

Unlocking the potential of novel targets for cancer and rare diseases

March 2022

Mereo BioPharma Group plc NASDAQ: MREO

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Mereo – A Rare Disease and Oncology Company

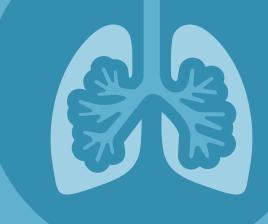


A Diversified Mid-Late Stage Pipeline

Core Programs Product candidate / indication Phase 1b Phase 2 Phase 3 **Next Milestone** Phase 1a **Etigilimab** Phase 1b/2 full enrolment and data Phase 2 cohort Solid tumors expansion **COPD/CF/Bronchiectasis** AATD **Alvelestat** Alpha-1 antitrypsin deficiency AATD: Phase 2 PoC data **BOS**** - Phase II initiated BOS: Phase 2 data COVID-19 **COVID-19**** BOS* ultragenyx Initiation of pediatric pivotal study (5-25 yrs) **Setrusumab** Osteogenesis imperfecta Initiation of pediatric ultragenyx phase 2 study (<5 yrs) With partnering opportunities on non-core programs **Financing Milestones** Acumapimod Separate funding/partner Acute exacerbations of COPD Leflutrozole Partner **HH** Infertility **OncXerma** Navicixizumab ~ \$300M milestones + **Ovarian Cancer** Key Completed Onaoina royalties 3

*BOS: Bronchiolitis obliterans; ** Investigator initiated studies in collaboration with University of Alabama in Birmingham & National Cancer Institute





Etigilimab (MPH-313)



The role of TIGIT in Immune Cell responses

TIGIT* is a Negative Regulator of T cell Responses

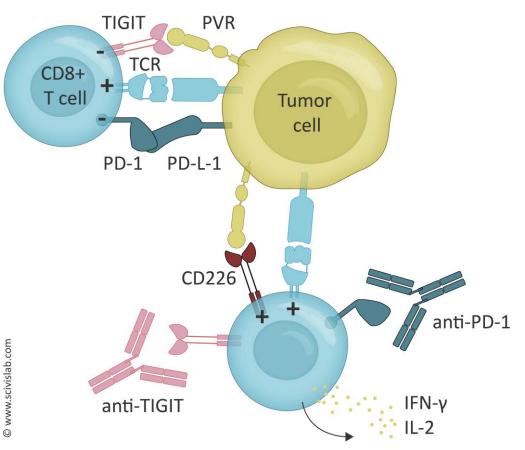
	Negative regulator of T-cell response
What is TIGIT?	 Competes with CD226 for PVR, and disrupts CD226 activation

Where is TIGIT	 Highly expressed on regulatory T cells (tregs), exhausted T-cells
Expressed?	 Also expressed on CD4, CD8 and NK cells

Inhibit TIGIT and PVR axis inhibiting T-cell inactivation Co-blockade of anti-TIGIT and anti-PD1 elicits

 Co-blockade of anti-TIGIT and anti-PD1 elicits anti-tumor activity

Blocking TIGIT in cancer





Etigilimab – Early but promising initial Phase 1b/2 data

Efficacy

- In Phase 1a monotherapy seven subjects (30%, n=23) with stable disease
 - Majority heavily pre-treated with prior check-point inhibitors and chemotherapy
- In Phase 1b combination with nivolumab– one partial response* and one stable disease (n=10)
- Some patients remaining on treatment for >200 days

Safety

- No DLTs observed; generally well-tolerated
- Adverse events consistent with immunerelated adverse events.
- Favorable PK profile and no evidence of anti-drug antibodies

Biomarker data

- Target engagement demonstrated in Phase 1a
 - Activation of T-cell and NK cell subpopulations
 - Reduced Tregs in circulation, with corresponding increase in CD8/Treg ratio

*Partial response in an ovarian patient



Guiding Principles for Differentiated Clinical Development of Etigilimab

Leverage TIGIT Biology: *Expression of TIGIT/PVR*

CPI-naïve Populations *Higher PoS for IO combination*

Low ORR with CPIs Demonstrate benefit of adding TIGIT

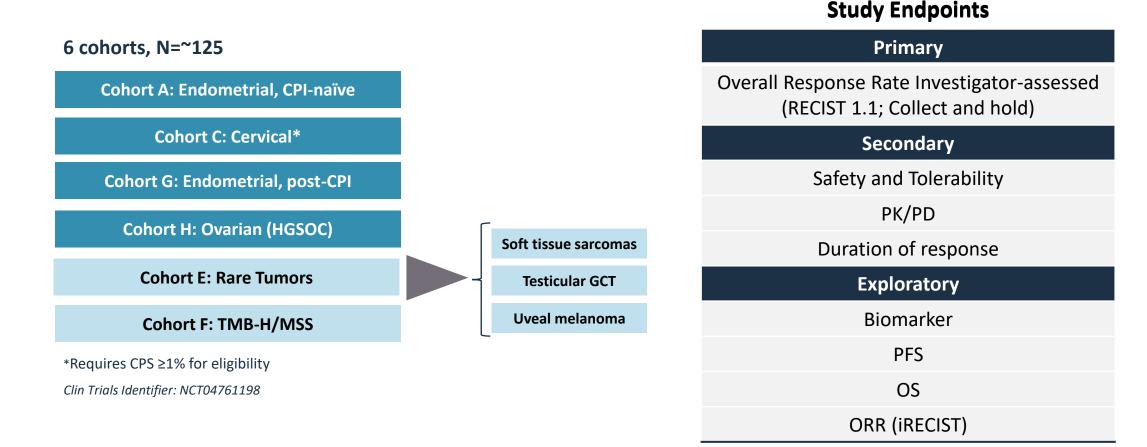
Clinical data from Phase 1a/b Potential signal in gynonc

> High Unmet Need Rare cancers

ACTIVATE



ACTIVATE Phase 1b/2 Study Design: Multiple Parallel Cohorts Evaluating Etigilimab + Nivolumab in Select Recurrent Advanced/Metastatic Solid Tumors



Statistical rigor provided by Simon Two-Stage design with futility monitoring for progression to stage two. Open label allows for dynamic decision making

Tumor responses at baseline, every 8 wk for the first 48 wk, and every 12 wk thereafter



ACTIVATE Trial: Preliminary Efficacy Investigator RECIST 1.1 assessment per timepoint*

Objective	Cohort							
Responses by RECIST	A EC (CPI- naïve) N=0	B H&N N=1	C Cervical N=1	E TMB- H/MSS N=4†	F Uveal- 6 Sarcoma-5 GCT-1 N=12 ⁺	G EC (Post- CPI) N=0	H Ovarian N=4	Total evaluable n=20 ¹ Efficacy analysis ² n=15
CR			1					1
PR							1	1
SD				1	2		1	4
PD		1		2	9		2	14
ORR (CR+PR)								13.3%
DCR (CR+PR+SD)								40.0%

¹Evaluable population data reflect a minimum of first scan at 8 weeks for all patients of the safety analysis set, data cut off date 11/18/2021 ²Efficacy analysis set excludes: 5 sarcoma subjects –non-prioritized histology enrolled early in trial



Preliminary Efficacy by Subject: Key Biomarker Correlations*

Benefit in PD-L1 negative/PVR positive patients

Subject ID	Cohort/Tumor	PD-L1 status	Other pertinent biomarkers	Response and Study Status
102-101-C001	Cervical cancer	Positive	PVR – N/A	cCR, Off study [^]
102-101-E025†	TMB-H/MSS Cervical cancer	Positive	PVR+	uSD Completed cycle 7
102-107-H024	Ovarian cancer	Negative	PVR+	uPR Completed cycle 8
102-107-H029	Ovarian cancer	Negative	PVR+	uSD Completed cycle 5
102-101-F020	Uveal melanoma	Negative	PVR+	uSD Completed cycle 8
102-101-F030	Uveal melanoma	Negative	PVR – N/A	uSD Completed cycle 5

*Statistical outputs for IDMC, Data cutoff date – 10/15/2021, unclean data from soft lock of database on 11/18/2001, RAVE database, PI communications ^ Subject withdrew consent, but CR was sustained at time of withdrawal

n/a (not available): C001 FFPE tumor not evaluable; F030 tumor not available at time of analysis

+ Subject 102-101-E025 is a TMB-high cervical patient





ACTIVATE Trial: Interim Biomarker Analysis

Tumor	#	Response	PDL1	PVR	TIGIT
Cervical	C001	CR	positive	n/a	n/a
TMB-H/MSS Cervical	E025	SD	positive	90%	positive
Ovarian	H024	PR	negative	65%	positive
	H029	SD	negative	55%	positive
Uveal	F020	SD	negative	70%	negative
	F030	SD	n/a	n/a	n/a
/a (not available): C001 FFPE tu	umor not evaluable; F030 tumor	not available at time of analysis	>1% PDL1 CF	PS ≥2+ on tumor cells	>1% CPS

 PVR
 FFPE Tissue
 SD
 PR
 CB

 High
 9
 3
 1
 4(44%)

 Low
 7
 0
 0
 0

High= 4 ovarian, 1 sarcoma, 2 uveal, 1 colon, 1 cervical; Low= 1 medialstinal germ cell, 3 sarcoma, 2 uveal melanoma, 1 HNSCC High: >50% at 2+ or greater



Summary of AEs (Safety Analysis Set - n=22)*

- AEs related to study treatment occurred in 10 subjects mostly low grades
 - There were 18 events related to study treatment
 - Most were related to both etigilimab and nivolumab
- The most common treatment-related AEs were due to skin reactions 7 events
- None of them required treatment with systemic steroids
- There was only one Grade 3 treatment-related AE requiring prolonged treatment (immune-related diabetes mellitus)

	n (%)
Any TEAEs	62
Grade >/=3 TEAEs	1 (1.6)
All Related AEs	18 (29.0)
Grade >/= 3 Related AEs	1** (5.5)
Related SAEs	0
Related discontinuations	0
Related deaths	0



٠

**Diabetes mellitus

Etigilimab - Anti-TIGIT Antibody With Differentiated Development Path

Etigilimab - IgG1 antibody	ACTIVATE 1b/2 data	Biomarker Strategy	
 IgG1 backbone activates antibody-dependent cellular cytotoxicity (ADCC) Preclinical data suggest advantages over ADCC-null anti-TIGIT mAbs Target engagement demonstrated 	 Early signs of efficacy esp gynonc - 1CR, 1PR and 4 SDs of 15 patients with a minimum of one scan PR in PDL-1 negative ovarian patient adds to PR in ovarian patient in Phase 1b The ovarian cohort has cleared futility for expansion to Stage 2 per Simon Stage design* 	 Biomarkers established for potential future patient selection Correlation of clinical benefit with PVR expression observed in tumors with typically poor responses to anti- PD-1/PDL-1 	ACTIVATE Tria Differentiated Phase 1b/2 Trial Design





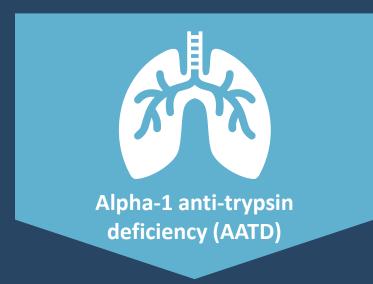
Alvelestat (MPH-966)



Alvelestat - An Oral Inhibitor Of Neutrophil Elastase (NE)

> Alvelestat is a potent, reversible, oral inhibitor of neutrophil elastase, with safety established in >1000 subjects

Two development pathways :





AATD - two Phase II PoC trials ongoing

Signal seeking studies in COVID-19 and GVHD BOS*



AATD-Lung Disease - A Rare Progressive Disease With A High Unmet Need

Alph-1 antitrypsin (AAT) inhibits the action of neutrophil elastase. Individuals who lack AAT or produced misfolded inactive AAT are at risk from progressive lung damage and early onset emphysema.

AATD-LD

- Presents age 20 to 50, symptoms include, shortness of breath, cough, reduced exercise tolerance
- Target population estimates 50,000 in North America and 60,000 in Europe and the UK^{1,2,3}
- AATD community groups are well established

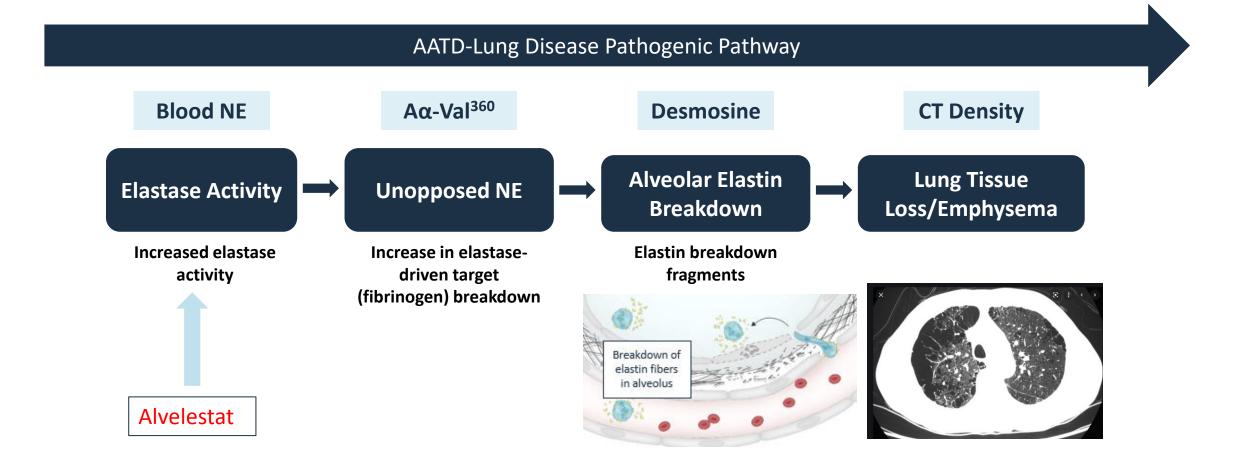
Unmet Need

- Current treatment options limited to intravenous plasma-derived augmentation therapy with limitations:
 - Clinical efficacy not uniformly recognized by physicians or payors
 - Inability to 'titrate' up for acute lung inflammation
 - Higher doses may be needed for clinical efficacy
 - IV administration places a burden on patients



1. Francisco et al (2012) Rare alpha-1-antitrypsin variants: are they really so rare? Therapeutic Advances in Respiratory Disease January 30; 2. Luisetti et al (2004) α1-Antitrypsin deficiency; 3. Epidemiology of α1-antitrypsin deficiency Thorax 59:164-169

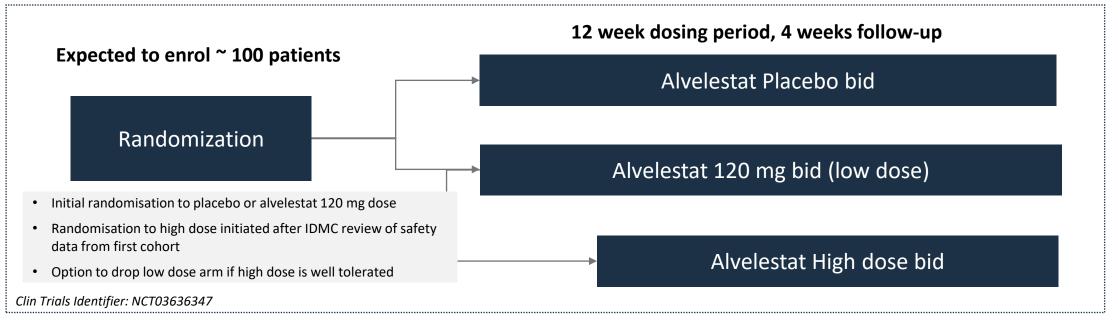
Linking Biomarkers to Pathological Pathway





Study Design: ASTRAEUS, A 12-week PoC Study In Participants With AATD-LD

A 12-week Study Treating Participants Who Have alpha1-antitrypsin-related COPD with alvelestat or Placebo.



			 Blood biomarkers of neutrophil elastase activity (Blood elastase and Aα-Val³⁶⁰),
Primary	% change in plasma	Secondary	Biomarkers of inflammation and lung damage
			Safety and tolerability
Endpoint	desmosine/isodesmosine	Endpoints	Spirometry & St. George's Respiratory
			Questionnaire
			 Frequency of acute exacerbations

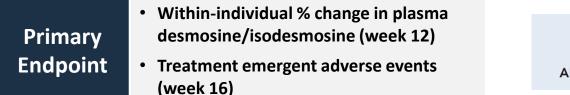
18

ATALANTa A 12 Week Investigator Led Study Of Alvelestat In AATD-LD Mark Dransfield, University of Alabama at Birmingham

• ATALANTa includes patients who are currently on augmentation therapy

Alvelestat Placebo bid N=33 Randomization N = 66 1:1 active to placebo Clin Trials Identifier: NCT03679598

Alvelestat for the Treatment of ALpha-1 ANTitrypsin Deficiency "ATALANTa"







Signal Seeking Studies For Indication Expansion



* Graft vs. host disease - Bronchiolitis Obliterans Syndrome

	COVID-19	GVHD BOS*
Rationale	 Neutrophil extracellular traps (NETosis) is a pathogenic mechanism in COVID- 19 infection highly dependent on neutrophil elastase (NE) 	 NE is a pro-inflammatory and pro-fibrotic driver of lung disease in BOS and BOS is significant cause of morbidity and mortality in GVHD and post lung transplant
Study Summary	 Phase 1b/2 study in patients with COVID-19 respiratory disease Enrolled 15 patients – randomised (1:1) to alvelestat or placebo BID for 5 days, with optional extension to 10 days 	 Phase 1b/2 open label study in 34 patients with moderate to severe BOS following hematopoietic stem cell-transplant. Alvelestat intra-subject dose escalation to 240mg
Key Endpoints	 Primary: Safety and tolerability to day 60 and mortality at day 90 Secondary: Biomarkers of NETosis and inflammation 	 Primary: Optimal biological dose and clinical efficacy (Ph2) and safety Other key endpoints: Desmosine, NE activity, lung inflammatory markers. Spirometry, PK, tox assessment & chronic GVHD scoring
Results to- date	 Alvelestat reported safe and well-tolerated in patients with COVID-19 Alvelestat, on top of standard of care resulted in a more rapid time to improvement in WHO Disease Severity score of >=2 in the first 5-7 days compared to placebo plus standard of care 	 Phase 1b interim data - progressive reduction of plasma desmosine over 8 weeks in 6 of 7 treated patients, all of whom had improved or stable lung disease (FEV₁) and reduction in stimulated neutrophil elastase activity. Suppressive effect on biomarkers of elastase activity and collagen synthesis
Collaborator	Led by Dr. James M. Wells, University of Alabama at Birmingham	• Study is under investigator IND, led by Dr. Pavletic (National Cancer Institute)



Alvelestat Key Differentiating Features

Profile for long term treatment of AATD lung disease and NETosis-driven diseases

Oral, twice daily dosing

High neutrophil elastase inhibition > 90% at doses in development Combination of twice daily dosing and high neutrophil elastase inhibition allows for 24/7 enzyme coverage Highly specific neutrophil elastase inhibition – reduces potential for side effects Rapid onset of action < 4 hours to > 90% enzyme inhibition







Setrusumab (BPS-804 / UX143)



Osteogenesis Imperfecta (OI): A Rare Genetic Bone Disease

- A rare genetic bone disease, linked to a mutation in Type I collagen.^{1,2}
- Symptoms include frequent bone fractures, skeletal deformities, pain, respiratory and gastric problems early diagnosis & no FDA or EMA approved therapies
- Affects approximately 60,000 individuals (pediatrics and adults)
- Community groups well established umbrella organizations OIFE & OIF* support national groups

- Antibody targeting sclerostin anabolic which also reduces resorption of bone
- Significant unmet need in both adult and pediatric populations.
- OI is a progressive condition. Care pathways less clear in adults
- Partnered with Ultragenyx leading the clinical development

The twins 'made of glass': 17-monthold sisters defy the odds after doctors gave them a 'zero per cent chance of survival' because of a rare disease that caused them to endure fractures in the WOMB

By ALEXANDRA THOMPSON SENIOR HEALTH REPORTER FOR MAILONLINE PUBLISHED: 12:11, 9 September 2019 | UPDATED: 15:09, 9 September 2019





makes her limbs so delicate she was BORN with a broken arm

By ALEXANDRA THOMPSON SENIOR HEALTH REPORTER FOR MAILONLINE PUBLISHED: 10:29, 9 September 2019 | UPDATED: 11:44, 9 September 2019





What is OI?

Setrusumab

* OIFE: Osteogenesis Imperfecta Federation Europe; OIF: Osteogenesis Imperfecta Foundation

1. Based on Osteogenesis Imperfecta Foundation estimates; 2. Based on Orphanet estimates

Summary of Phase 2b Results from ASTERIOD

Study Overview

Phase 2b study (n=90) blinded with 3 dose arms, monthly dosing for 12 months Enrolled adult OI types I, III, and IV (~90% of the prevalent population)

Efficacy Results

Clear, dose-dependent, statistically significant bone building effect (DXA scans) at multiple anatomical sites and consistent across all OI subtypes studied*

Statistically significant increases in bone failure load and bone stiffness at the high dose

Lower number of fractures and lower fracture rate observed at the high dose

Safety Findings

Setrusumab was well tolerated and no safety concerns were observed (including no cardiac)

Similar BMD gains in the first and second 6 months of treatment – longer term therapy



*Primary endpoints: Radial Tb vBMD at 12 months was not significantly changed after setrusumab treatment. However, setrusumab elicited dosedependent increases in bone strength indices and total vBMD at the radius, with stiffness and cortical vBMD also increased at the tibia (all significant at 20 mg/kg). Significant increases in DXA aBMD were observed at lumbar spine and total hip (all doses), as well as at the femoral neck (20 mg/kg).

Glorieux F, et al "Setrusumab for the treatment of osteogenesis imperfecta (OI): Results from the Phase 2b ASTEROID Study" ASBMR 2021; Abstract 1016.

Ultragenyx – Mereo Partnership and Long Term Plan

Mereo – Ultragenyx partnership

Clinical Development

- Ultragenyx funding global development plan in pediatrics and adults
- Mereo retains rights to commercialization in EU/EEA and UK – Ultragenyx US and ROW
- Received \$50M u/f with up to \$254M for clinical, regulatory and commercial milestones
- Ultragenyx pays Mereo tiered double digit % royalties on net sales
- Mereo pays Ultragenyx fixed double digit % royalty on net sales

- Led by Ultragenyx & supported by Mereo
- Phase 2/3 pediatric study in OI in patients 5-25 yrs old
 - Phase 2 to determine optimal dose based on collagen production (P1NP)
 - Phase 3 fractures over 15-24 months
 - Initiation by end-of 2021
- Phase 2 pediatric study in OI in young children < 5 yrs old
- Registrational pathway for adults with OI under discussion *Clin Trials Identifier: NCT05125809*

Commercialization in Mereo Territories

- Mereo's current focus is on European and UK commercialization of setrusumab
- IMPACT Survey, the largest data set on the impact of OI. Results will support OI advocacy & commercialization efforts







Upcoming Milestones



Upcoming Key Milestones & Opportunities

		Up	coming Milestone For (Core Programs		
Product Candidate	Indication	2022	2023	2024	Partner	Next Milestone
Etigilimab	Solid tumors	Phase 1b/2 basket study with	potential cohort expansion			Phase 1b/2 full enrolment and data Phase 2 cohort expansion
Alvelestat	AATD	Phase 2 PoC				AATD: Phase 2 data readout
Alvelestat	BOS	Phase 2				BOS: Phase 2 data
Setrusumab	Osteogenesis	Pe	diatric Phase 2b/3 fracture stud		ultrageny	Initiation of pivotal study pediatric & young adults (5- 25yrs old)
	imperfecta		Pediatric Phase 2 childre	en <5 years		Initiation of Phase 2 study pediatric (children <5 yrs old

Non-coreNavicixizumab has been partnered with OncXerma for further development. Next Milestone: Initiation of pivotal trial by OncXermaProgramsLeflutrozole and acumapimod are currently under partnering discussions. Next Milestone: Partnership agreement



Financial Highlights

Cash runway into 2024 \$134.2 million (£99.7m) as of September 2021, including:

- \$50 million upfront in January ٠ 2021 from setrusumab licensing deal
- \$115 million from follow-on ٠ financing in February 2021

Cap Table (September 30, 2021)	ADSs ¹ (in thousands)
Shareholders > 5% holding	47,489
Shareholders < 5% holding	63,613
Share capital - Issued and outstanding	111,102
Potential Future Dilution:	
Warrants ²	11,961
Convertible loan notes ³	22,630
Employee share schemes ⁴	4,193

- ¹ One ADS represents five ordinary shares
 ² Assumes a market price of \$4.00 per ADS and cashless exercise. The maximum number of warrants outstanding is 29.8m.
- ³ Excludes 2.9m ADSs payable either in ADSs or cash at election of the note holder ⁴ Excludes 1.9m ADSs for employee share awards with an exercise price in excess \$8.00



Investment Highlights

Developing therapeutics for oncology and rare diseases based on novel targets with strong biological rationale

- Etigilimab an anti-TIGIT antibody with early promising data in an ongoing Phase 1b/2 basket study
- Alvelestat an oral neutrophil elastase inhibitor in Phase 1b/2 studies for AATD and BOS with a COVID study completed
- Setrusumab an anti-sclerostin antibody that has completed a Phase 2b in adults with OI and expected to enter a pivotal study in pediatrics with our partner Ultragenyx

Programs for partnering income

- Navicixizumab partnered with OncXerna (\$300M + royalties)
- Leflutrozole for infertility
- Acumapimod for AECOPD

Multiple near-term clinical and pipeline milestones

Highly experienced management team with significant expertise in rare diseases and oncology

Cash runway into 2024





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Our Core Programs – A Diversified Mid-Late Stage Pipeline

Etigilimab	 An IgG1 anti-TIGIT antibody Phase 1b/2 ACTIVATE basket trial combination of etigilimab with nivolumab in multiple solid tumors Early clinical benefit observed in gyn/onc tumors with good safety profile Integral biomarker strategy
Alvelestat	 Oral neutrophil elastase inhibitor with clinical activity in multiple respiratory pathologies Phase 2 trials ongoing in Alpha-1 antitrypsin deficiency (AATD) with orphan drug designation Ongoing Phase 1b/2 investigator lead studies in GvHD Bronchiolitis Obliterans and COVID for NETosis (neutrophil extracellular traps)
Setrusumab	 Anti-sclerostin antibody which significantly increases bone mineral density in adults with osteogenesis imperfecta (ASTEROID study) Partnered with Ultragenyx with Mereo retaining commercial rights in the UK/EU/EEA (\$50M u/f, \$254M milestones, royalties) Entering Phase 2/3 pivotal registrational trial in pediatrics Orphan Drug Designation in EU and US, PRIME and Adaptive pathways in EU, Rare Pediatric Disease Designation in US



Etigilimab - designed to balance interaction with different cell populations

Etigilimab Depletes High Expressing T-reg Cells But Spares Effector T-And NK Cells

Activation of NK and T-cell subpopulations \geq 2nd Ab W/OAb 20 10 5 2.5 1.25 0.625 0.313 Etigilimab **Reduction of T-regulatory cells** Competitor Ab Increased CD8/Treg ratio PVR GFP Human TIGIT ECD fused to CD4TM-GFP was transiently expressed in 293T \geq cells and incubated with indicated amount of anti-TIGIT antibody followed Etigilimab has demonstrated dose dependent target by addition of human PVR-rabbit Fc fusion protein. engagement in patients Anti-TIGIT antibody dose-dependent suppression reflects specific blockade \geq of PVR binding to TIGIT.

Pre-clinical Model Showing PVR Binding

Ab concentration (ug/ml)



ACTIVATE Phase 1b/2 Early Data Summary and Conclusions

Efficacy

- Preliminary signs of efficacy noted with 1CR, 1PR and 4 SDs out of 15 patients with a minimum of one scan
- Potential early signal in gynonc cohorts
 - Heavily pre-treated/post-platinum ovarian cancer PD-L1 negative (PR)
 - PR also noted in an ovarian cancer patient in the FIH Phase 1b combination cohort
 - Post SOC, CPI-naïve cervical cancer (cCR)
- The ovarian cohort has cleared futility for expansion to Stage 2 per Simon Stage design (pending IDMC review)
- All other cohorts of the study are continuing to enrol toward completion of Stage 1

Safety

- The combination of Etigilimab + nivolumab is safe and well tolerated; no new safety signals seen to date
 - The most common treatment related adverse events were skin reactions, observed in seven patients, non of which required steroids
 - There was one case of immune diabetes mellitus

Biomarker Data

- Correlation of clinical benefit rates with PVR and TIGIT expression in tumor types that have typically very poor responses to anti- PD-1/PDL-1
 - Includes in PD-1 negative tumor samples
- CLIA validated assays allows for potential patient selection on the basis of PVR and TIGIT expression going forward
- Target engagement biomarker analysis including Treg, T cell subsets, Ki67 and other markers ongoing

Continued evaluation of the combination of etigilimab with an anti-PD-1 antibody is supported by these early data

