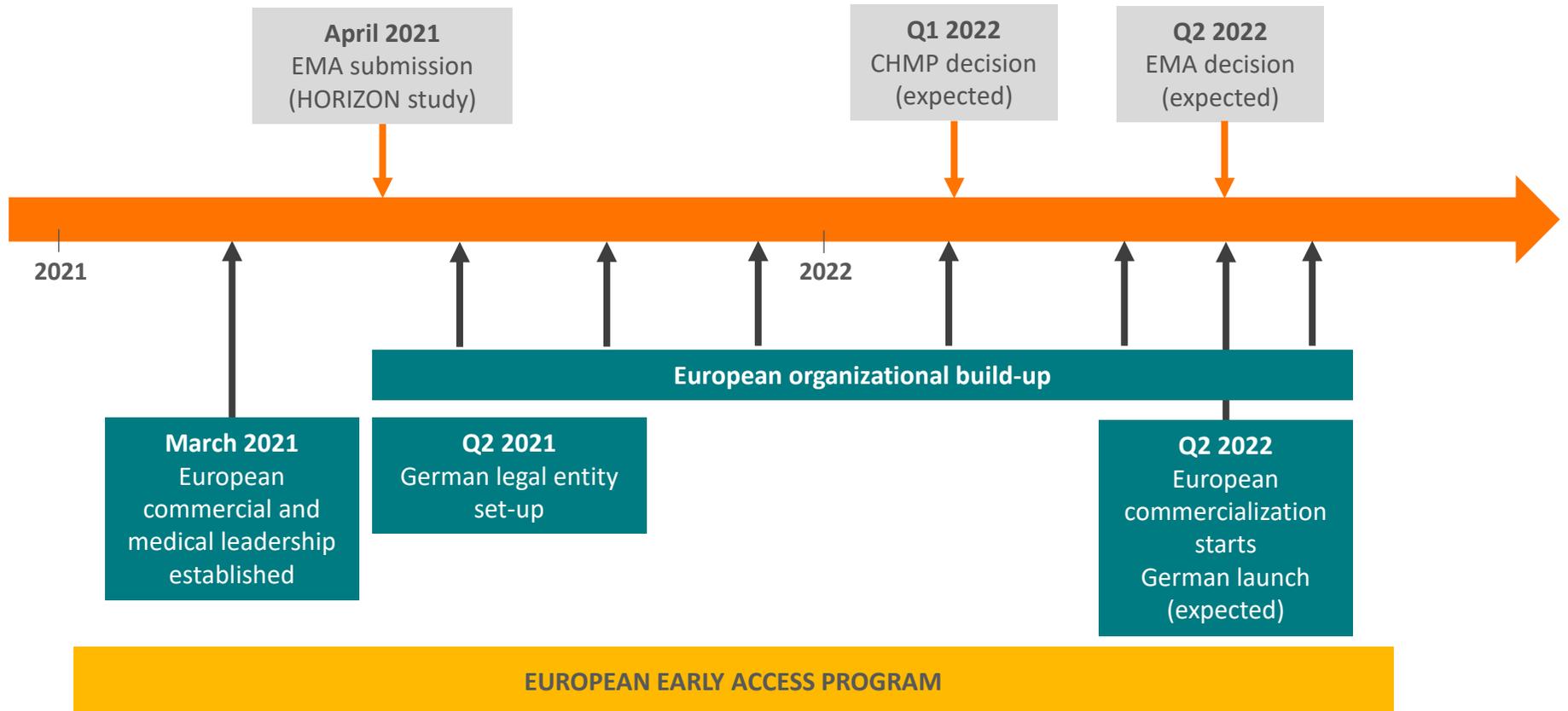
Payer coverage

Building the European Organization

Goal to start commercialization in Q2 2022

REGULATORY & TIMELINES & ACCESS

ONCOPEPTIDES MILESTONES



Clinical program drives label expansion



FDA-approval in triple-class refractory (TCR) patients who have received at least 4L of treatment

Average duration of therapy **3–4 months**

TCR RRMM **20,000+**
EMD **18,000**



Head-to-head study with pomalidomide may enable single agent 3L+ use

Average duration of therapy **6–9 months**

3L+ RRMM
Single drug use
25,000



Combination with PI or anti-CD38 may enable 2L+ combination treatment

Average duration of therapy **10–14 months**

3L+ RRMM
Single drug use
20,000+



Positive OCEAN data released May 26

Topline results and safety summary

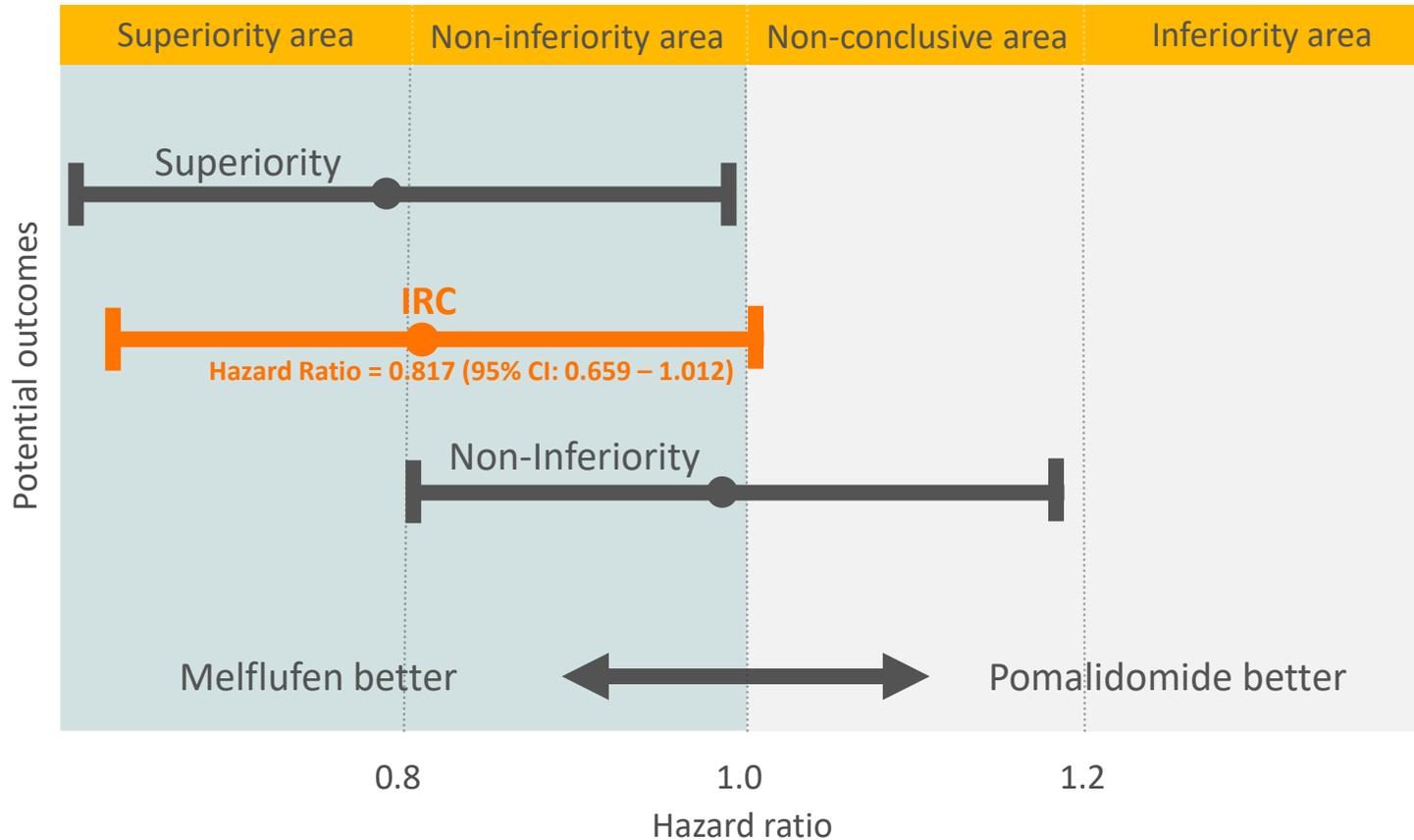


- Primary endpoint – Progression Free Survival (PFS)

	Hazard Ratio (95% CI)	P-Value	Relative mPFS improvement	Outcome
Independent Review Committee (IRC)	0.817 (0.659-1.012)	0.064	+41%	Non-Inferiority
Investigator Assessed Results (I-A)	0.790 (0.639-0.976)	0.029	+42%	Superiority

- Overall Response Rate 32.1% for melflufen vs 26.5% for pomalidomide
- Safety summary
 - Safety profile of melflufen was in line with previous studies
 - Pomalidomide had slightly more infections than melflufen
 - Similar levels of other non-hematologic toxicities were observed
 - Discontinuation rates for AEs were similar in both arms
- Full data to be presented as soon as possible, tentatively Q3

Putting the OCEAN outcome into perspective



What does that mean for engaging FDA and US PEPAXTO label?

We are currently in the process of engaging FDA on the OCEAN data

Presentations at key conferences

Publication in progress



We plan to file for supplementary NDA in Q4 2021



In light of the OCEAN trial results, we plan to ask for:

- Label change (new indication)
- Full approval (fulfill requirements for the accelerated approval)



We continue and focus on our commercialization efforts with PEPAXTO in the US



LIGHTHOUSE – Confirmatory phase 3 study

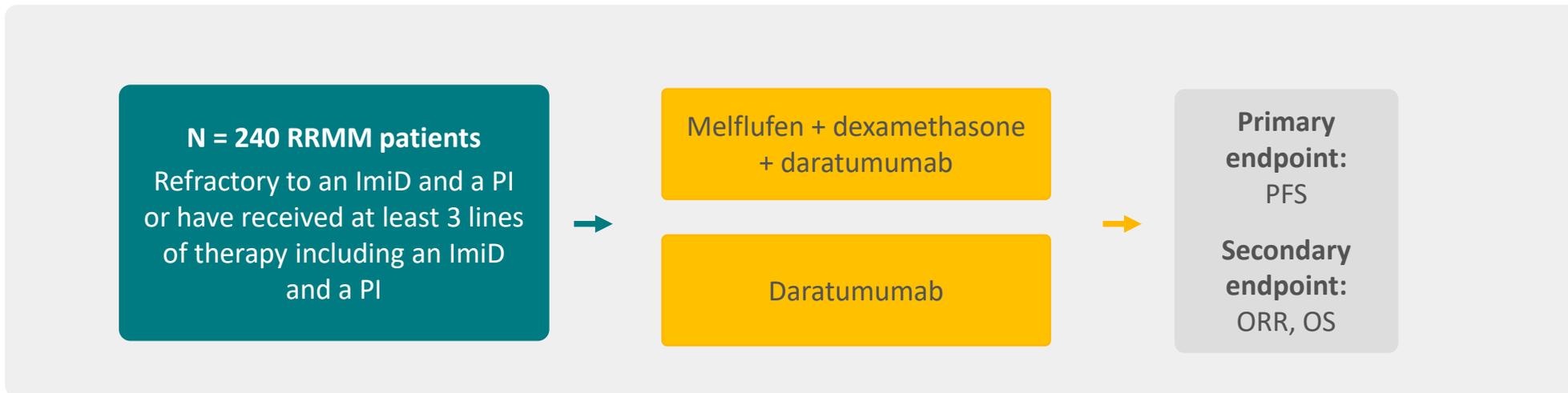


Randomized phase 3 study in RRMM

- Melflufen + subcutaneous daratumumab vs daratumumab alone
- Based on positive data from ANCHOR (ORR 73%, m PFS 12.9 months)

Objectives

- Increase market potential – expand label for melflufen in combination with daratumumab



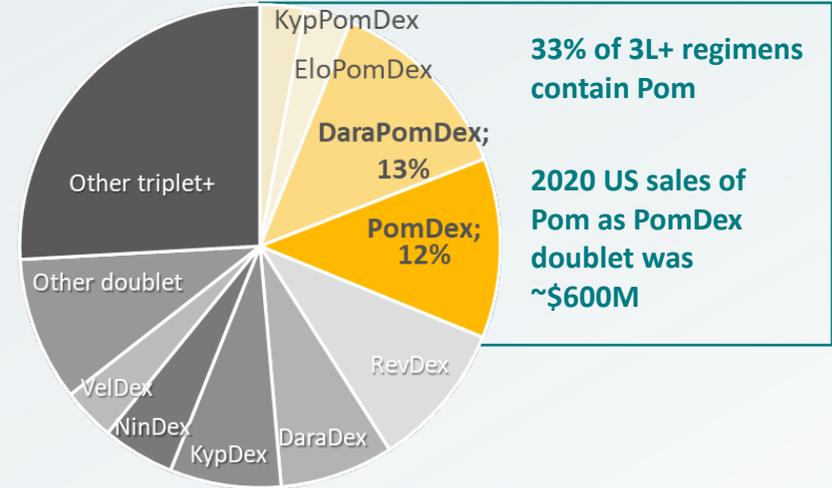
Pomalidomide is the largest drug in RRMM

PomDex and PomDex combos comprising 33% of US share

Pomalidomide Worldwide Sales (\$ Billion)

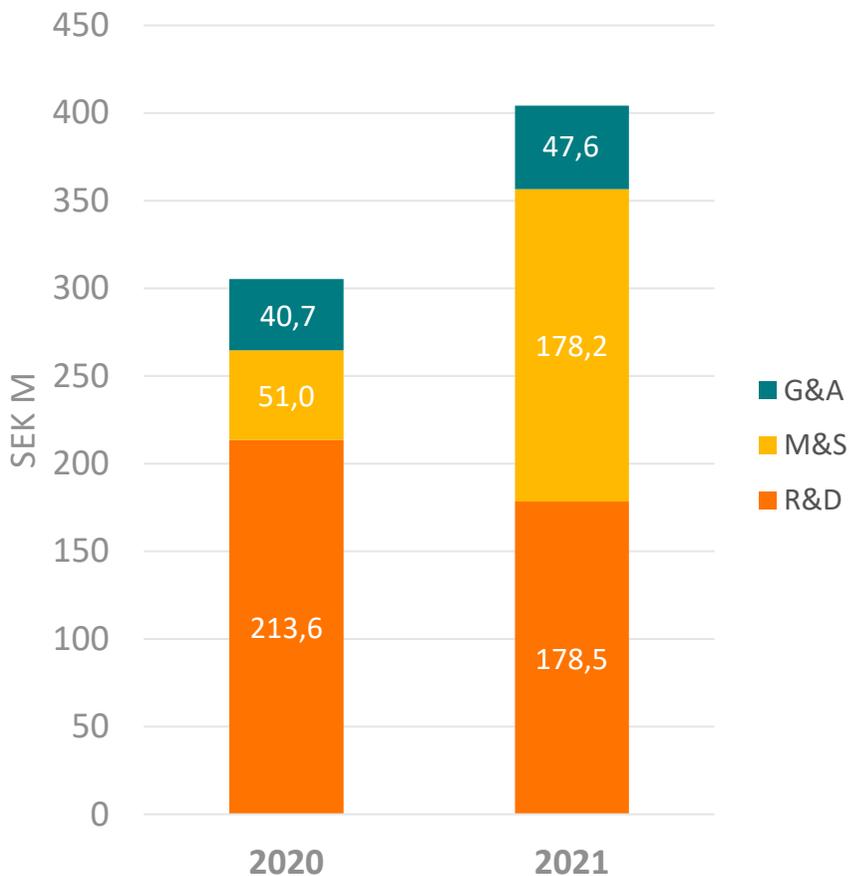


US 2020 - 3L+ Patient Market Share Intrinsic Data



Financial Results for January – March 2021

Operating Costs Jan-Mar



- Revenues amounted to SEK 19.4 M (-)
 - SEK 28.0 M in April
 - ~100 accounts
- Operating loss increased to SEK 347.9 M (loss: 287.3) for Jan-Mar
 - R&D decreased primarily due to less cost in OCEAN- and HORIZON projects
 - Number of co-workers increased to 294 (121) as of March 31
- Cash flow from operating activities neg. SEK 386.7 M (neg. 312.8)
 - Neg. exchange rate effect of SEK 83.9 M
- Cash position was SEK 372.5 M (617.8) as of Mar 31, 2021, SEK 1,411.4 M including raise closed in April
 - Directed share issue raising SEK 1,106 M before issue costs of SEK 67 M executed in March but completed in April
 - €40 M EIB loan facility unutilized

News flow

Value drivers and major milestones

Q1 2021	Q2 2021	Q3 2021	Q4 2021	2022
 Pepaxto [®] <small>(melphalan Dufosamid) Kapseln für Erwachsene und 20 mg/ml</small>	EMA file accepted for conditional approval	Presentation OCEAN full data	sNDA submission OCEAN	Potential EU conditional approval
Accelerated US approval	Expanded Access Program (EU) opened	Results PORT	Results BRIDGE	Launch in first wave of EU countries
Commercial launch in the US	LPI PORT	LPI BRIDGE	LPI ASCENT	Potential sNDA approval US
	Topline results OCEAN		LPI ANCHOR	Expansion of EU indication on OCEAN
	FPI COAST (OPD5)		FPI in new indication(s)	IND Submission (NCE)
	EHA data update		FPI LANTERN (EMD)	Final results ANCHOR
	ASCO data update		ASH data update	LPI LIGHTHOUSE

Key takeaway messages

- US PEPAXTO launch is off to a strong start
 - ~100 accounts using product
 - Net sales of SEK 19.4 M (\$2.3M) in March and SEK 28.0 M (\$3.3M) in April
 - EU build-up ongoing
- Positive OCEAN data has impact in several ways
 - Potential full approval in the US for existing label
 - Potential approval in the EU
 - Potential label update in the US to earlier lines of treatment
- LIGHTHOUSE may further broaden label into combination treatments in earlier lines of therapy
- On a path to make PEPAXTO a foundational treatment in RRMM





bringing hope through science