

Q1 Webcast

May 26, 2021

Participants



Marty J Duvall
Chief Executive Officer



Klaas Bakker
Chief Medical Officer



Anders Martin-Löf
Chief Financial Officer

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.

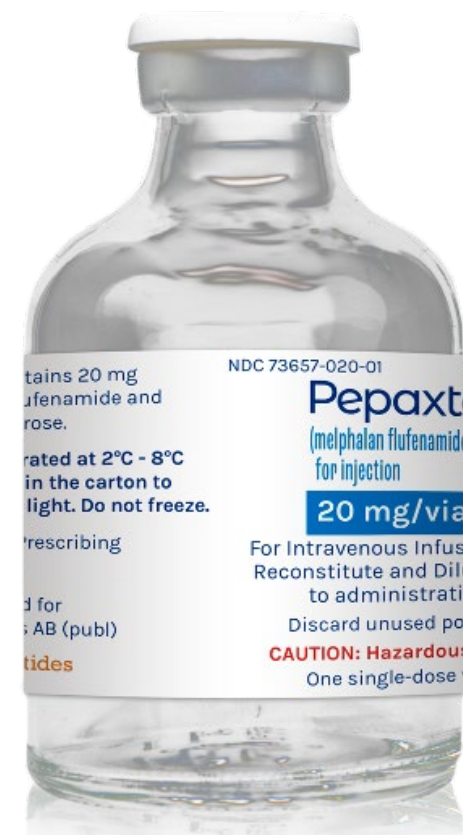
Melflufen is an abbreviated form of the international non-proprietary name (INN) melphalan flufenamide

The Information contains forward-looking statements. All statements other than statements of historical fact included in the Information are forward-looking statements. Forward-looking statements give the Company’s current expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. These statements may include, without limitation, any statements preceded by, followed by or including words such as “target,” “believe,” “expect,” “aim,” “intend,” “may,” “anticipate,” “estimate,” “plan,” “project,” “will,” “can have,” “likely,” “should,” “would,” “could” and other words and terms of similar meaning or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Company’s control that could cause the Company’s actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Company’s present and future business strategies and the environment in which it will operate in the future.

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Q1 – Key takeaway messages

- US PEPAXTO launch is off to a strong start
 - 90% awareness among targeted customers
 - over 90% of top tier targets reached
- Net sales of SEK 19.4 M (\$2.3M) in March and SEK 28.0 M (\$3.3M) in April
- PEPAXTO is on track with high performing analogues in RRMM
 - ~100 unique accounts
- Phase 3 OCEAN study – positive topline results released
 - Head-2-Head success versus pomalidomide the most used drug in RRMM
- On a path to make PEPAXTO a foundational treatment in RRMM



Q1 - Agenda



PEPAXTO – Launch success and building momentum – *Marty Duvall*



R&D Update | OCEAN topline results and key R&D highlights – *Klaas Bakker*



Financial Update – Quarterly results, milestones and news flow – *Anders Martin-Löf*



Q&A – *Oncopeptides team*



PEPAXTO

Launch success and building
momentum – Marty Duvall, CEO

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



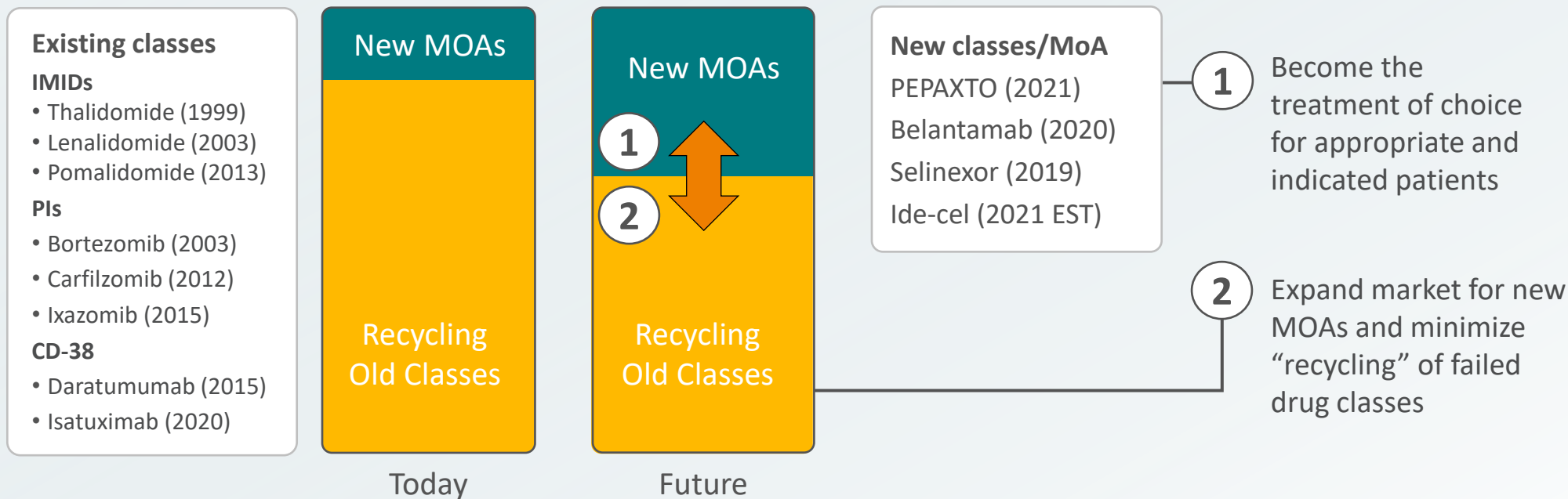
Account-based approach to ensure optimal customer experience



PEPAXTO strategy - Two-pronged approach

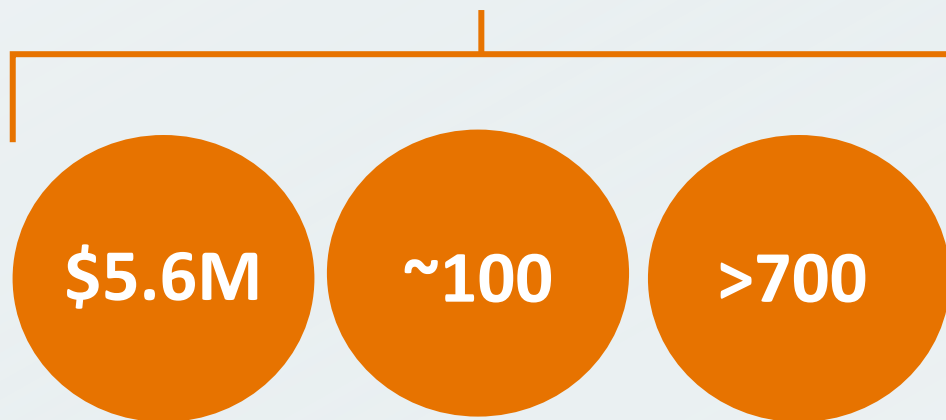
Becoming a foundational treatment in RRMM

Driving change in today's RRMM treatment paradigm where drug classes are "recycled"



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

Early adoption of PEPAXTO into NCCN Guidelines builds confidence



Stockholm, Sweden

Press release March 22, 2021

Oncopeptides announces that PEPAXTO® is included in new Multiple Myeloma guidelines of National Comprehensive Cancer Network®

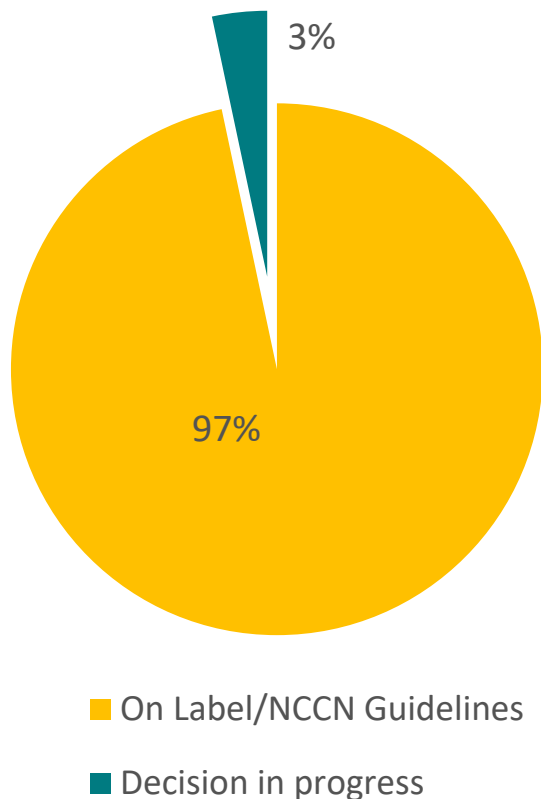
STOCKHOLM — March 22, 2021 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a global biotech company focused on the development of therapies for difficult-to-treat hematological diseases, today announces that PEPAXTO® (melphalan flufenamide) has been included in the new Multiple Myeloma Clinical Practice Guidelines of the National Comprehensive Cancer Network® (NCCN) in Oncology. PEPAXTO, in combination with dexamethasone, was granted accelerated approval by the FDA on February 26, 2021, 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.

"The NCCN Guidelines are a trusted resource for clinicians in the management of oncology patients," says Marty J Duval, Chief Executive Officer at Oncopeptides AB. "We are grateful that melphalan flufenamide is included in these guidelines and believe that they will facilitate the management of previously treated multiple myeloma patients, who need additional treatment options".



Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Nearly 97% of payers covering PEPAXTO on label or better



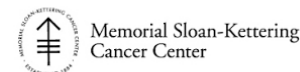
- Nearly 400 payer interactions to date including NCCN, CAC, Drug Utilization Review meetings, P&T, others
- Nearly 50 published commercial medical policies to label covering nearly 75 million lives
- 7 published FFS Medicare MACs policies to label covering 100% of medical lives
- PEPAXTO Medicaid National Drug Rebate Agreement was effective as of April 1
- PEPAXTO is listed in 98% of EMR systems by April 30

No reimbursement challenges to date!

Impressive breadth of use of PEPAXTO

Including leading academic centers and community practices

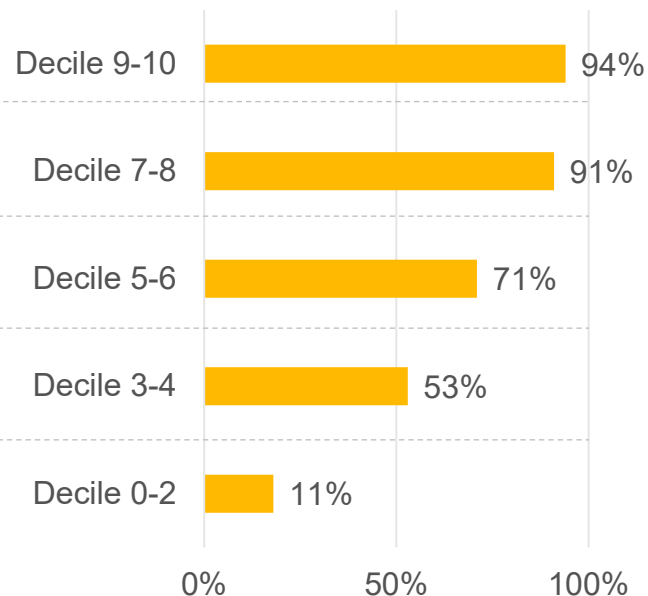
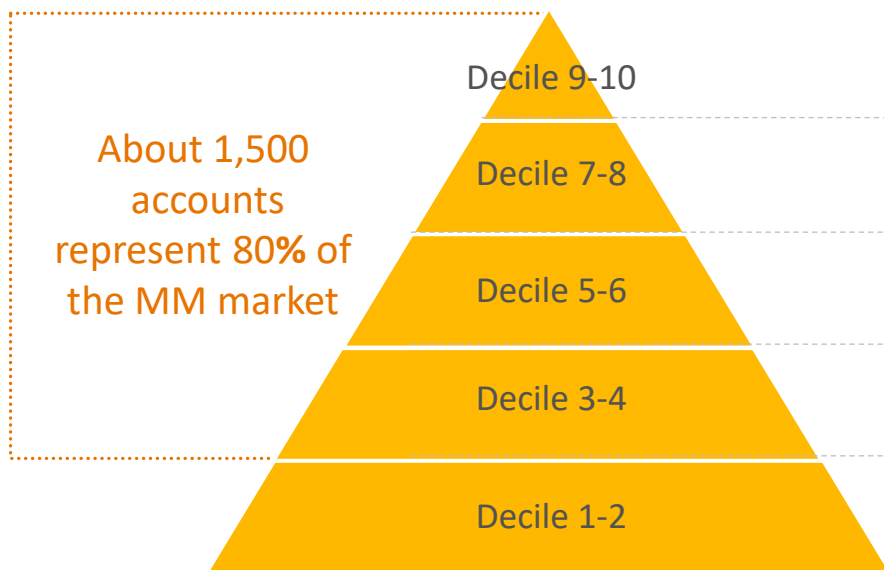
Nearly 100 unique accounts ordered PEPAXTO



More than 90% of top 4 decile accounts reached

Account targets ~ 5,200
Priority accounts* ~ 1,500

Account reach through April
Two-month goals... ACHIEVED



PEPAXTO messaging based on customer insights

Unique MOA, balance of efficacy and tolerability and convenient dosing schedule



Unmet needs

- Growing population of refractory patients, resistant to existing classes
- Existing need for new mechanisms of action

Unique mechanism of action

- PEPAXTO is the first anticancer peptide drug conjugate (PDC)
- MoA allows cytotoxic payload to be delivered directly into tumor cells

Efficacy in study population

- ORR of 24% in subset of triple-class refractory patients (TCR)
- Efficacy in heavily pretreated patient population
- Patients studied had medium 6 lines of prior therapy

Clear indication and eligibility

- Patients previously received a PI, IMiD and anti-CD38 (TCR)
- Eligible for patients with 4 prior lines of treatment

Manageable safety profile

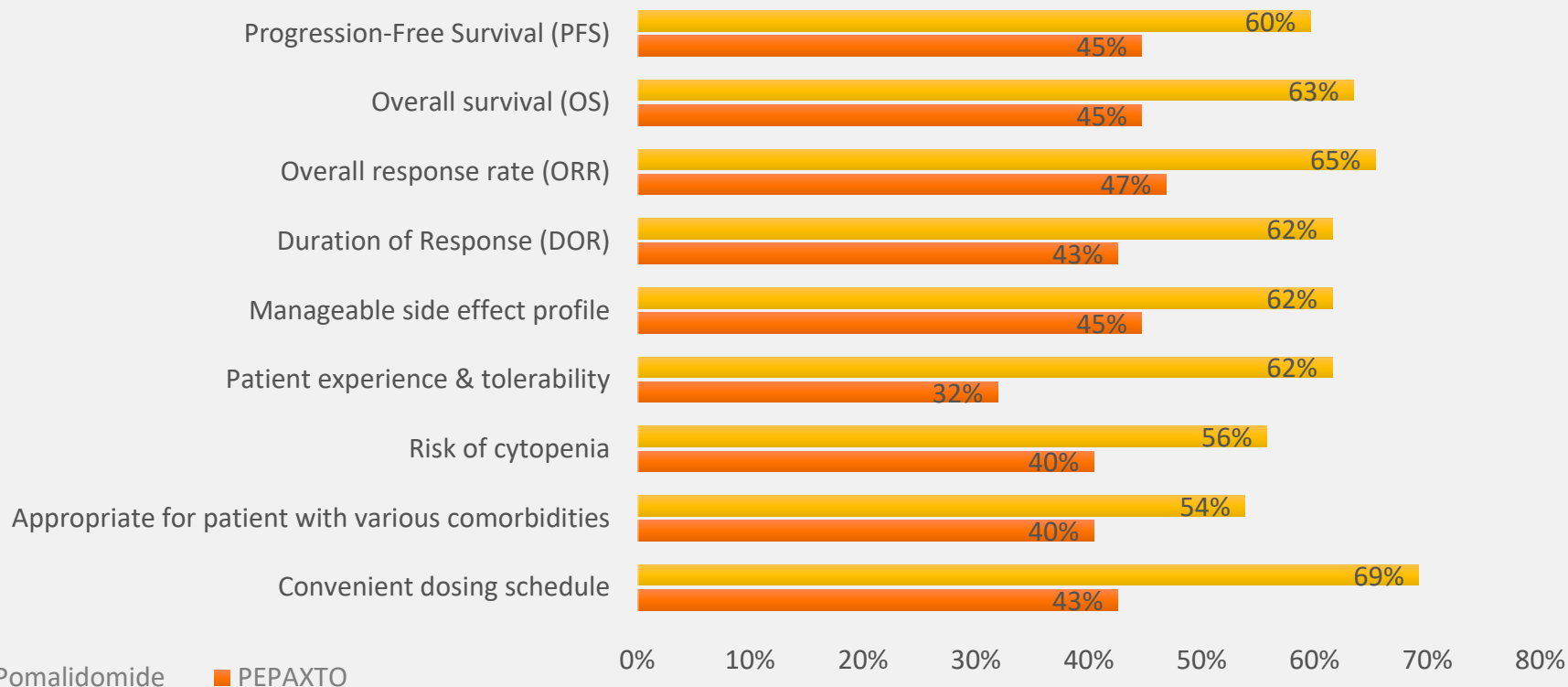
- Hematologic AEs; managed by dose modifications and supportive care
- Low rates of bleeding events, infections and hospitalizations

Convenient dosing schedule

- Once monthly dosing
- 30-minutes infusion

Market perceptions: PEPAXTO vs Pomalidomide*

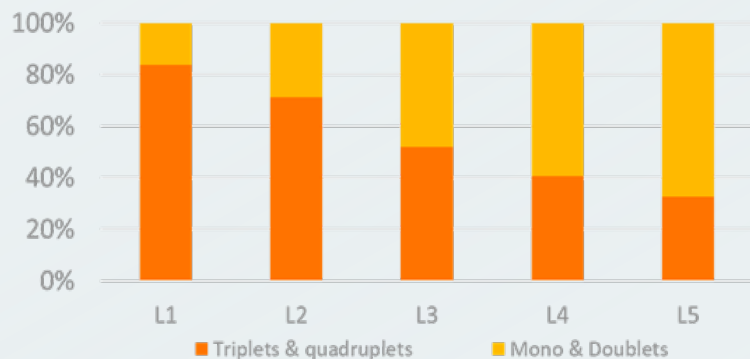
OCEAN study results expected to boost perception of PEPAXTO



*Data from proprietary market research study (April 2021). Based on a survey of appr. 60 physicians rating products across attributes on a 7-point Likert scale. Results shown are the % of physicians rating it a 6 or 7.

PEPAXTO well positioned for community-based care

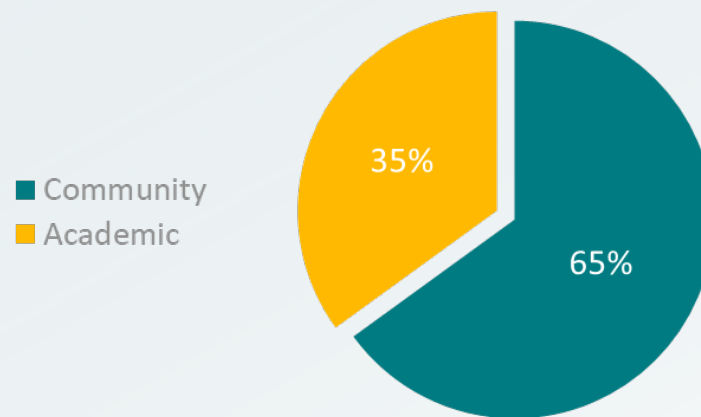
Use of Doublet “Mono and Doublet” therapy is higher in later lines of therapy



Source: Kantar Health 2020 report, Team Analysis

- Efficacy in later lines of therapy
- Manageable safety profile
- Convenient administration and better compliance

PEPAXTO Accounts - Community vs Academic



- Based on users in the first 6 weeks of sales

Building the European Organization

Goal to start commercialization in Q2 2022



OCEAN and LIGHTHOUSE opportunity

OCEAN

Pomalidomide is a \$3.1b product in a \$13b RRMM market

~\$600m US sales in 2020 or ~40% of Pom use is attributed to PomDex doublet use in RRMM

A positive OCEAN trial stands to gain share in the 3L+ setting, taking from PomDex and other doublettherapies, with doublet use making up a majority (~55%) of 3L+ treatments



LIGHTHOUSE

Darzalex has grown quickly into a \$4.2b product driven by increased combination use in the US

~\$600m US sales in 2020 or ~40% of Pom use is attributed to DaraPomDex triplet use in RRMM

While majority of Dara is currently used in combination regimens with other agents, single agent Dara is used in 5-10% of RRMM in the US



Our trials are linked to the largest drugs WW in MM

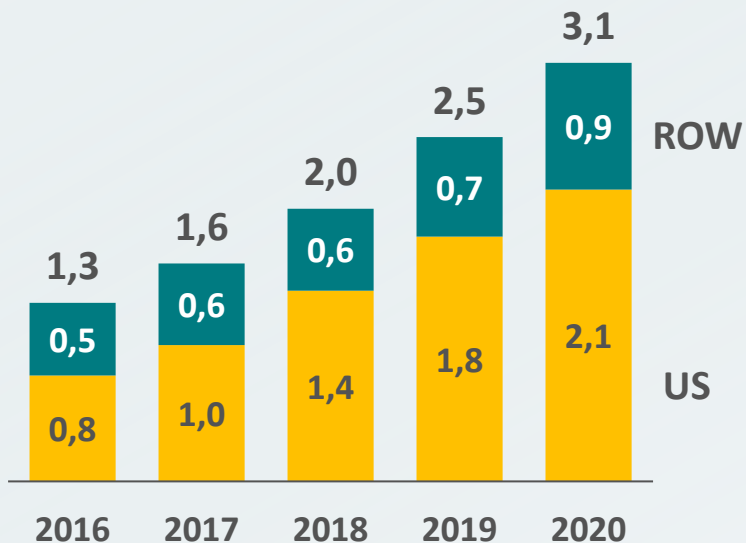
Clinical program drives label expansion

	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+ 

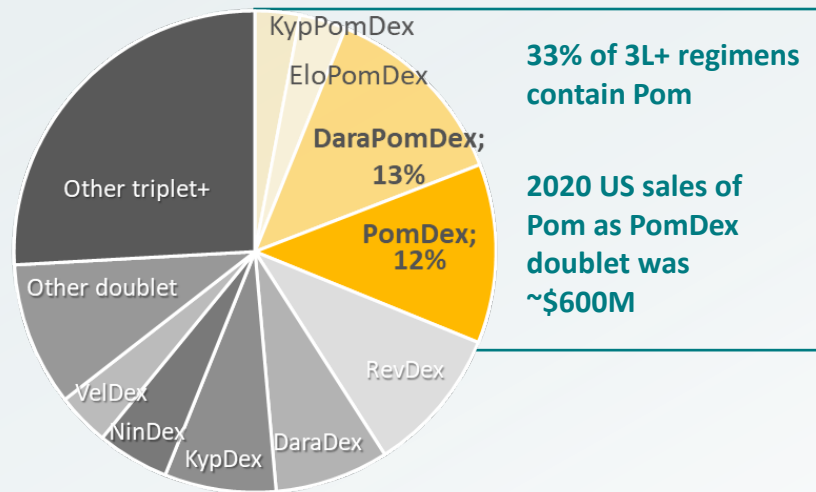
Pomalidomide is the largest drug in RRMM

PomDex and PomDex combos comprising 33% of US share

Pomalidomide Worldwide Sales
(\$ Billion)

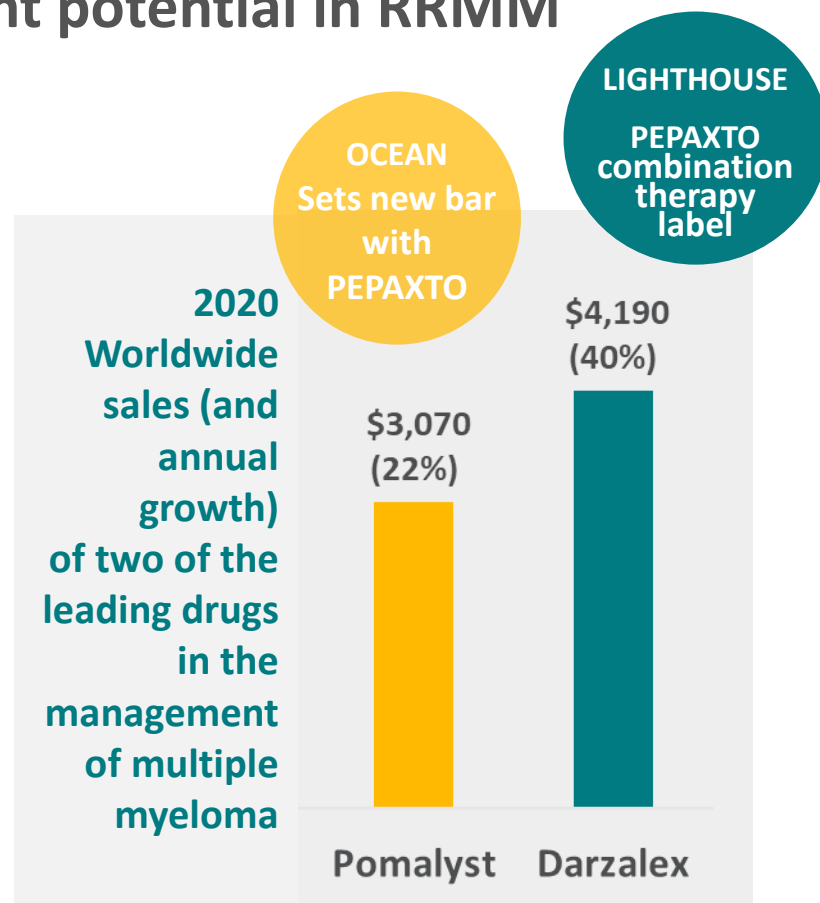


US 2020 - 3L+ Patient Market Share
Intrinsic Data



PEPAXTO's emerging profile has significant potential in RRMM

- OCEAN – Sets new bar with PEPAXTO with positive head-to head data
 - Strong efficacy profile as a doublet in 3rd and 4th line
- LIGHTHOUSE – First opportunity to expand label as part of a triplet regimen in RRMM
 - Opportunity to establish data in combination with the other workhorse drug in multiple myeloma

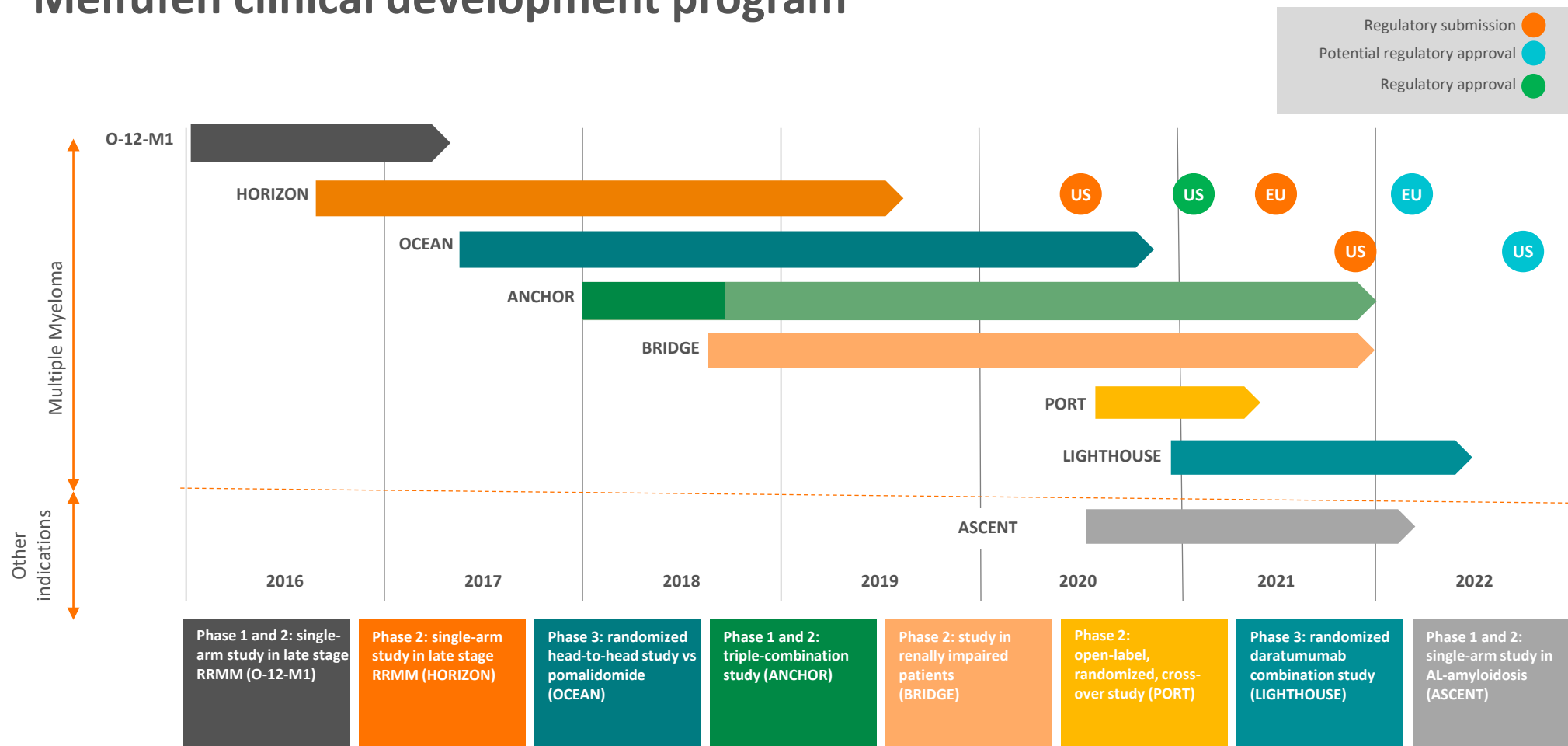




UPDATE

OCEAN Topline Results and Key R&D
Highlights – Klaas Bakker, MD, PhD, CMO

Melfufen clinical development program



The arrows show First Patient In (FPI) and estimated Last Patient In (LPI)

OCEAN DATA – Topline results



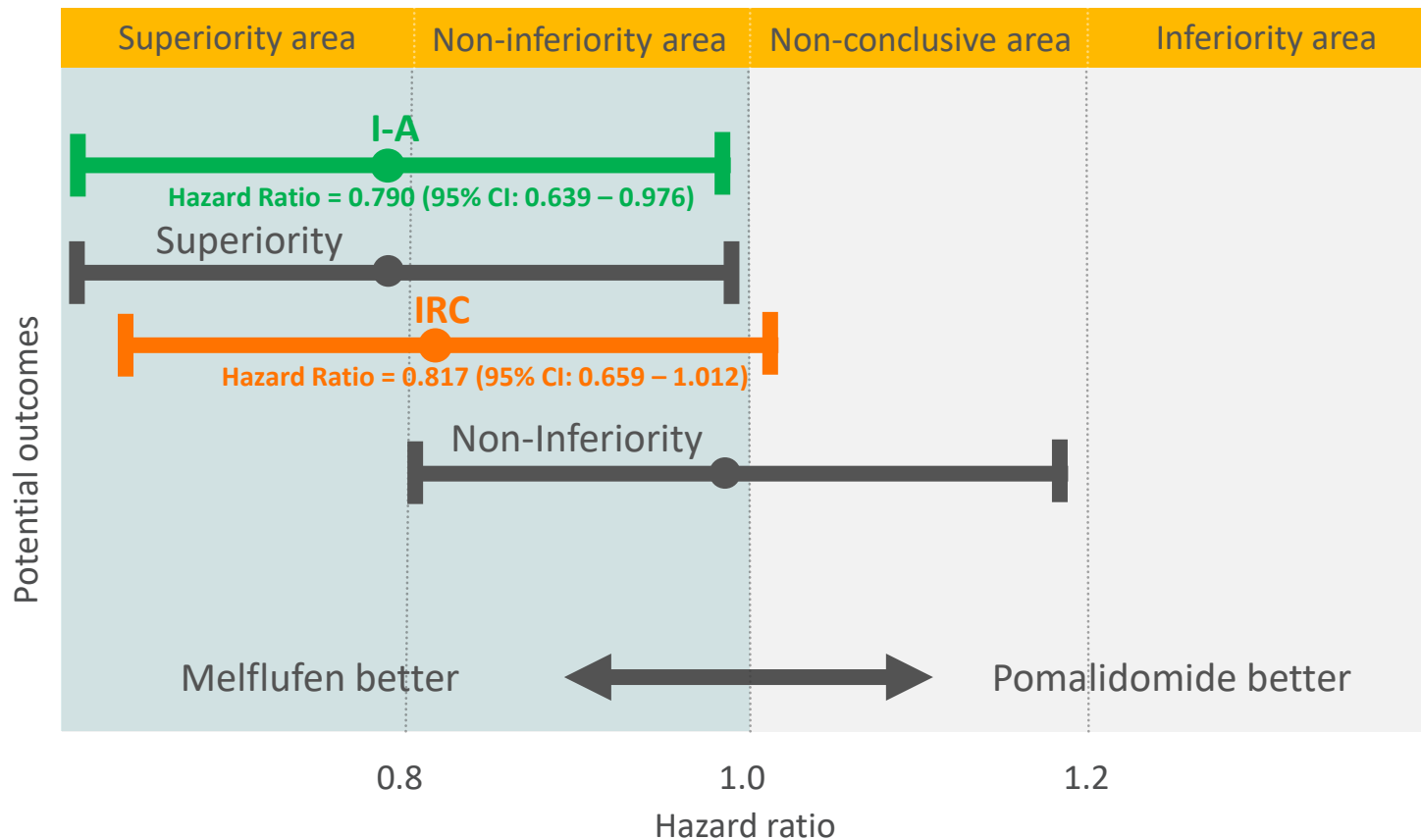
- Primary endpoint – Progression Free Survival (PFS)

	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

Putting the OCEAN outcome into perspective

IRC HR “non-inferiority” and Investigator Assessment HR “superiority”



OCEAN DATA – 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

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

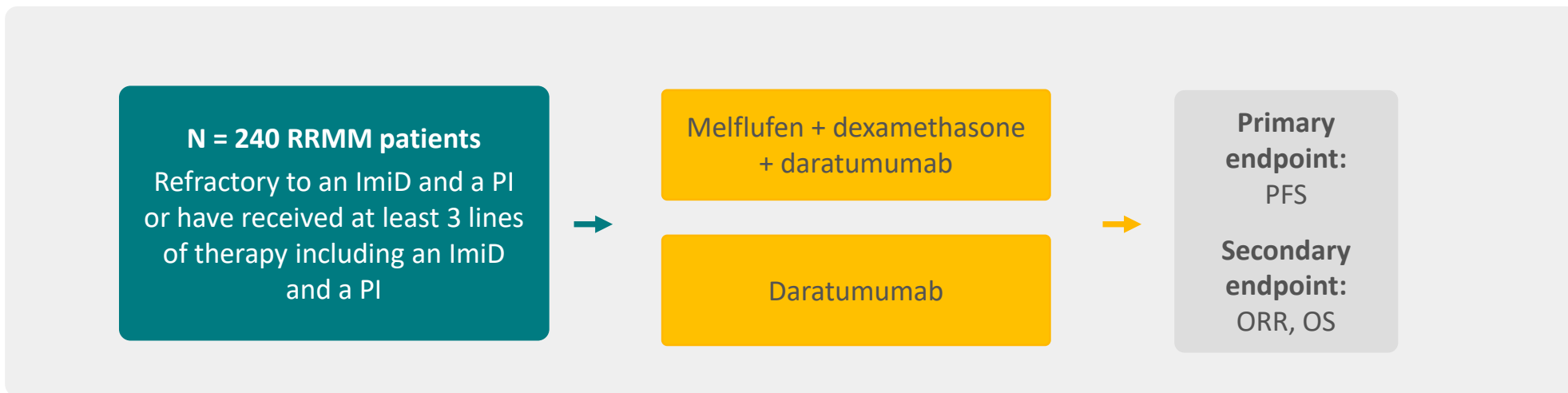


Randomized phase 3 study in RRMM

- 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



Upcoming presentations at EHA 2021



- Melflufen option in patients with renal impairment
 - Bridge (op-107): a phase 2 pharmacokinetic study of melflufen plus dexamethasone in patients with relapsed/refractory multiple myeloma and impaired renal function
- Breaking new ground with new indications
 - Melflufen demonstrates high efficacy in cytarabine and venetoclax resistant Acute Myeloid Leukemia models
 - Melphalan flufenamide is a highly potent anti-neoplastic agent in high risk Diffuse Large B-Cell Lymphoma
- New Mode of Action
 - Melflufen rapidly accumulates within tumor cells and distributes an alkylating payload to the nucleus and mitochondria

Upcoming presentations at ASCO 2021

- ANCHOR (op-104): melflufen plus dexamethasone and bortezomib in relapsed/refractory multiple myeloma patients
- LIGHTHOUSE (op-108): a phase 3 study of melflufen in combination with dexamethasone and daratumumab in relapsed/refractory multiple myeloma patients
- A pooled analysis of the O-12-M1 and HORIZON studies: melflufen plus dexamethasone in relapsed/refractory multiple myeloma patients (RRMM) who are exposed or refractory to prior alkylators



Planned future studies in new indications

Acute Myeloid Leukemia (AML)

High unmet medical need – limited survival –
OS less than a year

Phase 1/2 study in relapsed patients

FPI expected H2 2021

Relapsed Diffuse Large B-cell Lymphoma (DLBCL)

High unmet medical need – limited survival

Phase 1/2 study in relapsed high-risk patients

FPI expected H2 2021

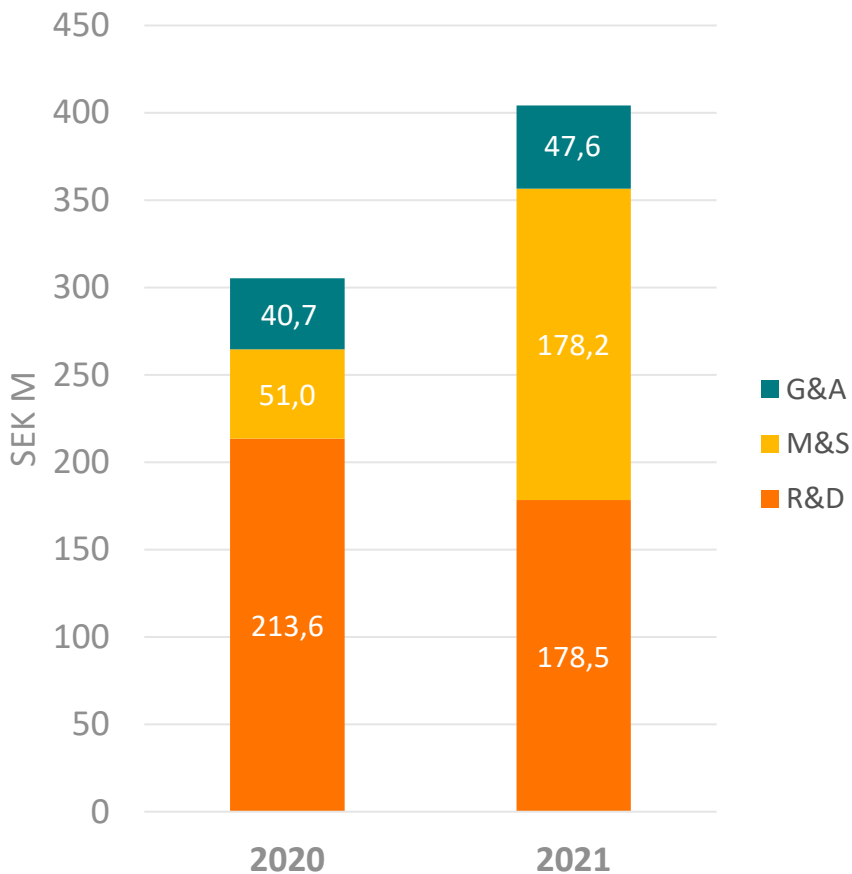


FINANCIAL UPDATE

Quarterly Results, Milestones and
News Flow – Anders Martin-Löf, CFO

Financial Results for January – March 2021

Operating Costs Jan-Mar



- Revenues amounted to SEK 19.4 M (-)
 - Two weeks of sales in the quarter
 - Gross margin of 98%, slightly elevated due to sales of drug batch recognized as cost pre submission acceptance
- 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
 - OCEAN SEK 49 M (78)
 - Number of co-workers increased to 294 (121) as of March 31
 - 138 (18) in US subsidiary
- 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 proforma 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
	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

New reporting dates 2021

- Interim report Q2 August 19
- Interim report Q3 November 4

Addressing a growing unmet medical need

Pepaxto®
(melphalan flufenamide)
injection for intravenous use 20 mg/vial





bringing hope through science