oncopeptides

Nomenclature

International non-proprietary name (INN)
Melphalan flufenamide

Chemical name
4-[Bis-(2-chloroethyl)amino]-L-Phenylalanine-4-fluoro-L-phenylalanine ethyl ester hydrochloride

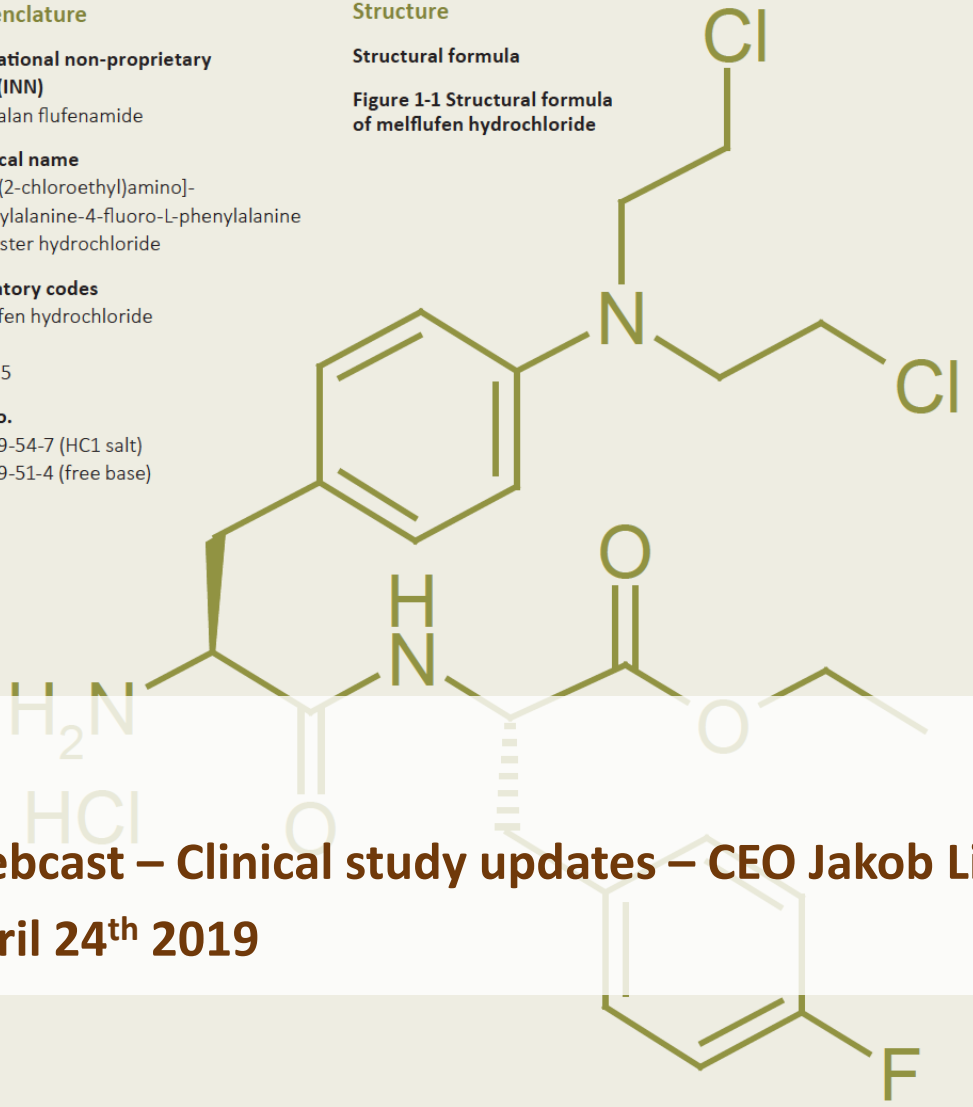
Laboratory codes
Melflufen hydrochloride
J1
CK 1535

CAS No.
380449-54-7 (HC1 salt)
380449-51-4 (free base)

Structure

Structural formula

Figure 1-1 Structural formula of melflufen hydrochloride

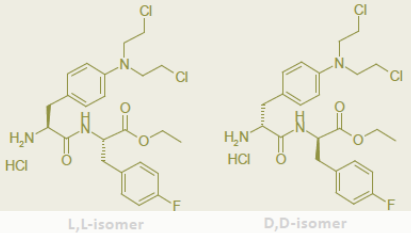


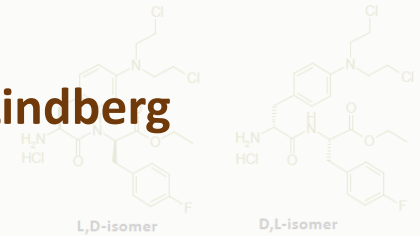
Molecular formula
C24 CH31C13FN3O3 (HC1 salt)

Molecular weight
534.9 (HC1 Salt)

Stereochemistry
Melflufen hydrochloride contains two stereogenic centers giving rise to four possible stereoisomers. Melflufen hydrochloride drug substance is the L,L-isomer. The structures are outlined in Figure 1-2.

Figure 1-2 Structure of melflufen hydrochloride isomer





General properties

Appearance
White to slightly yellowish powder

Solubility
Melflufen hydrochloride is soluble in most organic solvents. The solubility in water and buffers is limited.

Partition coefficient
ClogP = 4.04 (tecken) 0.66, calculated using ACD logP DB, v.6.0 (from Advanced Chemistry Development)

Dissociation constant
pKa 10.0 (determined in ethanol solution)

Optical rotation
[α]D 5.2° (c 1.9, CH3OH) at 20°C

Thermal behaviour
Differential scanning calorimetry (DSC) was performed using a Mettler Toledo DSC 822 instrument and a scanning rate of 2(tecken)C/minute. The melting temperature was measured using batch GF404528 and determined from the DSC thermogram to be 205.4°C, as shown in Figure 1-3.

Webcast – Clinical study updates – CEO Jakob Lindberg

April 24th 2019

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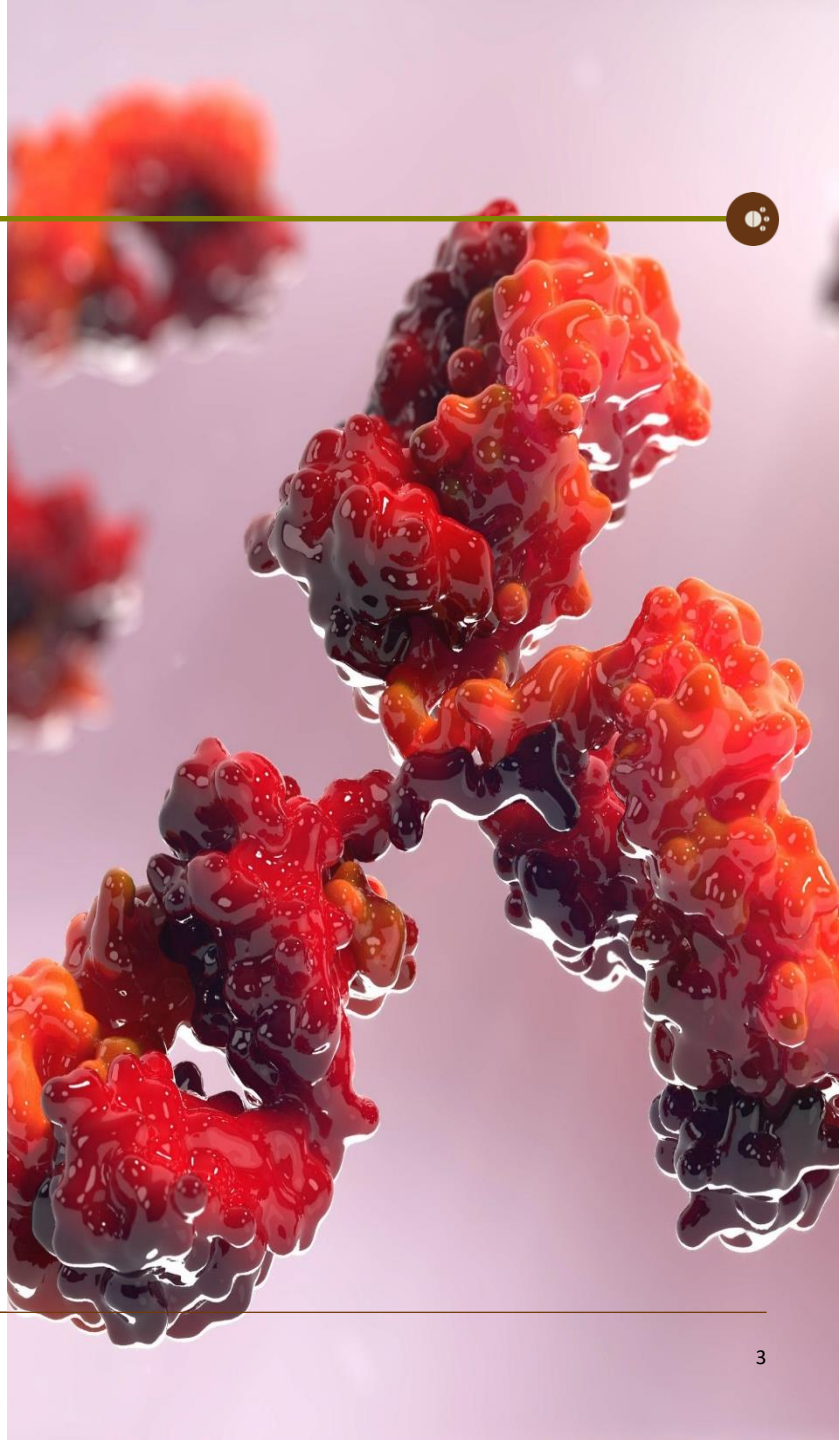
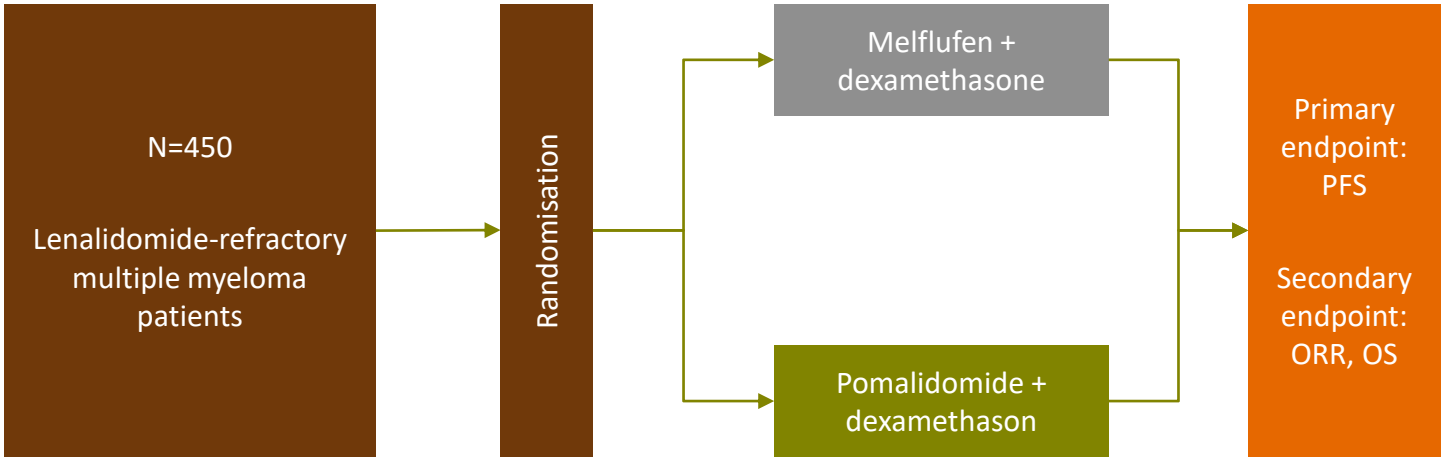
Oncopeptides at a glance

- **Develops targeted cancer treatments**
  - Proprietary peptidase-enhanced compounds
  - Lead compound Melflufen a peptide conjugated alkylator
- **Initial focus on Multiple Myeloma**
  - Significant market opportunity in orphan indication
  - Melflufen Phase 2 showed the best MM survival data to date
- **Phase 3 expected to be fully enrolled in Q1 2020**
  - Approximately 450 patients at 140 sites
  - Three additional supporting trials ongoing, additional Phase 3 to be started 2019
- **Listed on NASDAQ Stockholm, strong financial position**
  - Market cap: ~$700 M
  - Cash position Dec. 31, 2018: $40 M, raised an additional $55 M in January
- **New indications and NCEs in development**
  - Clinical trials expected to start in 2019



Data to date provides high conviction for success in pivotal trial OCEAN



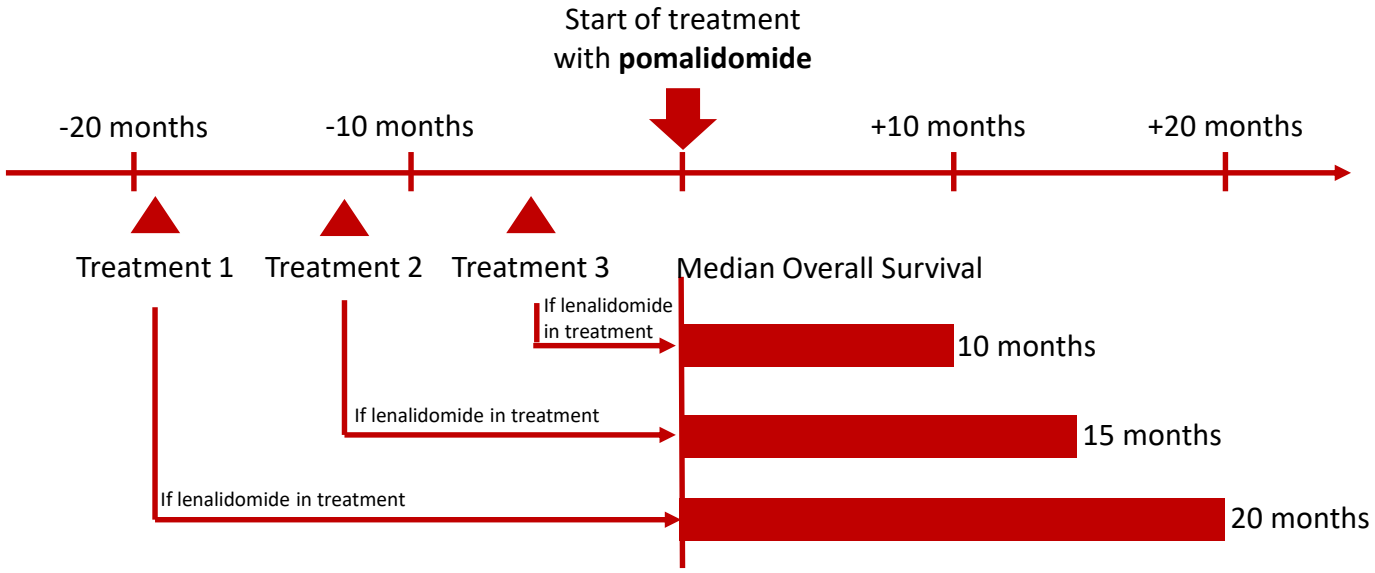
RRMM data from pomalidomide FDA label and O-12-M1 study

Treatment	ORR	CBR	Median PFS	Median DOR	Median OS
Melflufen + Dexamethasone	31%	49%	5.7 months	8.8 months	20.7 months
Pomalidomide + Dexamethasone	24%	NR	3.6 months	7.0 months	12.4 months

Pomalidomide shares resistance mechanism with lenalidomide

No assumption has been made in OCEAN power calculation about this factor

Dimopoulos research supporting an IMiD free period

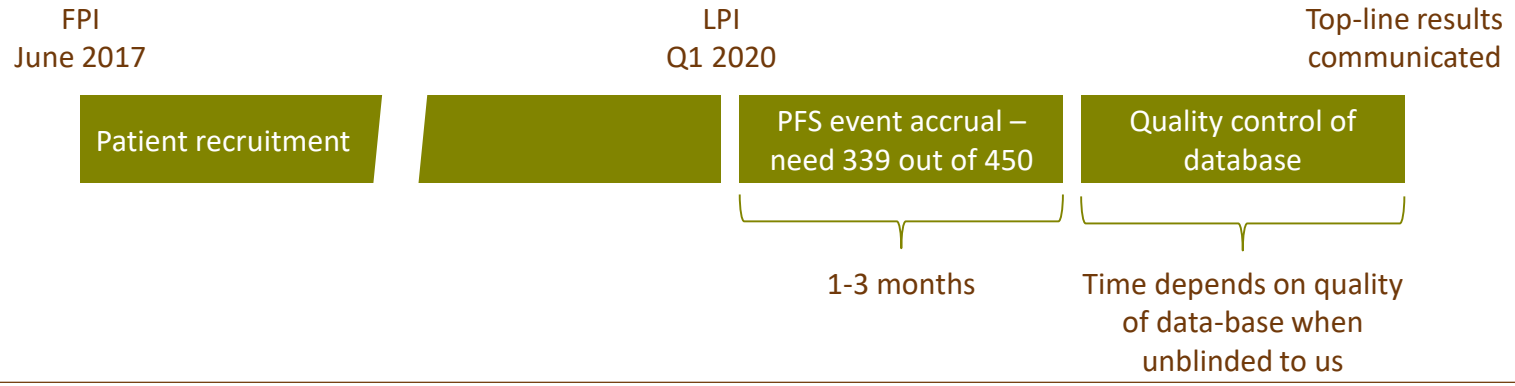


50% reduction in efficacy if patient recently failed on lenalidomide - suggests significant resistance overlap between lenalidomide and pomalidomide

Source: Pomalidomide with Low Dose Dexamethasone Is Effective Irrespective of Primary or Secondary Resistance to Lenalidomide but the IMiD-Free Interval Is Important (Dimopoulos et. al. ASH poster 2016).

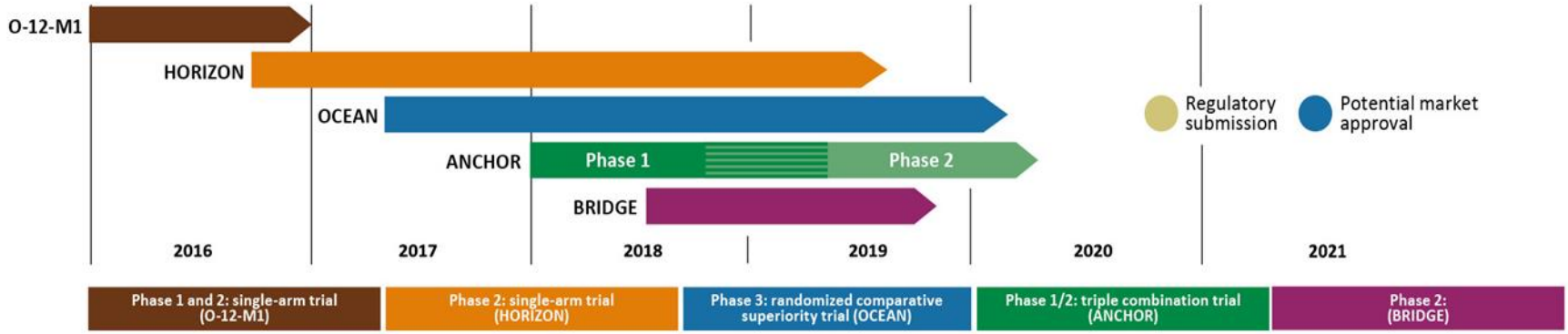
OCEAN recruitment update – new timelines

- Last patient in (LPI) estimated for Q1 2020 (6-9 months delay) – complete study going from roughly 24 months (first to last patient) to roughly 30 months
- The growing use of pomalidomide as a 2nd line treatment option is a strong positive for the value of OCEAN but at the same time a patient recruitment challenge
- Roughly 50% more hospitals have and still are being been added to the study
- High degree of variability between recruitment months with the added complexity of a growing number of hospitals meant it took time to create a new forecast
- Process and time-line from last patient in to top-line results:



Overview of our clinical development program in multiple myeloma

New timelines as of 24th of April



O-12-M1
Show single-agent activity in RRMM

HORIZON
Show single-agent activity in RRMM

OCEAN
Show single-agent superiority over SoC backbone in RRMM (pomalidomide)

ANCHOR
Show combination synergy and tolerability with daratumumab and bortezomib

BRIDGE
Show that melflufen can be used in patients with renal impairment

Upcoming discussion with the FDA with regard to HORIZON data before summer

- HORIZON is a study in myeloma patients with no or limited treatment options
- Potential for accelerated approval path in the USA – but not certain
- ODAC meeting regarding selinexor (a competitor) on February 26th confirmed the target population and efficacy hurdle in late-stage myeloma (i.e. triple-class refractory myeloma patients)
- FDA meeting has been scheduled before the summer regarding the HORIZON data and will guide Oncopeptides for the possibility to apply for accelerated approval

Competitive landscape in multiple myeloma

Less competition than what meets the eye

Approved

In development

IMiDs	Thalidomide	Lenalidomide	Pomnalidomide	Cellmods
PIs	Bortezomib	Carfilzomib	Ixazomib	New ones?
Anti-CD38	Daratumumab	Sub-cut. dara	Isatuximab	
Anti-BCL2	Venetoclax			
Anti-BCMA	bb2121(7)	GSK916	AMG420	Legend/J&J CAR-T
Nuclear Pore inh.	Selinexor			
Check-point inh.	Nivolumab	Pembrolizumab		

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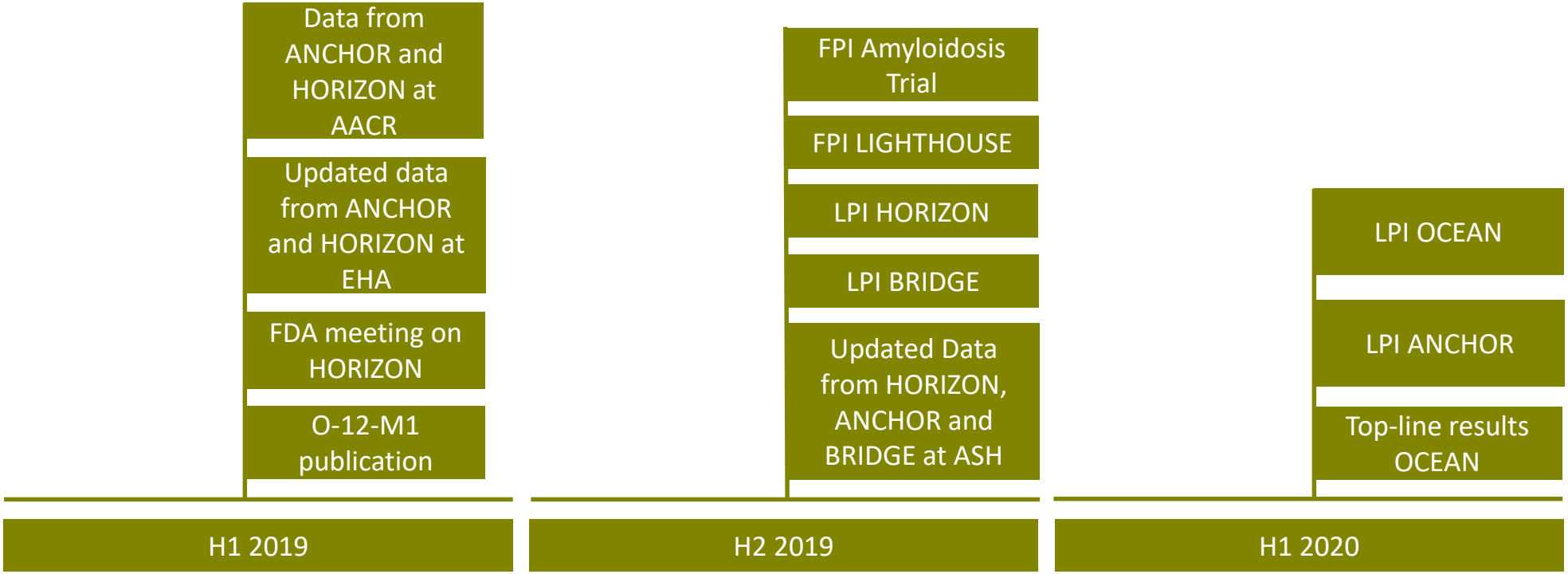
Upcoming newsflow – highly exciting year ahead of us



In Summary

- Last-patient-in in OCEAN delayed by 6-9 months compared to plan
  - Main reason being that pomalidomide is used in earlier lines of therapy which is positive in terms of the value of OCEAN but a challenge for patient recruitment
- All other studies on plan or above plan in terms of patient recruitment
- Recent developments in the competetive landscape strongly postitive for melflufen

Q/A

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IR, Oncopeptides