

Updated OCEAN Results and Partial Clinical Development Hold

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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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Updated OCEAN result and partial clinical hold

Key Takeaways



- **OCEAN result**

- IRC reassessment **met superiority on primary endpoint** of progression free survival across the ITT population
- **Mixed overall survival results**
- **IMWG Meeting** (September) targeted for full data disclosure

- **Clinical development**

- All trials are now placed on partial clinical hold

- **PEPAXTO commercialization**

- Continued marketing based on **HORIZON label**

Label expansion opportunity with phase 3 OCEAN Study

Confirmatory global study in 100+ sites in 21 countries



Head-to-head study versus pomalidomide

Patients have failed 2-4 lines prior therapy, including refractory to lenalidomide within 18 months or have progressed on lenalidomide within 60 days of randomization

N = 495
Lenalidomide-refractory multiple myeloma patients

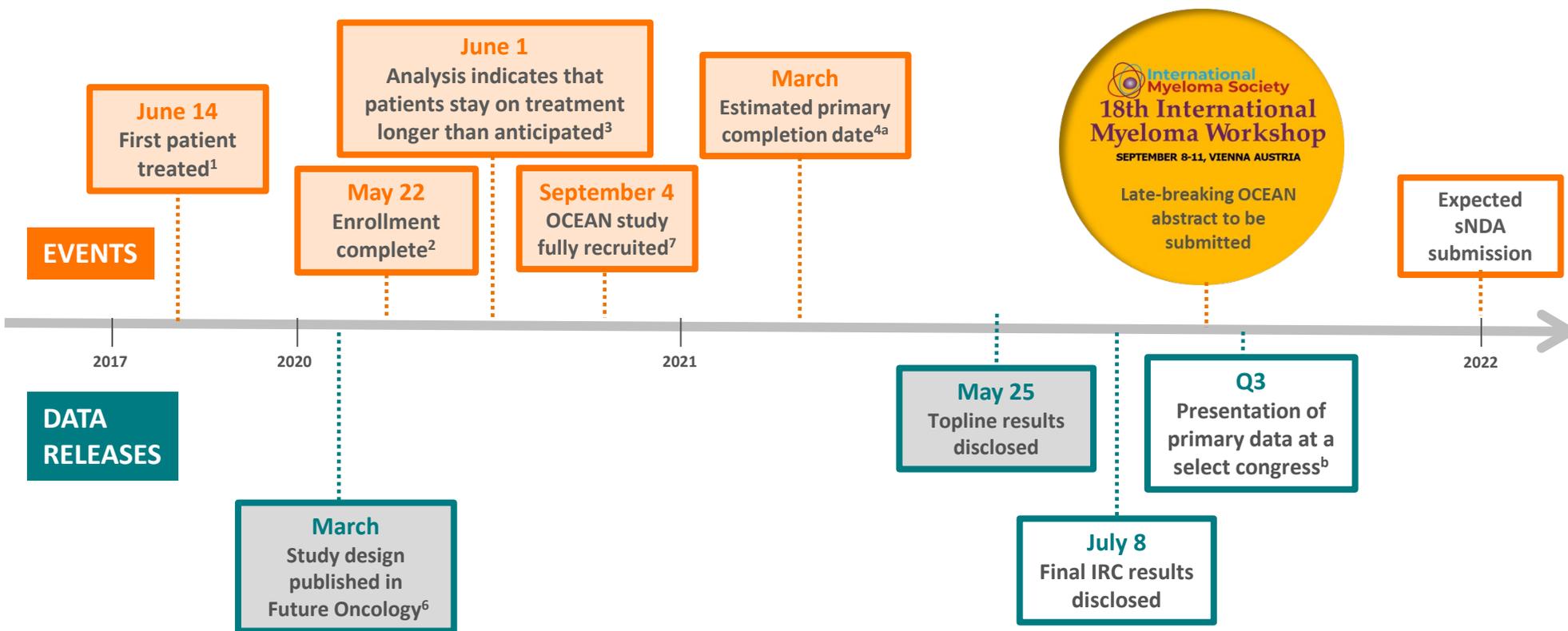
Melflufen +
dexamethasone

Pomalidomide +
dexamethasone

Primary
endpoint:
PFS

Secondary
endpoint:
ORR, OS

OCEAN Study – detailed timeline and upcoming events



^aEvent-driven; ^bCurrent assumption and plan.

1. Oncopeptides [Press Release](#). June 14, 2017; 2. Oncopeptides [Press Release](#). May 22, 2020; 3. Oncopeptides [Press Release](#). June 01, 2020; 4. ClinicalTrials.gov Identifier: [NCT03151811](#); 5. Sonneveld P, et al. [Poster Presentation P-036] Lymphoma & Myeloma Congress 2019; 6. Schjesvold F, et al. *Future Oncol.* 2020;16:631–641. 7. Oncopeptides [Press Release](#). Sep 4, 2020

The path to a final IRC result on OCEAN



- Topline result communicated on May 25
- A finding that all available data in the clinical trial database had not been provided to the IRC at the time of assessment
- Review conducted by CRO across all 495 patients which determined that 29 patients needed reassessment
- IRC performed a blinded reassessment of the 29 patients

NOTE: There has been continuous and ongoing dialogue with the FDA through this process.

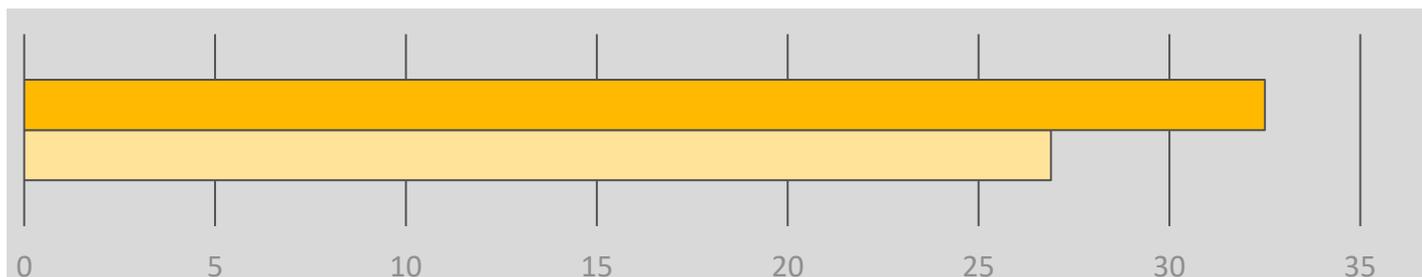
OCEAN data – final IRC ITT results



- Primary endpoint – Progression Free Survival (PFS)

	Hazard Ratio (95% CI)	P-Value	Relative mPFS improvement	Outcome
Independent Review Committee (IRC)	0.792 (0.640-0.979)	0.0311	+39%	Superiority

- Overall Response Rate 32.5% for melflufen vs 26.9% for pomalidomide



OCEAN Data – overall survival data



- OCEAN is the first head-to-head comparison of two different treatment modalities in MM
- Striking efficacy differences were seen across different patient populations
- Overall Survival Hazard Ratio was 1.104 in favor of pomalidomide for the ITT population
- Large differences in pre-specified subgroups are currently undergoing investigation in collaboration with the FDA

Clinical development program put on partial clinical hold

- This decision immediately impacts all clinical studies including the following:
 - LIGHTHOUSE study
 - ANCHOR Study
 - PORT Study
 - BRIDGE Study
 - ASCENT Study
 - COAST Study (OPD5)
- No new patients will be enrolled during the partial clinical hold effective immediately
- Patients already enrolled in the studies may continue their treatment (subject to re-consent and assessment by the investigator)

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