areteia therapeutics

Pioneering a new era in inflammatory airway disease

Areteia Therapeutics is a clinical stage biotechnology company committed to putting respiratory patients in better control of their disease—and back in control of their lives— with **the first potential oral drug for eosinophilic asthma**

June 2023

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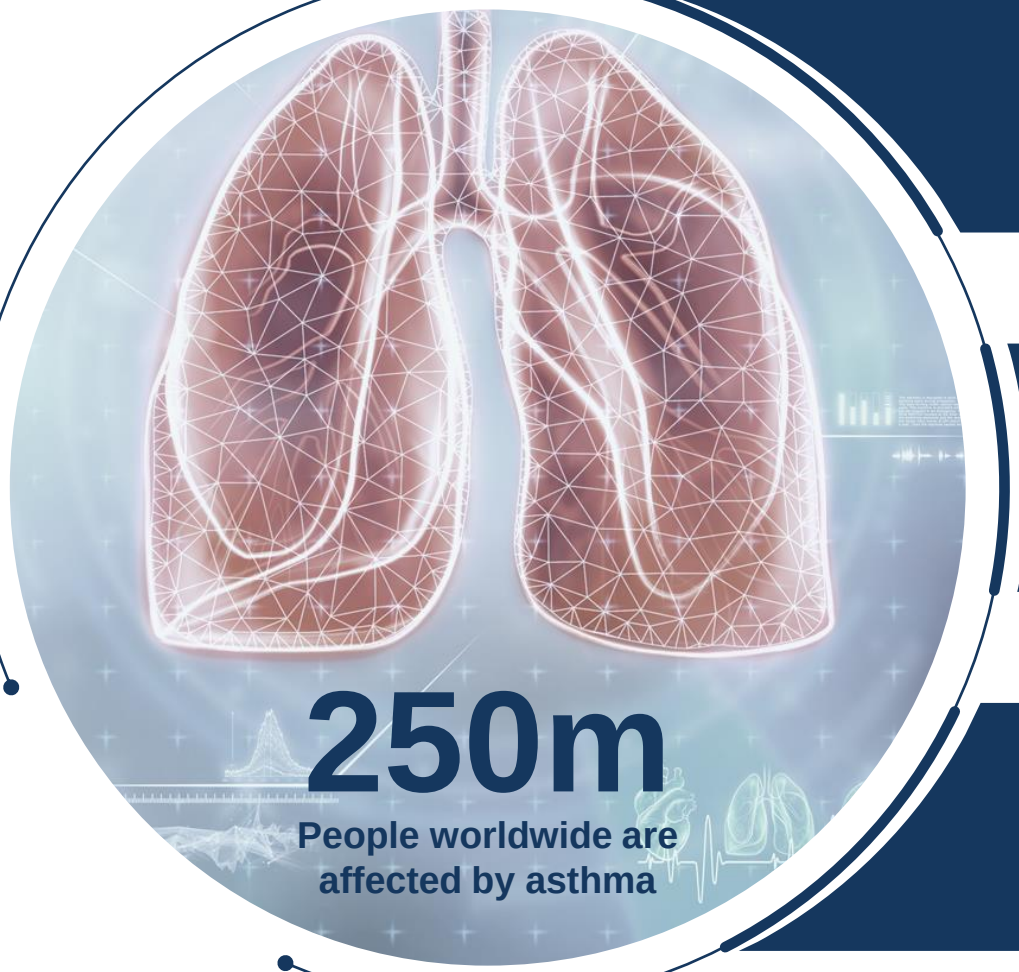
Areteia Therapeutics: Advancing the first-ever oral therapy for eosinophilic asthma

Key takeaways



Multi-billion-dollar **market opportunity upstream of biologics**

First-in-class oral for eosinophilic asthma entering Phase 3

Experienced, well financed team **executing on FDA and EMA aligned development path**

Introducing Areteia Therapeutics

Proven team led by industry veterans

Executive Team

Jorge Bartolome
Chief Executive Officer
Industry leader with deep respiratory experience

Peter Wijngaard
Chief Development Officer
Led inclisiran global development program

Calman Prussin, MD
Chief Scientific Officer
Led dexpramipexole Phase 2 asthma clinical trial

Mark Kreston
Chief Commercial Officer
Led global launch of Otezla at Celgene

Eric Bradford, MD
Chief Medical Officer
Led development of IL5 program

Robin Walker
Chief Legal Officer
Extensive Biotech and Pharma experience

Chris Courts
Chief Financial Officer
Extensive Biotech and Pharma experience

Dan Tokich
Manufacturing
Extensive Biotech and Pharma experience

Eshan Vasudeva
BD and Corporate strategy
Extensive life science strategy, investment experience

Tamsin Berry
Head of Partnerships & Policy
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Senior Scientific Advisor, Biohaven pharmaceuticals

Multi-billion-dollar market opportunity upstream of biologics

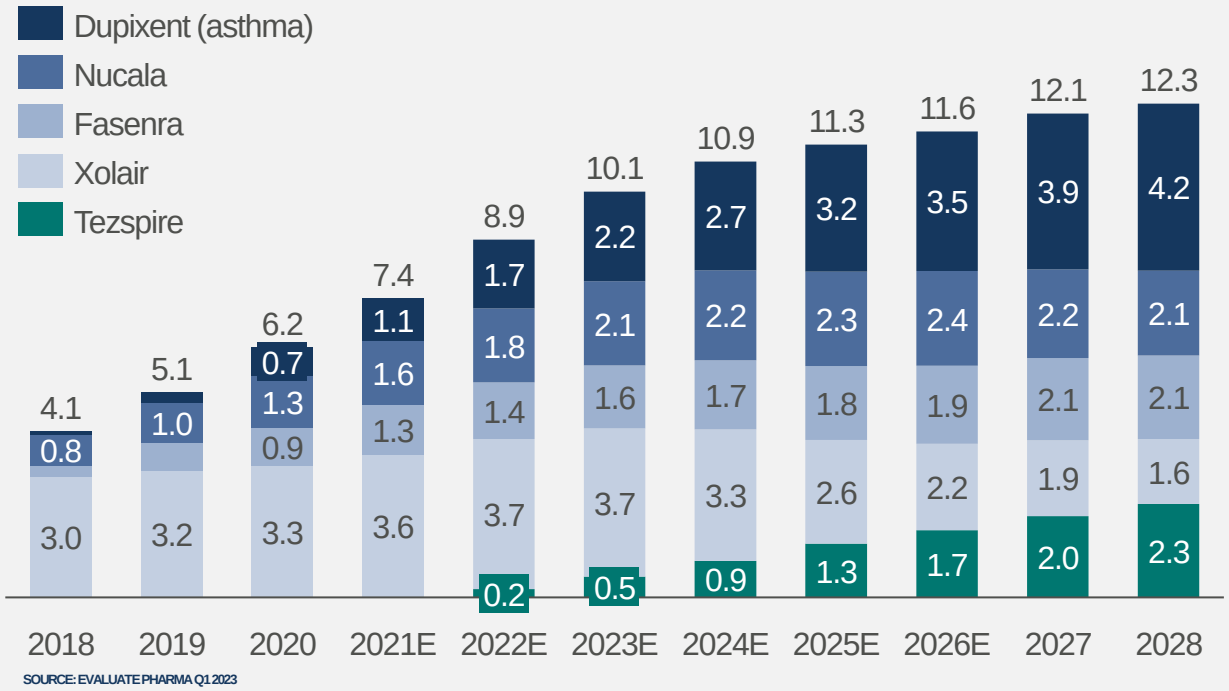
~$10B asthma biologics market, growing to $12B by 2026, driven by IL-5's and Dupixent

Advanced therapy landscape in moderate-severe asthma

Key Marketed Assets

Molecule	MoA	Indication
Fasenra (benralizumab)	IL-5 mAb	Severe eosinophilic asthma, age 12+ (6+ Nucala)
Nucala (mepolizumab)	IL-5 mAb	
Dupixent (dupilumab) Injection 200mg · 300mg	IL-4 / IL-13 mAb	Mod/sev eosinophilic or OCS-dependent asthma, age 12+
Xolair Omalizumab FOR SUBCUTANEOUS USE 75 mg • 150 mg	Anti-IgE mAb	Mod/sev allergic asthma age 6+
TEZSPIRE (tezepelumab-ekko)	Anti-TSLP mAb	Severe asthma of any phenotype

Projected WW asthma biologics revenue to 2028 ($B)

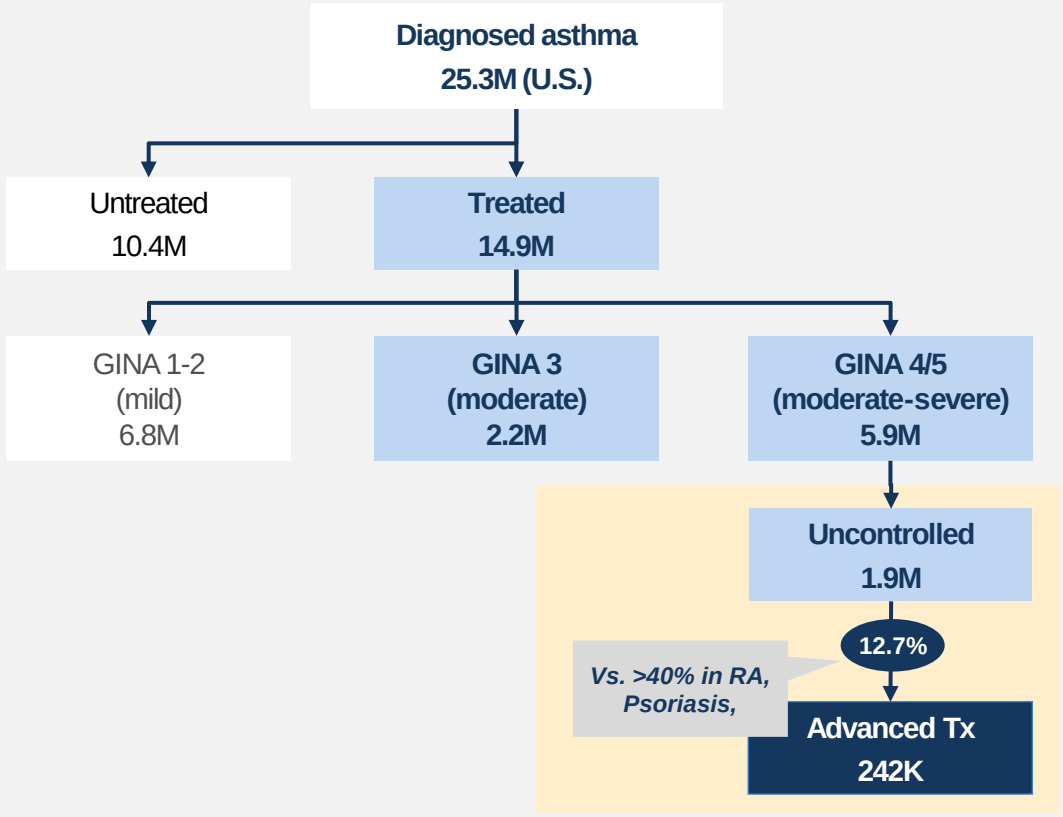


SOURCE: EVALUATE PHARMA Q1 2023

Biologic therapies dramatically underpenetrated

Fewer than 13% of moderate-severe patients currently receive a mAb – driving significant unmet need

A large, undertreated market…



…with significant medical and economic unmet need

- >50% of moderate-severe patients have *eosinophilic* phenotype
- ~2.5M moderate-severe *eosinophilic* asthma patients in US, ~4.5M across U.S., EU
- >30% moderate-severe patients uncontrolled
- >50% of severe asthmatics hospitalized >1x/yr
- 2M+ annual ER visits
- $28B addressable healthcare spend (U.S.)

...and multiple barriers to broad mAb adoption

- Injection fear
- Patient refusal
- Burden of product administration / logistics
- Access to specialist prescribers / cost

SOURCE: Trinity Market Research, Datamonitor, Evaluate Pharma 2022
Identified in qualitative / quantitative market research conducted by Trinity Associates in Q1, 2021; validated by independent market research by Areteia

Dexpramipexole: First-in-class oral for eosinophilic asthma entering Phase 3

Takeaways from clinical data to-date

Validated target

Elevated blood and tissue eosinophils drive significant unmet need in multiple immunologic conditions

- Eosinophilic asthma: 60% of moderate-severe asthma cases (4.5 mm+ U.S./EU patients)

Validated Pathway

Mechanism of Action: Eosinophil maturation inhibitor → blood and tissue eosinophil depletion → validated in asthma by IL-5 successes

Consistent, biologic-like efficacy

Potent and selective eosinophil lowering in blood and tissue across multiple populations

Consistent, robust safety and tolerability

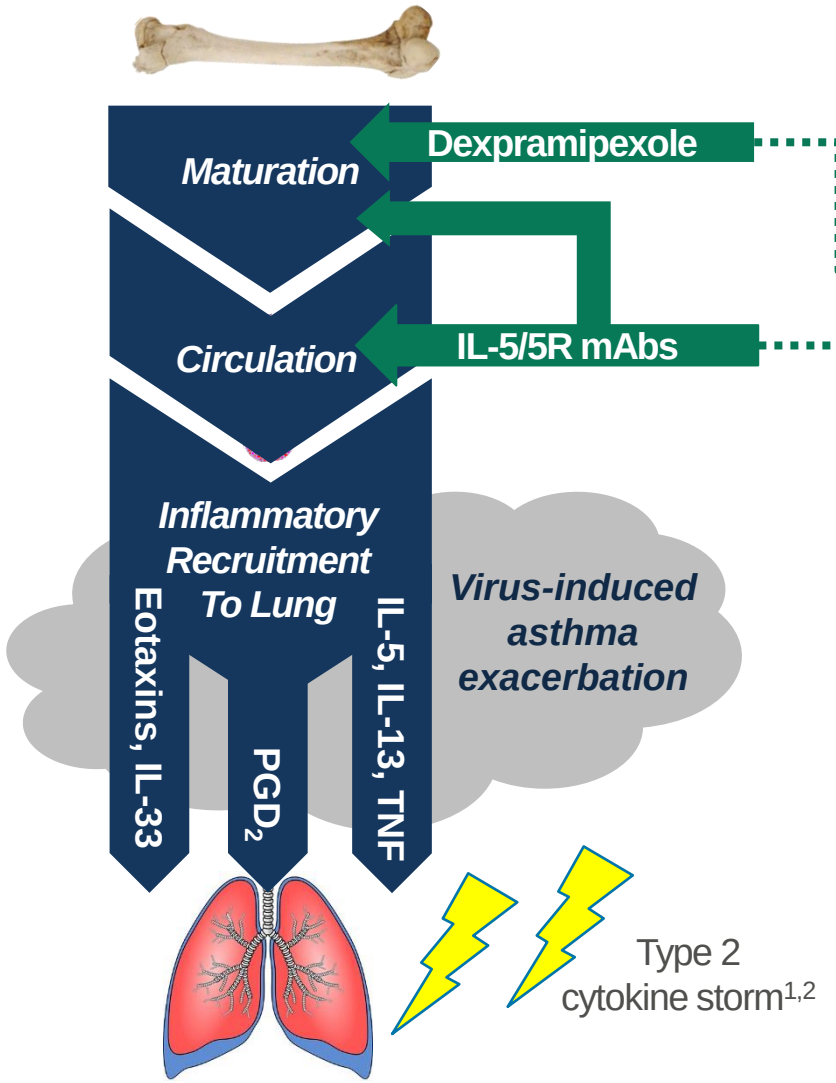
Clean safety profile from 1,500+ patients over 10+ years of large-scale clinical research

Ph. 3 started in asthma

Phase 2 demonstrates clear dose response with biologic-like lung function improvement

Validated Target

Clinical benefits of lowering eosinophils validated in asthma by recent successes



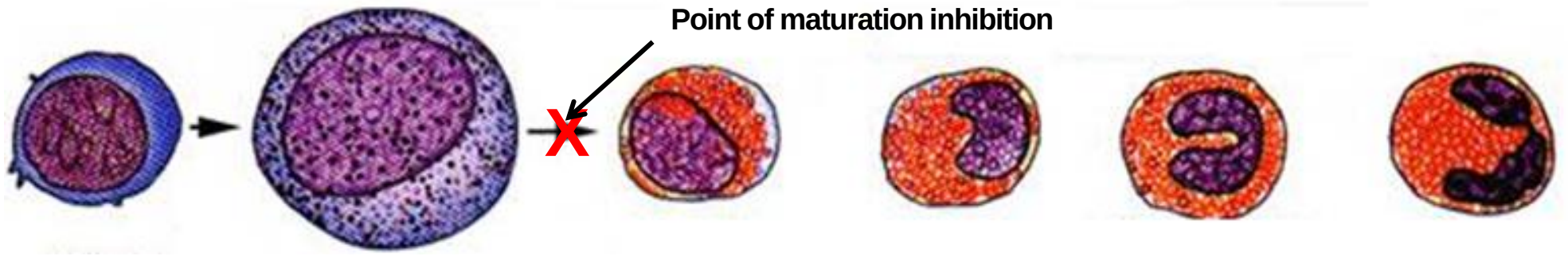
MoA	Molecule	↓ Blood Eos	↓ Exacerbations
EMI	Dexpramipexole[6]	-80%, -94%	Ph. 3
IL-5/5R mAbs	Mepolizumab[3] (Nucala)	-86%	- 53%
	Benralizumab[4] (Fasenra)	-99%	- 51%
	Reslizumab[5] (Cinqair)	-92%	- 54%

1. Calhoun, JCI (1994)
2. Jackson, AJRCCM (2014)
3. Ortega, NEJM (2014)
4. Bleecker, Lancet, (2016)
5. Castro, Lancet Resp Med (2015); Cinqair product label
6. Phase 2: Asthma and CRSwNP

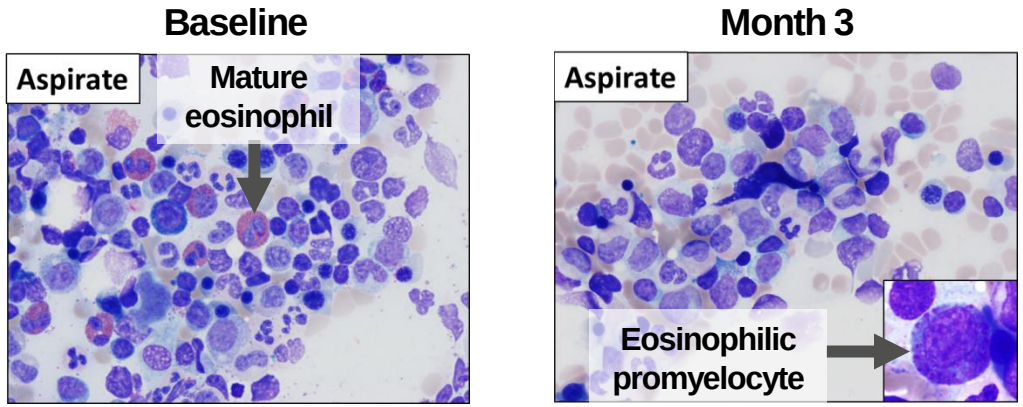
MoA: Lowers Eosinophils in blood and tissue

Dexpramipexole Inhibits Eosinophil Maturation prior to myelocyte stage

Less differentiated → *More differentiated*



- Effect limited to the eosinophil and basophil lineages
- Eosinophil-lowering kinetics consistent with eosinophil maturation inhibition
- Eosinophil maturation inhibition has been confirmed in CD34 derived eos culture system



Bone marrow aspirate from NIH HES trial showing effect of dexpramipexole on eosinopoiesis

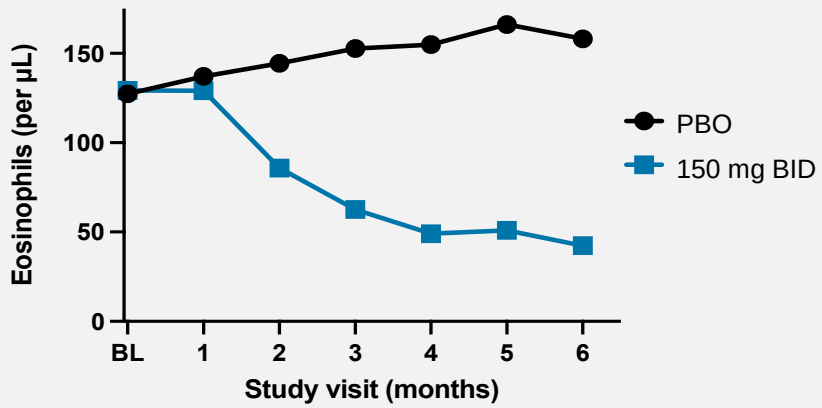
Source: Panch, Blood (2018).

Consistent efficacy

Potent and selective blood eosinophil lowering across multiple populations

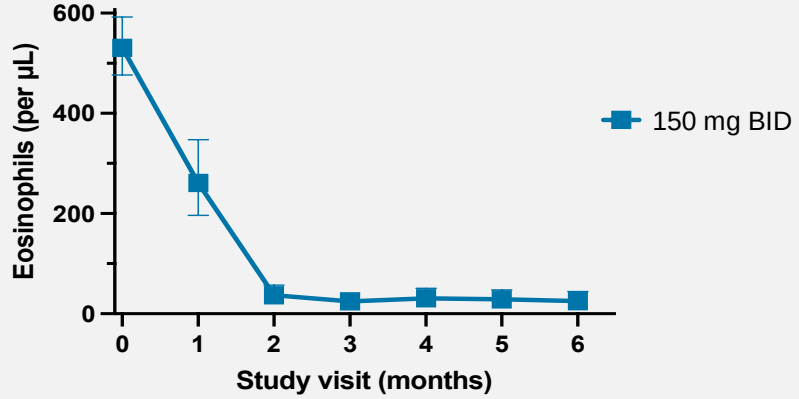
Phase 3 ALS (N=942)

p<0.001



Phase 2 CRSwNP* (N=20)

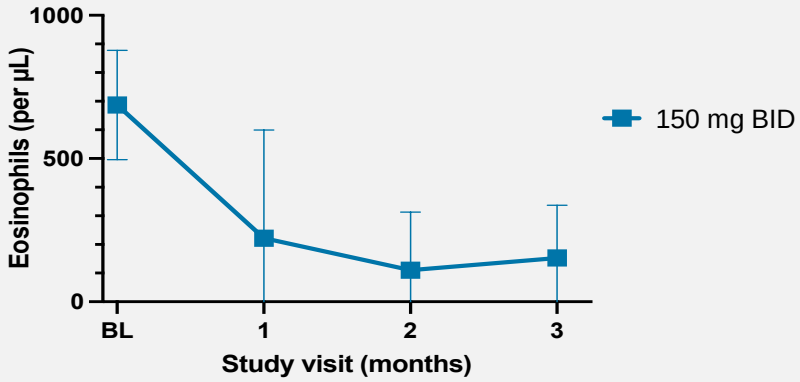
p<0.001



Chronic rhinosinusitis with nasal polyps (CRSwNP)

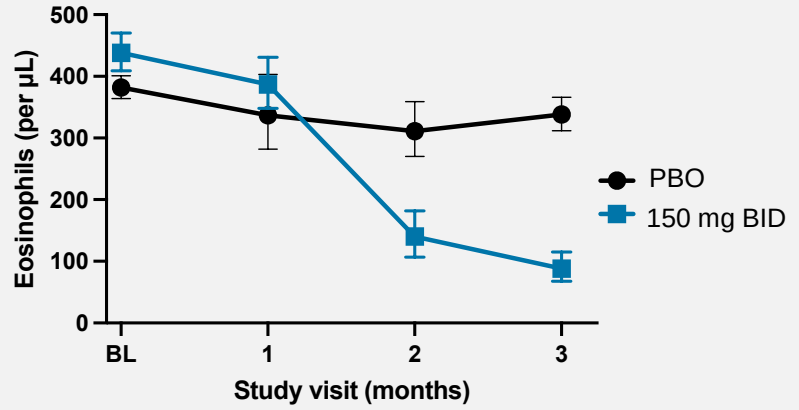
Phase 2 HES* (N=10)

p<0.03



Phase 2 asthma (N=103)

p<0.001

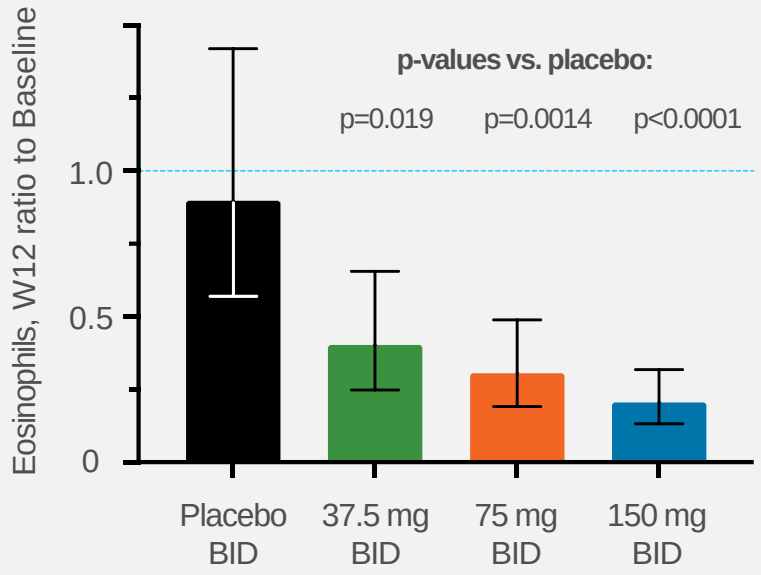


(1) *Open-label

EXHALE-1 Primary Outcome: Blood eosinophil reduction highly significant

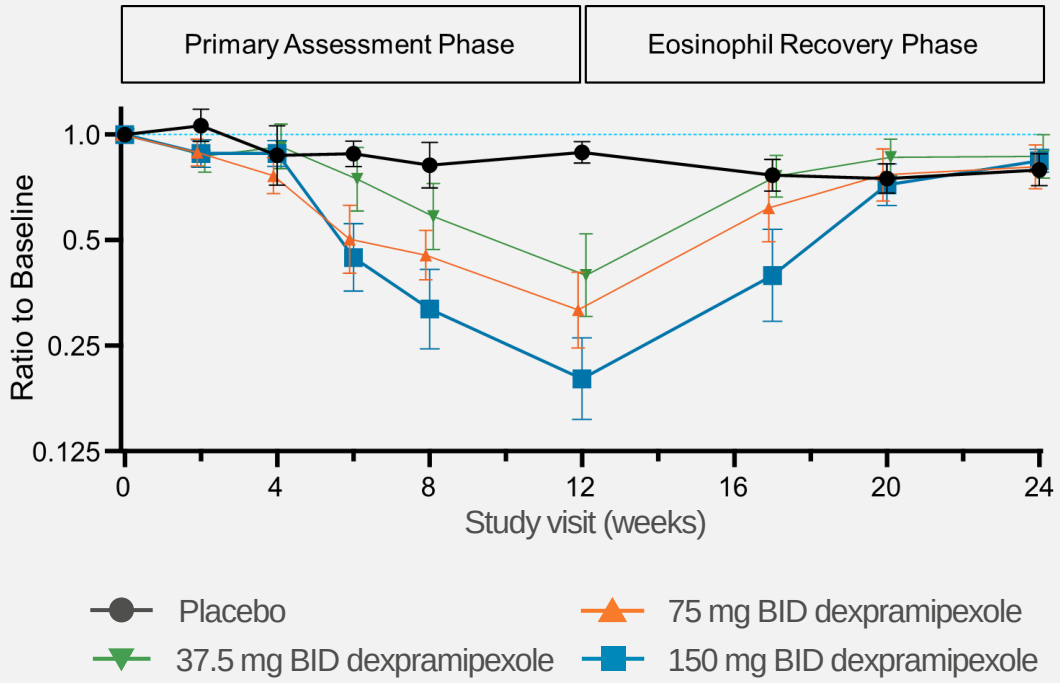
Clear dose response, with mepolizumab-like efficacy in 150 mg BID dose

Highly significant, ~80% eosinophil reduction vs. placebo with 150 mg BID dose



Week 12 log-linear dose response trend: p<0.0001

Recovery to baseline across all doses

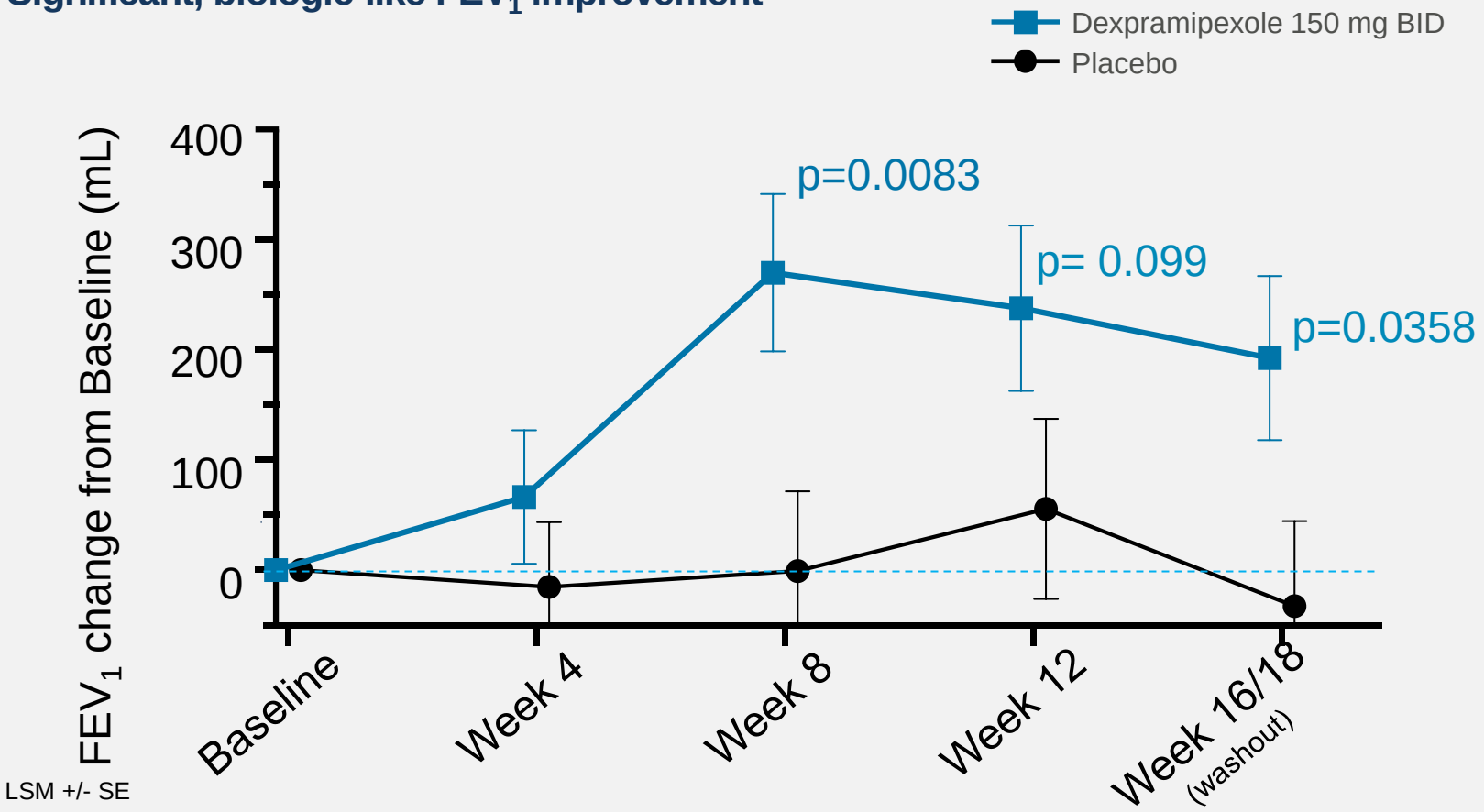


(1) N=103

EXHALE-1: Biologic-like efficacy in lung function improvement

IL-5-like FEV_1 improvement reinforces clinical benefit

Significant, biologic-like FEV_1 improvement



Results competitive with IL-5 mAbs

Eosinophil reduction and FEV_1 improvement predictive of exacerbation success in Ph. 3

Reinforces a differentiated target product profile

- Biologic-like efficacy
- First-to-market oral
- Well-tolerated (>1,300 Dex patients)

(1) N=103

EXHALE-1: Adverse events well balanced across treatment groups

Summary of TEAEs during the Primary Assessment Phase

	Placebo (N=27)	37.5 mg BID dexpramipexole (N=22)	75 mg BID dexpramipexole (N=26)	150 mg BID dexpramipexole (N=28)
	Number of subjects (%)	Number of subjects (%)	Number of subjects (%)	Number of subjects (%)
Overall	9 (33.3%)	7 (31.8%)	12 (46.2%)	12 (42.9%)
Serious (TESAE)	---	---	---	---
Leading to Discontinuation	1 (3.7%)	---	---	---
Leading to Death	---	---	---	---
Severity				
Mild	7 (25.9%)	4 (18.2%)	6 (23.1%)	8 (28.6%)
Moderate	5 (18.5%)	5 (22.7%)	8 (30.8%)	7 (25.0%)
Severe			2 (7.7%)	1 (3.6%)

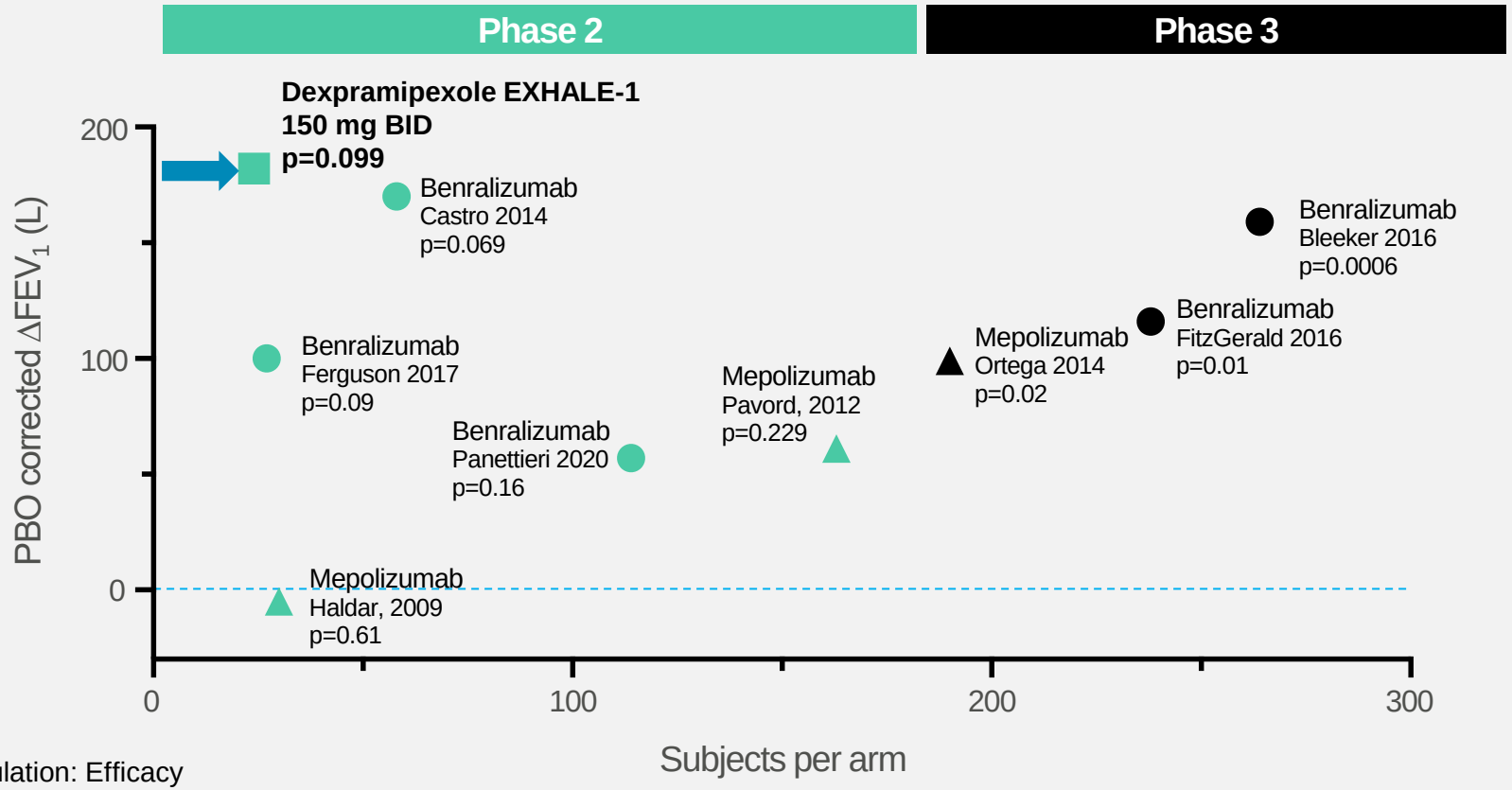
CSR Table 14.3.1-2

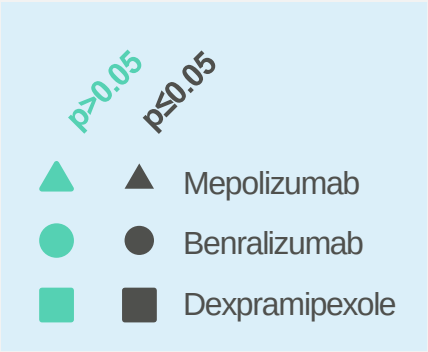
Note: N = number of subjects; % = percentage of subjects with an adverse event
Note: Severe AES were not treatment related as judged by study investigators
Note: TEAE = Treatment Emergent Adverse Events; TESAE = Treatment Emergent Serious Adverse Events

EXHALE-1: Biologic-like efficacy in lung function improvement

Lung function improvement consistent with mepolizumab and benralizumab

EXHALE-1 FEV_1 improvement in context of published IL-5 Ph. 2 and Ph. 3 results





*Data shown are for study arms corresponding to the approved dose**

Population: Efficacy
LSM +/- SE

*excluding Haldar, which used mepolizumab 750 mg I.V.

Veteran Development Team

Proven team led by industry veterans and development experts, guided by leading Asthma KoLs

Development team

Eric Bradford, MD
Chief Medical Officer

Led GSK IIL-5 Development programs for GSK Respiratory franchise

Calman Prussin, MD
Chief Scientific Officer

Led dexpramipexole Phase 2 asthma clinical trial, former senior investigator at NIH/NIAID and A&I expert

Peter Wijngaard
Chief Development Officer

Led inclisiran global development program at MedCo

Steve Yancey
Development team

Led GSK small molecule and biologic development programs at GSK, including IL-5 programs

Scientific Advisory Board

Ian Pavord
Professor,
Respiratory Medicine
University of Oxford, UK

Mona Bafadhel
Professor,
Chair Respiratory Medicine
Kings College London, UK

Roland Buhl
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Head Pulmonary Dept.
Mainz University, Germany

Dan Jackson
Professor, Allergy
Immunology & Rheumatology
University of Wisconsin, US

Michael Wechsler
Professor of Medicine
National Jewish Health, US

Salman Siddiqui
Professor, Respiratory Medicine
Imperial College London, UK
Via Imperial Consultants

Chris Brightling
Professor,
Respiratory Medicine
Univ. of Leicester, UK

EXHALE-4 and EXHALE-2 and 3: Asthma lung function and exacerbation studies

3 trials, 3,075 patients

Lung function

EXHALE-4: Change in Forced Expiratory Volume (FEV_1), Global
High eosinophil only (≥300/µL) | Inadequately controlled GINA 3/4/5 | FEV_1 <80% | ACQ ≥1.5

Screening	Treatment 24 Weeks	Follow up
5 weeks	N=750 → 75mg BID; 150mg BID; PBO BID	*4 weeks*

Exacerbation

EXHALE-2: Change in Asthma Exacerbation Rate (AER), NA/EU
High/Low eosinophil strata (2:1, ≥ 300/µL and < 300/µL) | Historical exacerbation rate of 2

Screening	Treatment 52 weeks	Follow up
4 weeks	N=1395 → 75mg BID; 150mg BID; PBO BID	*4 weeks*

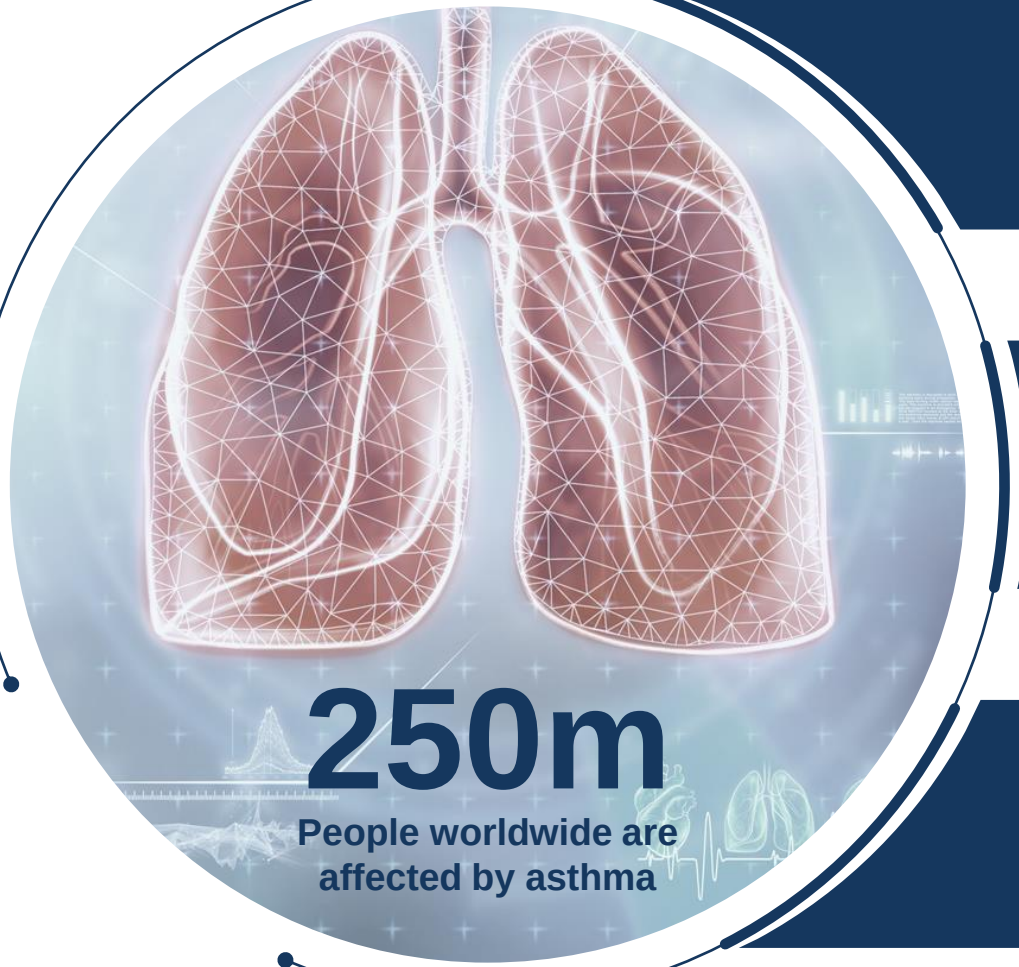
EXHALE-3: Change in Asthma Exacerbation Rate (AER), NA/LA/AP
High eosinophil only (≥300/µL) | Historical exacerbation rate of 2

Screening	Treatment 52 weeks	Follow up
4 weeks	N=930 → 75mg BID; 150mg BID; PBO BID	*4 week*

(1) Adolescents and Adults age 12 and up

Areteia Therapeutics: Advancing the first-ever oral therapy for eosinophilic asthma

Key takeaways



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