



Final data from the pivotal HORIZON trial

Stockholm, March 26th 2020
Jakob Lindberg, CEO



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Editorial in Lancet Haematology regarding melflufen

Is there a role for new drugs with alkylating properties in multiple myeloma?



Multiple myeloma, a complex disease originating in plasma cells, was primarily treated with melphalan until the last years of the 20th century. Advances in knowledge of the biology of the disease have led to the introduction of new drugs, and its transition of new drugs from the relapse setting to first-line treatment has been fast and as a result, most patients with multiple myeloma will receive proteasome inhibitors

intravenously every 4 weeks in combination with weekly dexamethasone can lead to clinical improvement (overall response rate was 31% [14 of 45 patients; 95% CI 18–47]; median progression-free survival was 5.7 months [95% CI 3.7–9.2]; and overall survival was 20.7 months [11.8 to not reached]). The most common toxicities were haematological toxicity and grade 3–4 thrombocytopenia and neutropenia

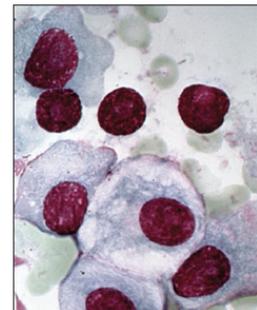
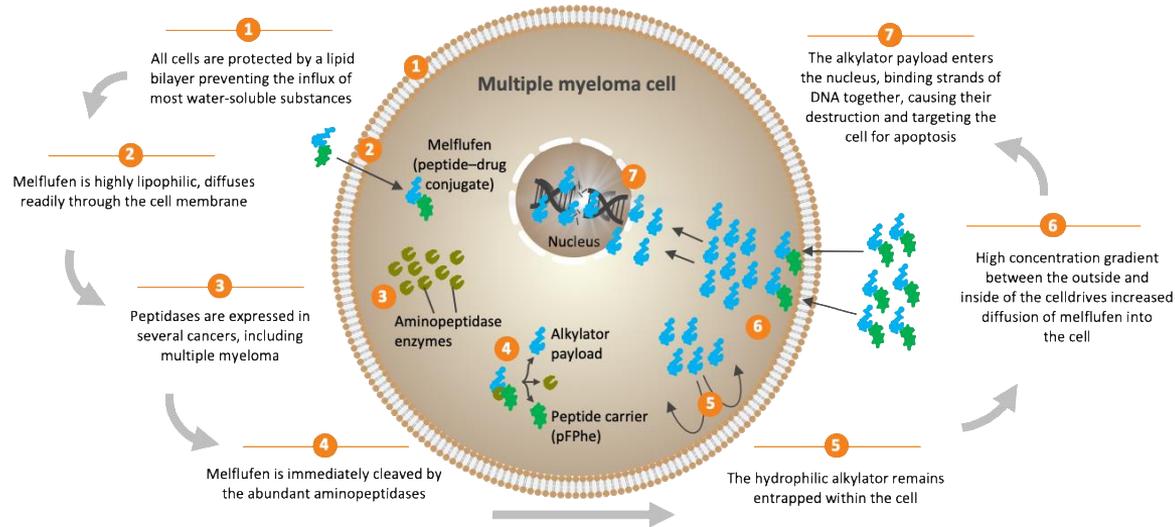


Photo Library

Melflufen is a first in class peptide-drug conjugate (PDC)

– Uses high peptidase levels to target myeloma cells



- Melflufen is a first-in-class anti-cancer peptide-drug conjugate with an alkylating payload
- Unique enzymatic motifs for tumor targeting

Overview of the HORIZON clinical study

- Single-arm clinical study investigating melflufen administered every 28 days with weekly dexamethasone in relapsed refractory multiple myeloma (RRMM) patients
- Patients had to have exhausted all or most available treatment options
- A total of 157 patients were enrolled in the study
- The patient population includes the largest clinical trial population of multiple myeloma patients with extramedullary disease (EMD) to date
- RRMM patients that are triple-class refractory and/or have EMD represent the two largest unmet medical needs in myeloma per today
- Secondary end-points and safety results will be published in a peer-reviewed journal

Final HORIZON data in triple-class refractory RRMM

Independent Review Committee (IRC) data

Primary End-Point	Investigator Ass. Data Jan 14 th	IRC Data Jan14 th	Incl. unconfirmed Responses Jan 14 th
Overall Response Rate (ORR) – ITT n=157	29%	30%	31% (inv. and IRC)
ORR – 3x RRMM n=119	26%	26%	27% (inv. and IRC)
ORR – EMD n=55	24%	27%	NA

Note: Two unconfirmed responses on January 14th have later been confirmed.

Safety profile similar to the profile reported at ASH 2019, i.e. haematological toxicities were common but manageable – non-haematological toxicities were infrequent

Final data from the HORIZON study. Data in triple-class refractory patients.

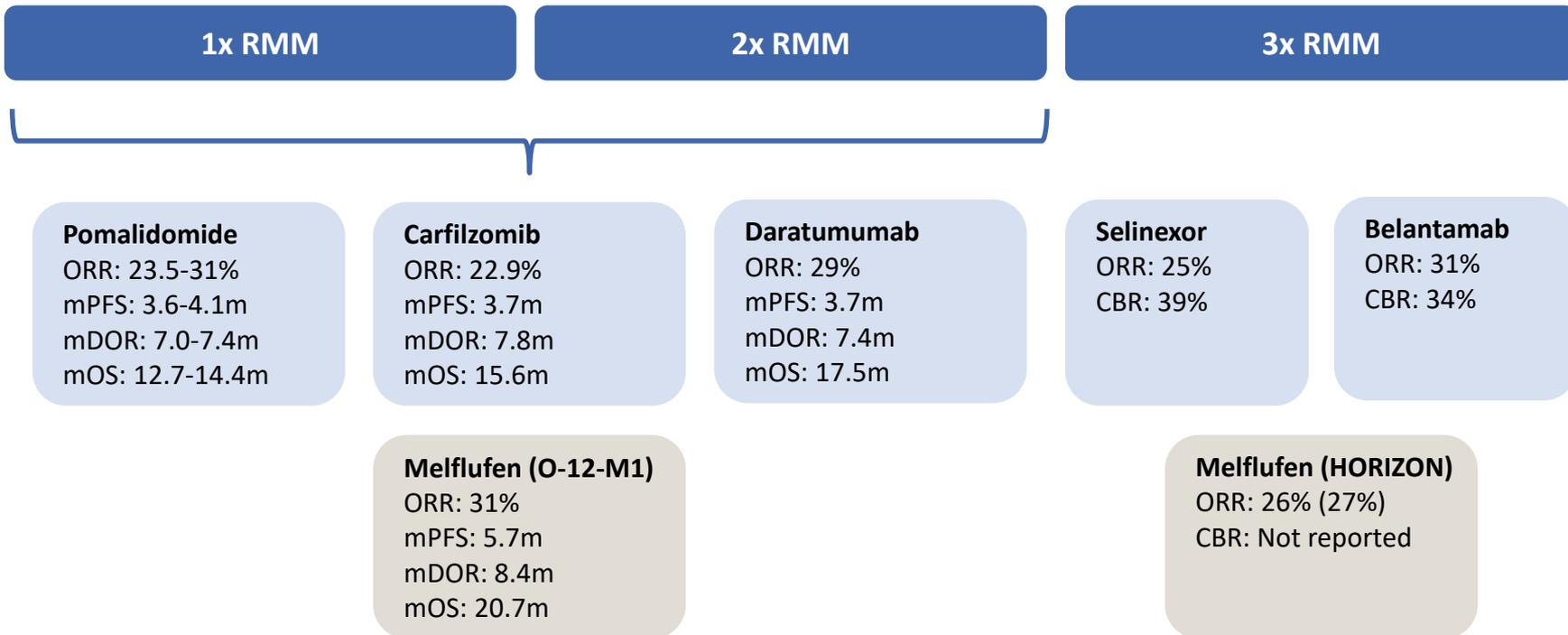
Melfufen is not currently approved in any indication and any potential label is subject to FDA review.

Positive HORIZON read: Submission and US commercialization of melflufen on track – key focus 2020

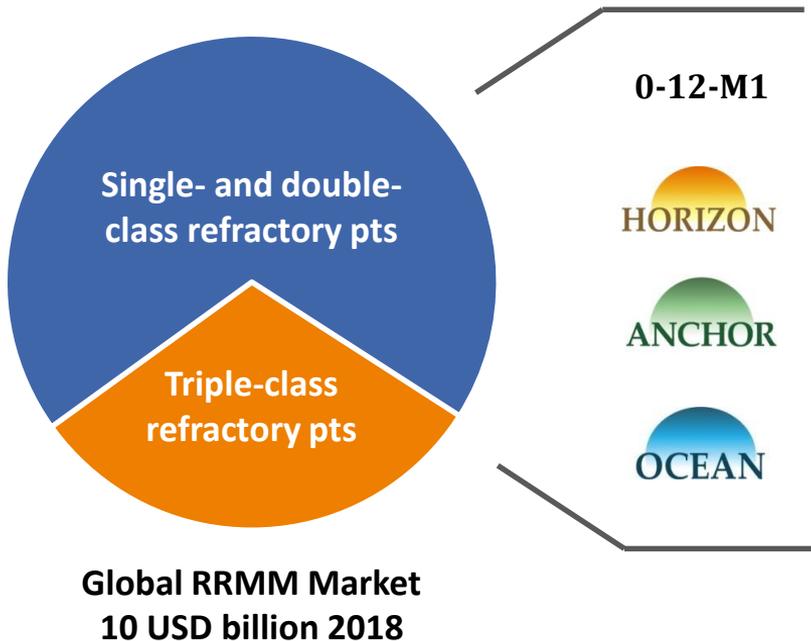
- Submission is on track for end of Q2 2020
- Early Access Program in the US to be launched as soon as feasible in RRMM patients
Patient population without treatment options but COVID-19 makes environment challenging
- US Commercialization build-up
The commercial organization will be built up sensibly as we get clarity on FDA timelines and financial market conditions in light of COVID-19 pandemic

Melflufen has shown excellent efficacy and tolerability in RRMM

Single-agent +/- steroid – cross-study comparison

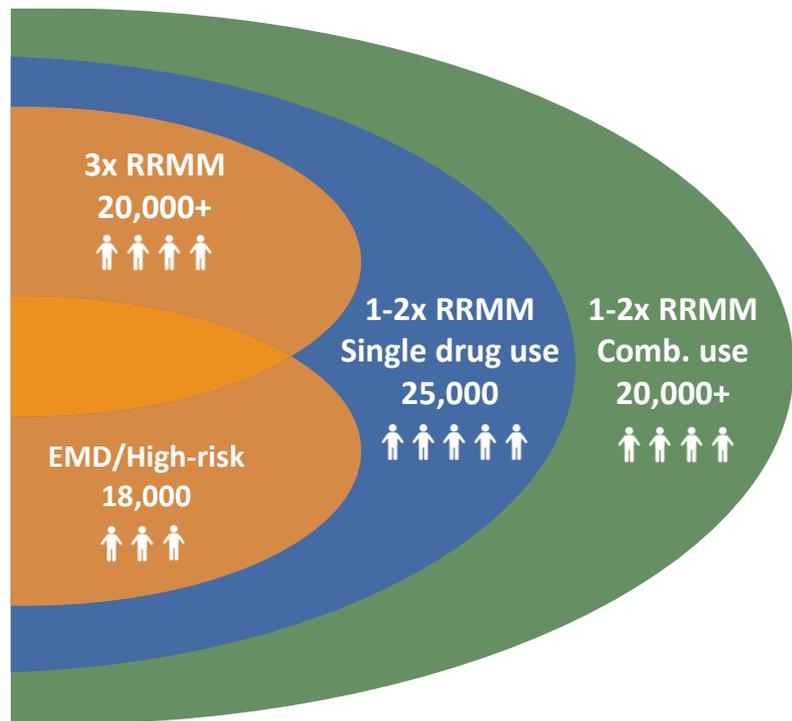


Melflufen has shown excellent efficacy and tolerability in over 250 RRMM patients



- In comparison with other compounds in RRMM, once monthly melflufen has shown the strongest data as single-agent +/- steroid in O-12-M1 and HORIZON
- Top-line data from OCEAN estimated end of Q3 2020
- Activity for once monthly melflufen in combination regimens (ANCHOR) highly encouraging
- After reporting OCEAN the reported clinical data with melflufen will include more than 700 myeloma patients

The market opportunity is significant for melflufen's planned label journey in RRMM (US patient numbers)



Clinical Program



Anticipated label in triple class refractory patients.



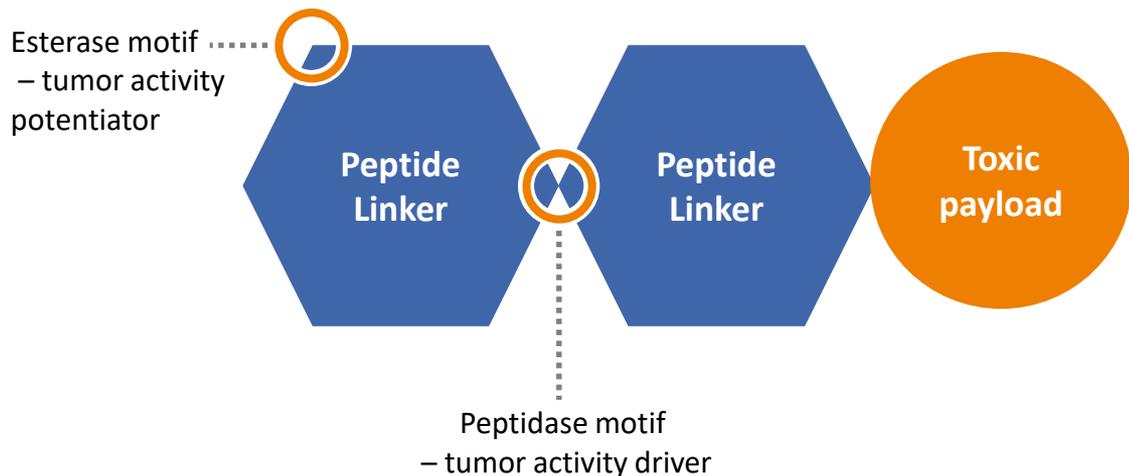
Head to head superiority study with the most commonly used regimen in RRMM. Majority of RRMM patients use single agent +/- steroid.



Combination with PI or anti-CD38 opens up 2L+ combination treatment opportunity.

Source: Patient numbers based on IntrinsicQ analysis.
Melflufen is not currently approved in any indication and any potential label is subject to FDA review.

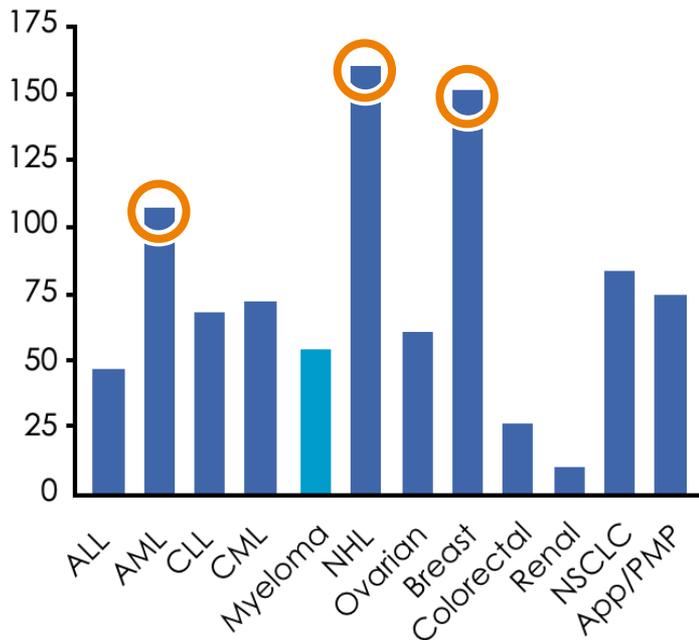
Positive pivotal HORIZON trial reading validates unique Peptide-Drug Conjugate (PDC) platform



- Targetted delivery of toxins to tumor cells
- Utilizing unique enzymatic motifs
 - Peptidase motif necessary
 - Esterase motif potentiating

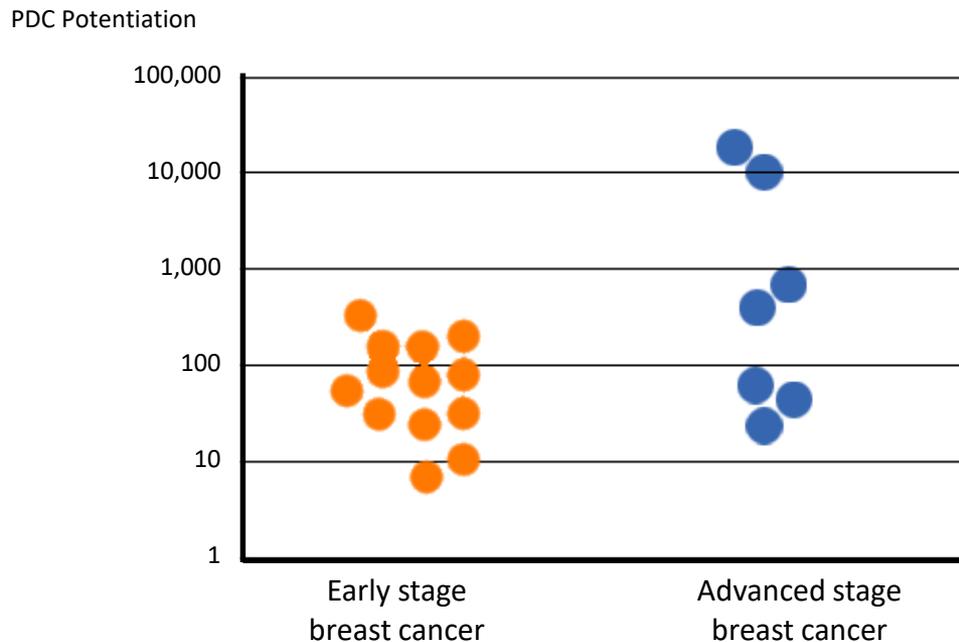
PDC platform exhibits significant therapeutic activity across several cancers

PDC Potentiation



- The PDC platform show good activity across a majority of cancers (data to the left on patient material)
- Based on the PDC platform, Oncopeptides have (and will) develop a portfolio of novel molecules
- Our initial focus will be in patients suffering from AML, NHL and breast cancer

The single strongest activity is seen in high-risk and advanced stage breast cancer



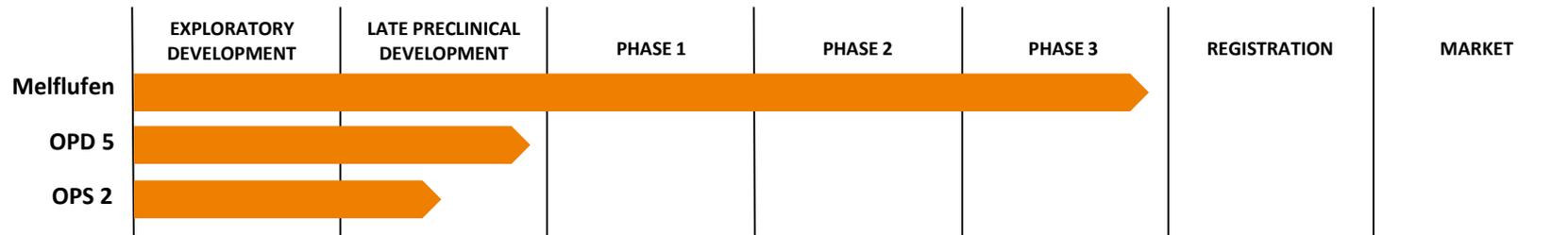
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Indication broadening with the PDC platform will focus on AML, NHL and breast cancer (US data)

Indication	Triple Negative Breast Cancer	DLBCL	AML
Incidence (US)	28K (10% of breast cancer pts)	22K-29K pts (30%-40% of NHL pts)	21K
5-year survival	around 75%	30%-90% Based on cytogenetics	around 25%-30%
Standard of care	Surgery, RT, chemotherapy, PARP inhibitors, PD-(L)1 inhibitors	Relapsed: bendamustine, lenalidomide, platinum combos	Relapsed: novel therapies such as venetoclax
Initial development focus - PDC platform	Improvement of efficacy in late stages and improved toxicity profiles	Efficacy in high risk DLBCL subpopulations	Improvement of survival rates
Market opportunity - development focus (US)	~10K patients	~ 7.5-10K patients	~10-15K patients

Melfufen is not currently approved in any indication and any potential label is subject to FDA review.

Two more PDC candidates ready for the clinic in 2020 and 2021

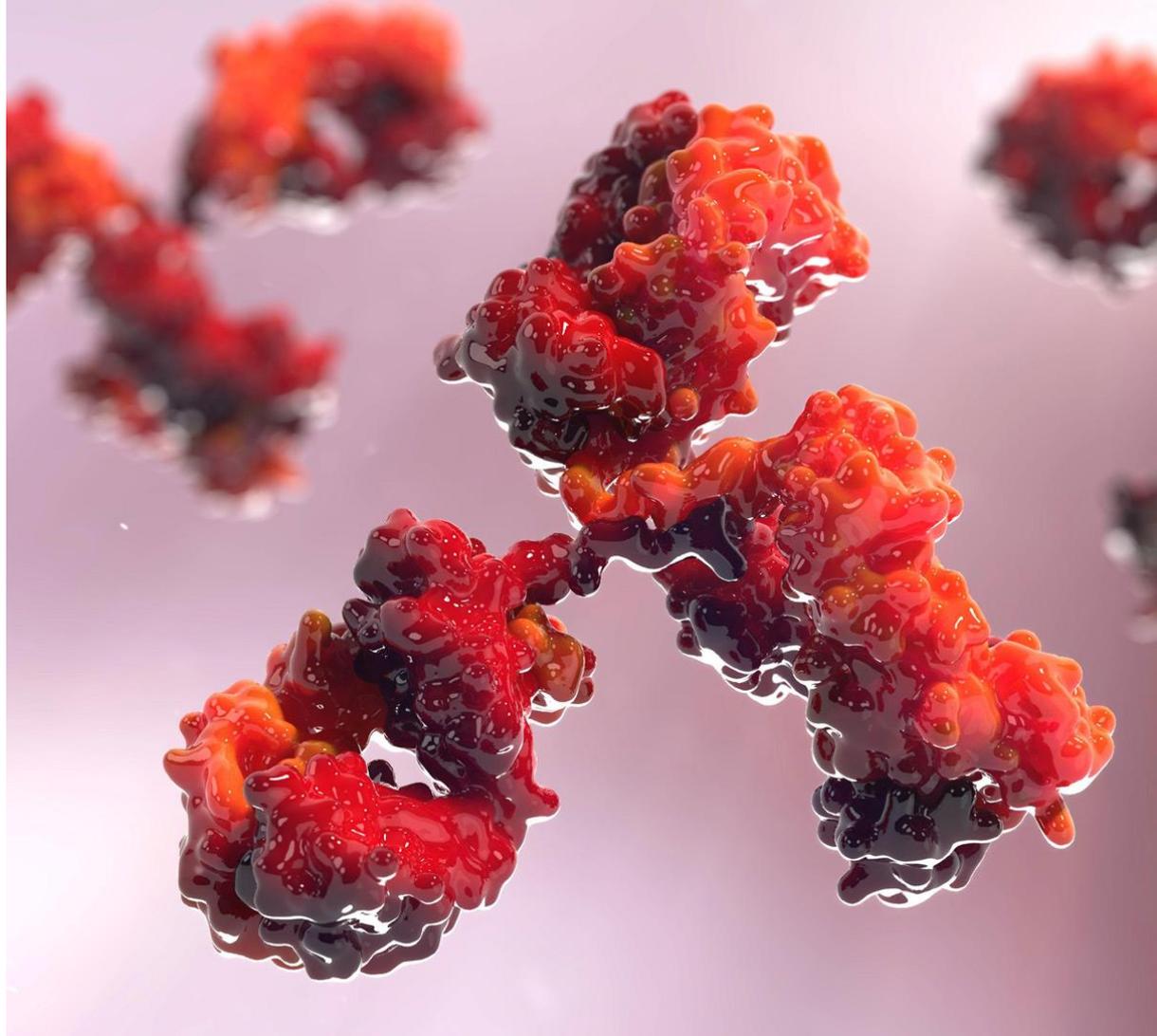


- OPD5 and OPS2 will be ready for the clinic in 2020 and 2021 respectively
 - OPD5 – specialized alkylating PDC candidate for high-dose treatment of patients (i.e. bone-marrow transplantation)
 - OPS2 – second generation PDC compound with an alkylating payload
- Both are novel molecules with composition of matter patents
- Full optionality to fully explore the PDC platform in 2021 and beyond
- All new clinical programs need to be viewed through the lens of the current COVID-19 environment

Great news under exceptional circumstances

- Positive pivotal read-out from HORIZON with ITT ORR of 30%, an ORR of 26% in triple-class refractory RRMM patients and an ORR of 27% in EMD RRMM patients
- Submission to the FDA on track for end of Q2 2020 submission
 - Unclear impact – if any – on FDA review time-lines due to COVID-19
- HORIZON read-out validates our PDC platform with two new development candidates ready for clinical development in 2020 and 2021 – OPD5 and OPS2
 - Initial development focus outside of RRMM in triple-negative breast cancer, DLBCL and AML
- All new activities will be considered against the ongoing COVID-19 pandemic and the implications in the financial markets
 - Commercialisation ramp-up (sales-reps, promotion etc) will be gated related to the clarity on FDA time-lines and financial environment
 - Clinical trials outside of HORIZON and OCEAN are paused or not initiated as previously communicated

Q&A



***Thank you for
your attention!***

