
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT
TO RULE 13a-16 or 15d-16 UNDER THE
SECURITIES EXCHANGE ACT OF 1934**

For the month of March, 2022

Commission File Number: 001-38452

MEREO BIOPHARMA GROUP PLC
(Translation of registrant's name into English)

4th Floor, One Cavendish Place,
London, W1G 0QE, United Kingdom
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)
(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)
(7):

Highlights from Virtual Research and Development Day

On March 14, 2022, Mereo BioPharma Group plc (the “Company”) is hosting a virtual research and development (R&D) day to review the Company’s alvelestat (MPH966) program focused on the ongoing Phase 2 studies evaluating alvelestat in the treatment of alpha-1 antitrypsin deficiency (AATD)-related lung disease, and to provide updates on the ongoing investigator sponsored Phase 1b/2 study in patients with Bronchiolitis Obliterans (BOS) following hematopoietic stem cell transplantation (HCT) and the Phase 1b/2 hospitalized COVID-19 trial. This event features scientific opinion leaders and members of the Company’s management team.

Highlights from the virtual R&D Day include:

- An update on the ASTRAEUS 12-week Phase 2 trial for alvelestat in AATD patients with lung emphysema, including blinded baseline data for three key biomarkers, desmosine, neutrophil elastase and A α -Val³⁶⁰
- Discussion of the revised biomarker primary endpoints of the study following development of the Company’s biomarker strategy and a Type C meeting with the FDA
- An update on the ATALANTa Phase 2 study
- An up-to-date report on the safety profile of alvelestat from all the ongoing clinical studies
- An update on the study of alvelestat in bronchiolitis obliterans following allogenic hematopoietic stem cell transplantation, with Phase 2 set to be initiated in earlier stage patients in 2022

A live audio webcast of the R&D Day can be accessed through the Investors section of the Company’s website at www.mereobiopharma.com/investors. An archived replay of the webcast will be made available on the Company’s website. No part of the Company’s website is incorporated by reference herein. Highlights from the presentation are furnished as Exhibit 99.1 hereto.

Exhibit Index

Exhibits

99.1 [R&D Day Presentation Highlights dated March 14, 2022 titled “Mereo BioPharma Alvelestat \(MPH966\) R&D Day.”](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 14, 2022

MERO BIOPHARMA GROUP PLC

By: /s/ Charles Sermon

Name: Charles Sermon

Title: General Counsel

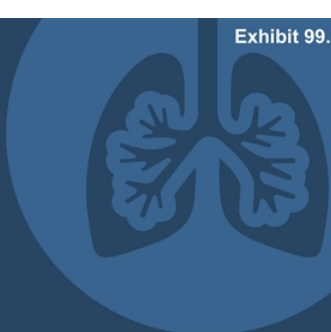


Alvelestat (MPH966) R&D Day

March 14 2022

Mereo BioPharma Group plc

NASDAQ: MREO



Disclaimer

This presentation has been prepared by Mereo BioPharma Group plc (the "Company") solely for your information and for the purpose of providing background information on the Company, its business and the industry in which it operates or any particular aspect thereof. For the purposes of this notice, "presentation" means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed during any related presentation meeting.

This presentation has not been independently verified and no representation or warranty, express or implied, is made or given by or on behalf of the Company or any of its subsidiary undertakings, or any of any such person's directors, officers, employees, agents, affiliates or advisers, as to, and no reliance should be placed on, the accuracy, completeness or fairness of the information or opinions contained in this presentation and no responsibility or liability is assumed by any such persons for any such information or opinions or for any errors or omissions. All information presented or contained in this presentation is subject to verification, correction, completion and change without notice. In giving this presentation, none of the Company or any of its subsidiary undertakings, or any of any such person's directors, officers, employees, agents, affiliates or advisers, undertakes any obligation to amend, correct or update this presentation or to provide the recipient with access to any additional information that may arise in connection with it. To the extent available, the data contained in this presentation has come from official or third-party sources. Third party industry publications, studies and surveys generally state that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data. While the Company believes that each of these publications, studies and surveys has been prepared by a reputable source, the Company has not independently verified the data contained therein. In addition, certain of the data contained in this presentation come from the Company's own internal research and estimates based on the knowledge and experience of the Company's management in the market in which the Company operates. Further, certain of the data has been provided to the Company by contract research organizations that the Company retains to conduct clinical trials, or by other third parties contracted by the Company. While the Company believes that such internal research and estimates and such other data are reasonable and reliable, they, and, where applicable, their underlying methodology and assumptions, have not been verified by any independent source for accuracy or completeness and are subject to change without notice. Accordingly, undue reliance should not be placed on any of the data contained in this presentation.

Forward-Looking Statements

This presentation contains "forward-looking statements." All statements other than statements of historical fact contained in this presentation are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements usually relate to future events and anticipated revenues, earnings, cash flows or other aspects of our operations or operating results. Forward-looking statements are often identified by the words "believe," "expect," "anticipate," "plan," "intend," "foresee," "should," "would," "could," "may," "estimate," "outlook" and similar expressions, including the negative thereof. The absence of these words, however, does not mean that the statements are not forward-looking.

These forward-looking statements are based on the Company's current expectations, beliefs and assumptions concerning future developments and business conditions and their potential effect on the Company. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates. Factors that could cause actual results to differ materially from those in the forward-looking statements include risks relating to unanticipated costs, liabilities or delays; failure or delays in research and development programs; the safety and efficacy of the Company's product candidates and the likelihood of clinical data to be positive and of such product candidates to be approved by the applicable regulatory authority.

Summary

- The ASTRAEUS 12-week trial is on track to deliver top-line Phase 2 data for alvelestat in AATD patients with lung emphysema in early Q2 2022*
 - Primary endpoints evolved to three key biomarkers on the pathogenic pathway of the lung disease including detection of neutrophil elastase levels in patients
 - More comprehensive - allows investigation of a number of causal pathway biomarkers for further development
 - In-vivo neutrophil elastase assay more akin to “functional PK” in-vitro assays used as a primary end-point in Phase 2 studies for AAT augmentation
 - Follows on from Mereo's development of the biomarker strategy and the Type C meeting held with the FDA
- The ATALANTa Phase 2 study will currently read-out in early 2023 and is complementary to ASTRAEUS
- Alvelestat has demonstrated a clean safety profile in all studies to-date with a tendency for headaches managed through dose escalation*
- Plan to engage in discussions with the FDA on Registrational trial design for AATD in end of Phase 2 meeting in 2H 2022
- Alvelestat has potential in other indications
 - Demonstrated impact on biomarkers of elastin breakdown and fibrosis in BOS following allogeneic hematopoietic stem cell transplantation, with encouraging pulmonary function outcomes. Phase 2 to be initiated in earlier stage patients, with clinical endpoints.
 - Demonstrated a clinically meaningful effect in short term 5-10 day dosing in hospitalised COVID-19 supports anti-inflammatory effects on top of those achieved by high dose corticosteroids

Upcoming Key Milestones & Opportunities

Upcoming 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 ASTRAEUS*	Phase 2 ATALANTa			AATD Phase 2 top-line data
	BOS	Phase 1b	Phase 2			BOS Phase 2 initiation
Setrusumab	Osteogenesis imperfecta	Pediatric Phase 2b/3 fracture study			ultragenyx pharmaceutical	Initiation of pivotal study pediatric & young adults (5-25yrs old)
		Pediatric Phase 2 children <5 years				Initiation of Phase 2 children <5 yrs old)

*ASTRAEUS is a proof-of-concept phase 2 study

Non-core Programs	Details
	Navicixumab has been partnered with OncXerna for further development. Received a \$2M CMC milestone
	Leflutrolole and acumapimod are currently under partnering discussions. Next Milestone: Partnership agreement

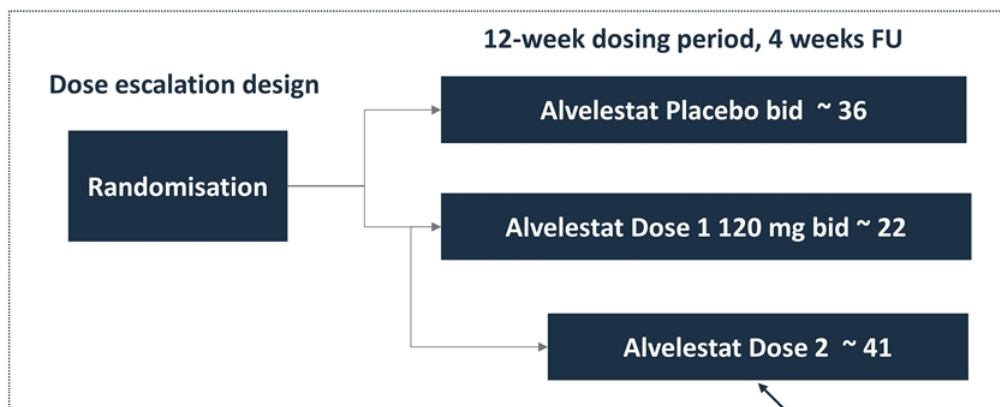
 Projected milestone

ASTRAEUS Phase 2 Study in AATD-Associated Emphysema

A randomized double blind-placebo-controlled study in patients naïve to augmentation or following a 6-month wash-out period. **Total of 99 patients enrolled.** Chief Investigator – Prof. Rob Stockley

Trial Population

- Age ≥ 18 and ≤ 80 years
- Pi*ZZ, Pi*Z Null, Pi*Null genotype/phenotype, other rare types
- FEV1 $\geq 20\%$ predicted



IDMC –both doses deemed safe to proceed
Preferential recruitment to highest dose per protocol



ASTRAEUS Phase 2 Initial Endpoints

Primary Endpoints

- Within individual % change from baseline in plasma desmosine/isodesmosine at end of treatment compared to placebo to week 12

Secondary and Exploratory Endpoints

- Blood Neutrophil Elastase activity
- Blood A α -Val³⁶⁰ levels
- Safety and tolerability
- Lung damage and inflammation biomarkers
- Pharmacokinetics
- St. George's Respiratory Questionnaire
- Spirometry including - Forced expiratory volume in 1 second (FEV₁), FVC and FEF25-75
- Exacerbations

ASTRAEUS Demographics And Baseline AATD Characteristics

➤ Similar to other baseline data for randomized control trials in severe AATD patients[§]

	ASTRAEUS	RAPID*	
	All, (N=99)	A1PI(n=93)	Placebo (n=87)
Age years Mean ±SD (Range)	57.3 ±10.1 (26-75)	53.8±6.9	52.4±7.8
Sex Male (%) Female (%)	39(40%) 60(60%)	48(52%) 45(48%)	50(57%) 37(43%)
Race White (%)	95(96%)	93(100%)	87(100%)
FEV₁ % predicted Mean± SD	56.7±20.7	47.4±12.1	47.2±11.1
A1AP concentration μm Mean±SD (Range)	3.9 ±1.6 (0.04-9.0)	6.38±4.62	5.94±2.42
Mutation status	All ZZ	^NR	^NR
Time from AATD diagnosis years - Median (Range)	9 (1-42)	^NR	^NR

§ Preliminary uncleaned data

*Chapman et al. (2015)
Lancet. 2015 Jul
25;386(9991):360-8

^NR- Not Reported



Note: Uncleaned data. Final values may differ from those presented here.

Plasma Desmosine as a Biomarker of Proposed Pathogenic Mechanism (Elastosis)

Marker of Effect on Target Tissue

- Measure of elastolytic rate (desmosine/isodesmosine = "desmosine")
- Consistently increased in AATD-associated lung disease (emphysema)
- Addresses question of whether NE inhibition alone modifies a marker within the pathogenic pathway

Desmosine increased in diseases associated with increased NE and shows response to NE suppression with alvelestat in signal-seeking clinical studies

- Cystic Fibrosis: ~19% reduction alvelestat (n=26) compared to placebo (n=29) (p=0.105) by 4 weeks[§]
- Bronchiectasis: ~10% reduction in alvelestat compared to placebo (p= 0.120) by 4 weeks[#]
- Bronchiolitis Obliterans Syndrome (BOS): decrease of ~ 16% from baseline by week 8 (p=0.066)[^]

Elevated Blinded Baseline Desmosine Levels In ASTRAEUS Consistent With Other Studies

Data, including therapeutic response, available in AATD

- Correlate with clinical measures of disease severity (FEV1), respiratory function (diffusion factor) and structure (lung density) in AATD population
- Elevated in AATD across different studies
- Responsive to AAT replacement (~ 6.5% reduction at 3 months) in RAPID study[§]

Elevated (blinded) baseline desmosine levels in ASTRAEUS, consistent with other studies of severe AATD

- **ASTRAEUS baseline = 0.386 ng/ml (SD 0.137)**
- RAPID study baseline = 0.365 ng/ml (SD 0.101)
- Healthy volunteers = 0.21ng/ml (SD 0.03)



Note: Uncleaned data. Final values may differ from those presented here.

[§] Ma et al *Chronic Obstr Pulm Dis.* 2017; 4(1): 34-44
^{**} Albarbarawi et al. (2013) *Bioanalysis.* 2013 Aug;5(16):1991-2001

Monitoring Neutrophil Elastase (NE) Levels In Patients With AATD

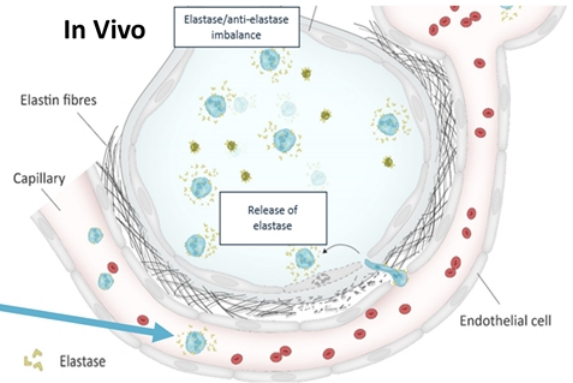
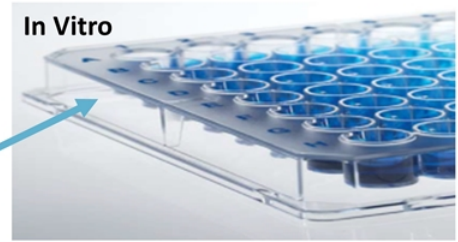
“Functional PK” assays used in AAT augmentation measure NE inhibiting capacity of serum to quantitate level of “biologically active” AAT

- Does not measure NE activity within a patient and cannot be used as a measure of ongoing *in vivo* suppression

Measurement of elastase in AATD to monitor therapeutic intervention is challenging:

- Limited sensitivity of assays for blood NE activity
- NE activity assays available for sputum, but minority with AATD produce sputum

Increased sensitivity of an established NE activity method (ProAxis®) now enables measurement of blood elastase activity in patients enrolled in ASTRAEUS

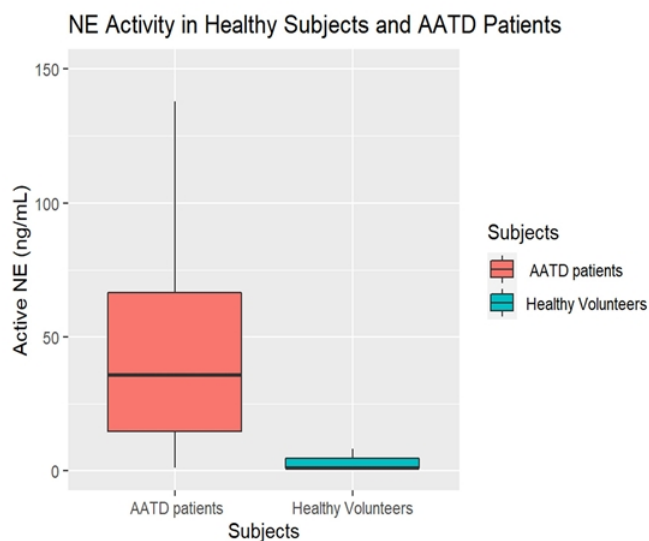


Measurement Of Target Engagement - Activity-based NE Immunoassay For In-vivo Blood Monitoring Of NE Suppression

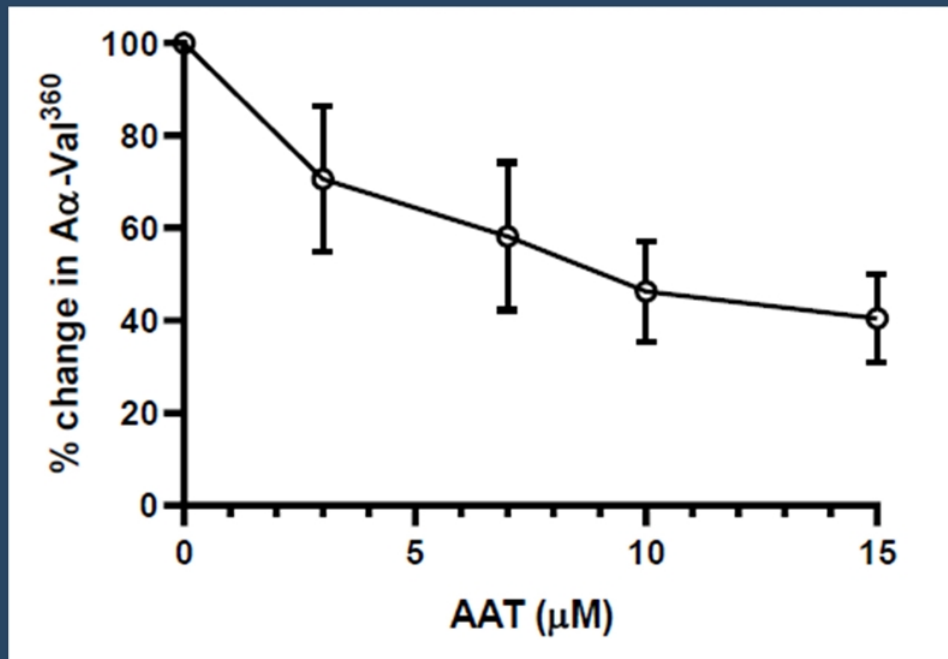
- The ProteaseTag® activity-based immunoassay specifically measures active neutrophil elastase levels
- Improved sensitivity, enables detection in blood supports potential detection of therapeutic effect.

Active NE (ng/ml)		
	ASTRAEUS Baseline Blinded data (N=82)	Healthy Subjects Recent data (N=39)
Mean	63.6	9.6
Median	40.7	0
Range	0-685.6	0-104.2

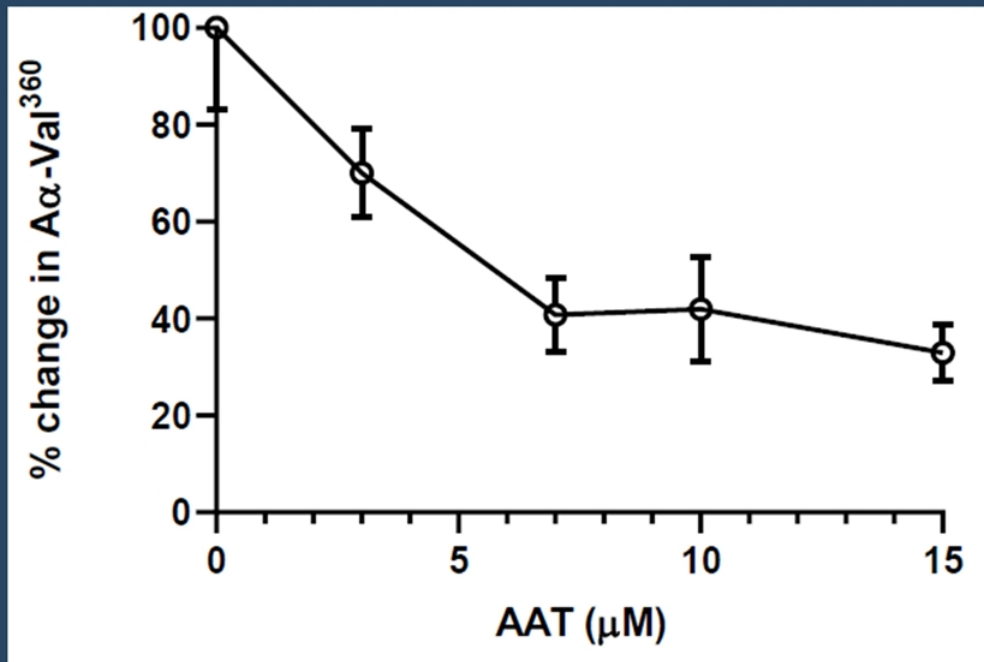
Significant difference between the active NE concentrations in each group ($p = <0.0001$)



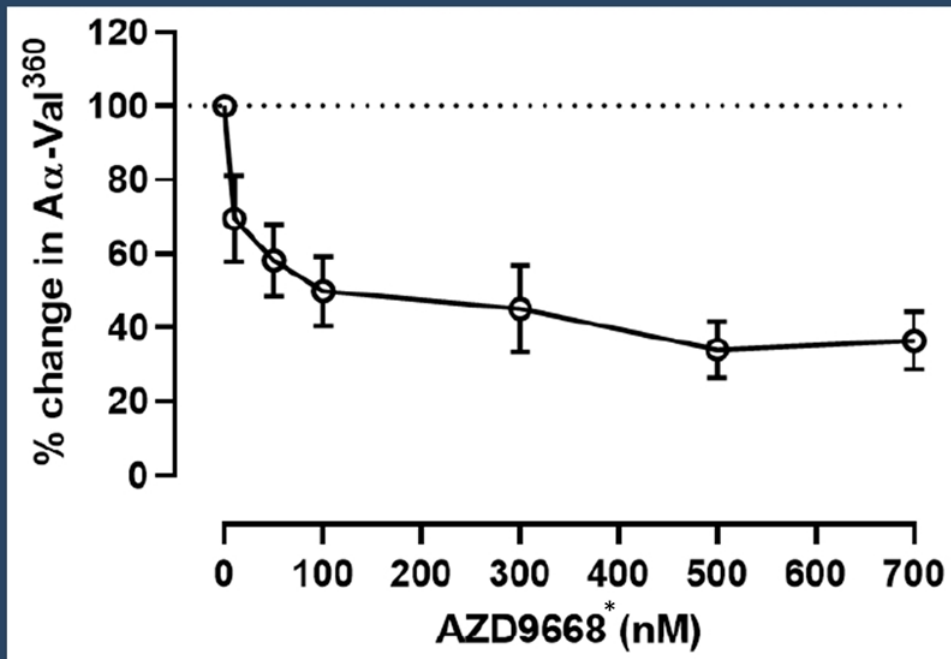
Simultaneous incubation



Preincubation

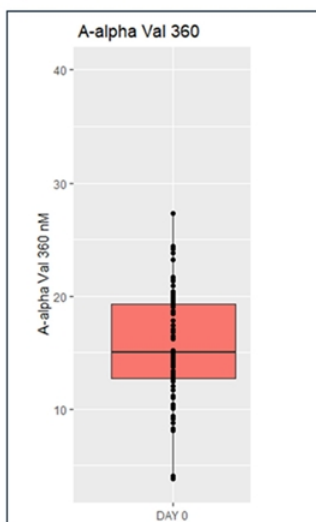


Alvelestat/elastase

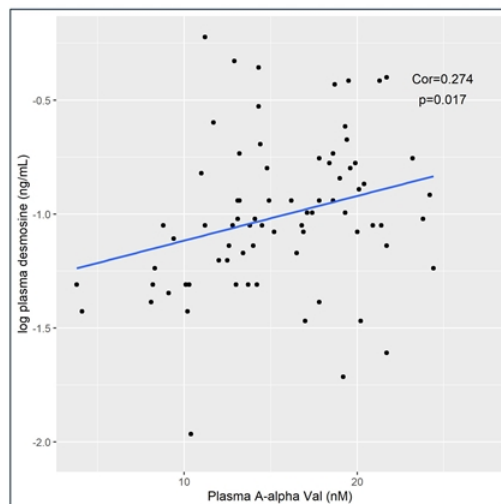


*AZD9668: alvelestat

Plasma A α -Val³⁶⁰ Blinded Baseline Levels Raised In ASTRAEUS AATD Population



- Blinded baseline level ASTRAEUS mean **15.05nM (SD 4.81)**
- Similar to levels in AATD Registry study in PiZZ (Carter et al 2013)

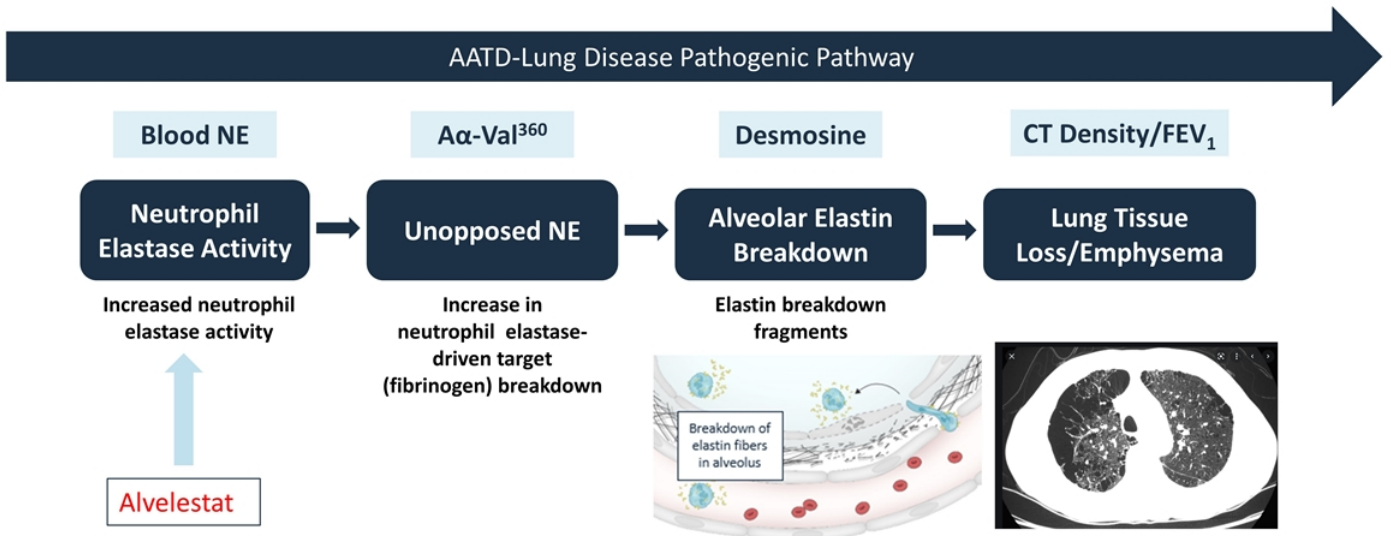


Positive correlation between desmosine and A α -Val³⁶⁰ levels at baseline in ASTRAEUS

No Safety Signals Identified To-date In AATD Patients (Data Blinded To Mereo)

- Independent Data Monitoring Committee reviews unblinded safety data ~ quarterly.
- There have been no safety signals detected on adverse event or lab monitoring, including in infectious events, liver, hematology or ECG review.
- Most commonly reported treatment-emergent adverse event (TEAE) has been headache- considered a tolerability issue and not a safety issue for alvelestat.
- Headache is a known side effect of alvelestat and was most frequent in the highest dose arm. Dosing amended to include a within-participant dose escalation step which reduced the frequency/severity of headache

Linking Biomarkers To Pathological Pathway



ASTRAEUS Phase 2 Revised Endpoints

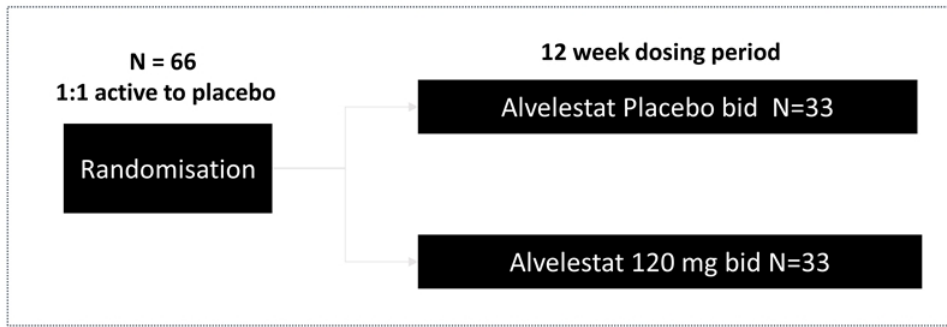
Primary Endpoints

- Within individual % change from baseline up to end of treatment **within treatment arm** and in comparison, to placebo up to week 12 in:
 - Plasma desmosine/isodesmosine levels
 - **Blood Neutrophil Elastase activity**
 - **Blood A α -Val³⁶⁰ levels**

Secondary and Exploratory Endpoints

- Safety and tolerability
- Lung damage and inflammation biomarkers
- Pharmacokinetics
- St. George's Respiratory Questionnaire
- Spirometry including - Forced expiratory volume in 1 second (FEV₁), FVC and FEF25-75
- Exacerbations

Alvelestat (MPH966) For The Treatment of Alpha-1 ANTitrypsin Deficiency “ATALANTa” (Investigator-initiated – Principal Investigator Prof Mark Dransfield, UAB)



Trial Population

- Age ≥ 18 and ≤ 80 years
- Pi*ZZ, Pi*SZ, Pi*Z Null, or Pi*Null genotype/phenotype
- Emphysema, FEV1 $\geq 25\%$ predicted
- Not currently receiving augmentation OR on stable augmentation for at least 12 weeks prior to screening

Primary Endpoints

- Within-individual % change in plasma desmosine/isodesmosine (week 12)
- Safety and tolerability

Secondary Endpoints

- Blood A α -Val³⁶⁰, Neutrophil elastase
- Protease neo-epitopes
- Collagen peptides/chemoattractants
- Pro-inflammatory cytokines

Exploratory Endpoints

- PK/PD
- Spirometry
- PROMs

ATALANTa - Consistent Supportive Safety Profile Of Alvelestat In Patients With AATD

10 active sites in USA

37 patients randomized

- No SAEs reported in the study to date
- No clinically important abnormalities in hematology and clinical chemistry reported to date
- 6 monthly DSMB meeting (last Dec 2 2021) “We reviewed AEs and safety data and noted no concerning trends”

Note: Uncleaned data. Final values may differ from those presented here.