

# Driving Long-Term Growth: IMDELLTRA™ Approval and Inflammation Update

May 20, 2024

**AMGEN**



# Safe Harbor Statement

This presentation contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), our acquisitions of Teneobio, Inc., ChemoCentryx, Inc., or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, any potential strategic benefits, synergies or opportunities expected as a result of such acquisition, and any projected impacts from the Horizon acquisition on our acquisition-related expenses going forward), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems on our business, outcomes, progress, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this presentation and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

# Agenda



## Murdo Gordon

Exec. VP, Global Commercial Operations, Amgen  
*Opening • IMDELLTRA™*



## Jay Bradner, MD

Exec. VP, Research & Development, Amgen  
*IMDELLTRA™ • Inflammation Strategy • Rocatinlimab • Conclusion*



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Sr. VP, Global Development Oncology, Amgen  
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Sr. VP, Global Marketing, Access Capabilities, Amgen  
*TEZSPIRE®*



## Primal Kaur, MD

VP, Global Development, Inflammation, Amgen  
*TEZSPIRE® • AMG 104*

The AMGEN logo in white, bold, uppercase letters, set against a dark blue background.

# Four Therapeutic Area Pillars Driving Long-term Growth

GENERAL  
MEDICINE



ONCOLOGY



INFLAMMATION



RARE DISEASE



Marketed Products  
Innovative Pipeline  
Biosimilars



IMDELLTRA™ for Patients with  
Advanced Small Cell Lung Cancer

# IMDELLTRA™ Approved for the Treatment of Adult Patients with Extensive Stage SCLC with Disease Progression On or After Platinum-Based Chemotherapy

- First highly selective mechanism of action in SCLC
- First medicine with clinically meaningful and unprecedented efficacy in advanced ES-SCLC\*
  - 40% overall response rate\*
  - 9.7 month median duration of response\*
  - 14.3 month median overall survival\*
- First bispecific T-cell engager therapy for a major solid tumor
- Rapidly advancing into earlier treatment lines with robust clinical development program



SCLC, small cell lung cancer; ES-SCLC, extensive-stage small cell lung cancer.

\*Based on results from the Phase 2 DeLLphi-301 clinical trial that evaluated IMDELLTRA™ in patients with SCLC who had failed two or more prior lines of treatment.

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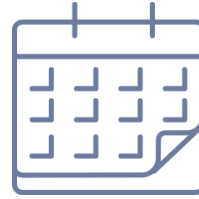


# Patients with SCLC are at Risk for Rapid Disease Progression<sup>1</sup>

**2/3** 

of patients with SCLC are diagnosed with **EXTENSIVE-STAGE** disease<sup>2</sup>

**7%**



**5-YEAR SURVIVAL RATE**  
for patients with  
invasive disease<sup>3,\*</sup>

**≥ 75%**



of patients with  
SCLC **EXPERIENCE**  
**DISEASE PROGRESSION**<sup>1</sup>

SCLC, small cell lung cancer; SEER, Surveillance, Epidemiology, and End Results.

\*Based on SEER 9 in patients diagnosed with invasive small cell cancer of the lung and bronchus between 2010 and 2016.<sup>3</sup>






**1.** Rudin CM, et al. *Nat Rev Dis Primers*. 2021;7:3. **2.** Sabari JK, et al. *Nat Rev Clin Oncol*. 2017;14:549-561. **3.** National Cancer Institute. [www.cancer.gov](http://www.cancer.gov). Accessed March 26, 2024.

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# World Overall Survival in ES-SCLC is Poor Across Geographies

Median Real World Overall Survival (95% CI) in months					
					
<b>1L</b>	8.1 (7.9–8.2) n=4308	8.1 (7.9–8.2) n=14700	8.6 (8.2–9.0) n=1526	11.3 (9.7–12.2) n=343	8.4 (8.1–8.7) n=2237
<b>2L</b>	4.8 (4.5–5.1) n=1822	5.6 (5.3–5.8) n= 3220	5.6 (4.9–6.2) n= 589	6.9 (6.3–7.9) n= 202	4.9 (4.5–5.4) n=981
<b>3L</b>	4.1 (3.7–4.6) n= 680	5.0 (4.7–5.5) n=640	4.5 (4.0–5.1) n=213	5.1 (3.9–5.8) n=97	4.4 (3.9–5.5) n=349

1L, front-line; 2L, second line; 3L, third-line; 95% CI, 95% confidence interval; SCLC, small cell lung cancer; ES-SCLC, extensive stage small cell lung cancer; RWE, real-world evidence.

**Methods:** Kaplan Meier curves were regenerated using Engauge Digitizer Software. Final combined graph was generated in R with standard ggplot package.

**References:** Mark Mitchell, Baurzhan Muftakhidinov and Tobias Winchen et al, "Engauge Digitizer Software." Webpage: <http://markummitchell.github.io/engauge-digitizer>, Last Accessed: February 6, 2024

Amgen sponsored RWE studies: United States (Study 20220192); United Kingdom (20220199); Spain (20230020); South Korea (20230021); Taiwan (20210117)

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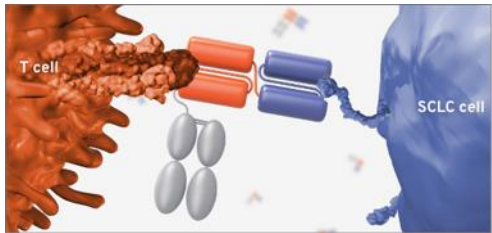


# The First and Only DLL3-Targeting BiTE<sup>®</sup> Therapy that Activates the Patient's Own T-Cells to Attack DLL3-Expressing Cells<sup>1</sup>



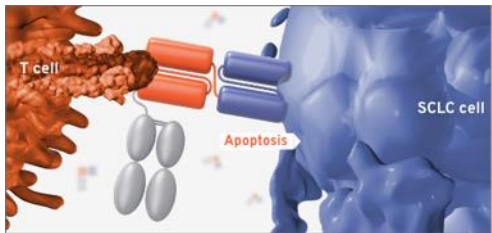
## TARGET

IMDELLTRA™ targets the DLL3 antigen while simultaneously engaging the patient's own T-cells through the CD3 antigen<sup>1</sup>



## ACTIVATE

The binding of IMDELLTRA™ results in the formation of a synapse between T-cells and DLL3-expressing cells, including tumor cells, leading to T-cell activation<sup>1</sup>



## ATTACK

The activated T-cells cause release of inflammatory cytokines and lysis of DLL3-expressing cells<sup>1,\*</sup>

~ 85%–96% of patients

with SCLC express **DLL3**<sup>2,3,†,‡</sup>

**DLL3 testing is not required** for treatment with IMDELLTRA™<sup>1</sup>

BiTE<sup>®</sup>, Bispecific T-cell Engager; CD, cluster of differentiation; DLL3, delta-like ligand 3; ES-SCLC, extensive-stage small cell lung cancer; SCLC, small cell lung cancer.

\*IMDELLTRA™ had anti-tumor activity in mouse models of SCLC.<sup>1</sup> <sup>†</sup>Based on a multicenter, international, noninterventional study of 1,050 patients with SCLC, with 1 specimen and evaluable DLL3 expression. DLL3 positivity was based on immunohistochemistry staining with ≥ 25% of tumor cells that expressed DLL3. DLL3 staining defined as present if tumor cells showed punctate and/or diffuse cytoplasmic and/or partial or circumferential membranous staining.<sup>2</sup>

<sup>‡</sup>Based on the DeLLphi-301, phase 2, open-label study of 157 patients with ES-SCLC and an evaluable tumor-tissue sample. 151 out of 157 patients were DLL3-positive (96%). DLL3 expression was defined as detection of expression on more than 0% of tumor cells.<sup>3</sup>

1. IMDELLTRA™ (tarlatamab-dlle) prescribing information, Amgen. 2. Rojo F, et al. *Lung Cancer*. 2020;147:237-243. 3. Ahn M-J, et al. *N Engl J Med*. 2023;389:2063-2075.

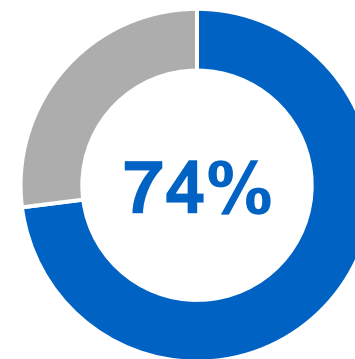
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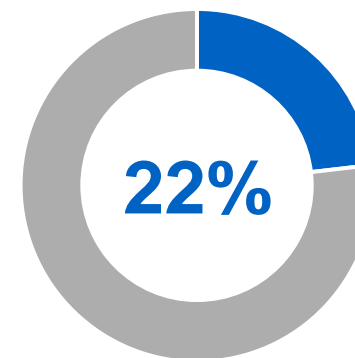
# IMDELLTRA™ was Studied in Heavily Pretreated Patients with Poor Prognoses

Age	
Median, years (min, max)	64 (35, 82)
≥ 65 years, n (%)	48 (48.0)
≥ 75 years, n (%)	10 (10.0)
Sex, n (%)	
Male	71 (72.0)
Race, n (%)	
Asian	41 (41.0)
White	57 (58.0)
Hispanic or Latino	1 (1.0)
ECOG status, n (%)	
0	26 (26.0)
1	73 (74.0)
Metastatic at baseline, n (%)	
Yes	96 (97.0)
No	3 (3.0)

Brain metastases at baseline, n (%)	
Yes	22 (22.0)
No	77 (78.0)
Prior therapy, n (%)	
Prior platinum-based chemotherapy	99 (100)
Prior topoisomerase I inhibitor therapy	50 (51.0)
Prior anti-PD-L(1) therapy	73 (74.0)
Smoking history at baseline, n (%)	
Never	8 (8.0)
Former/Current	91 (92.0)



received prior anti-PD-(L)1 therapy



had brain metastases

BICR, blinded independent central review; ECOG, Eastern Cooperative Oncology Group; PD-L1, programmed cell death ligand.

\*Based on patients in the study who received at least 1 dose of IMDELLTRA™ 10 mg and had measurable disease at baseline per BICR.

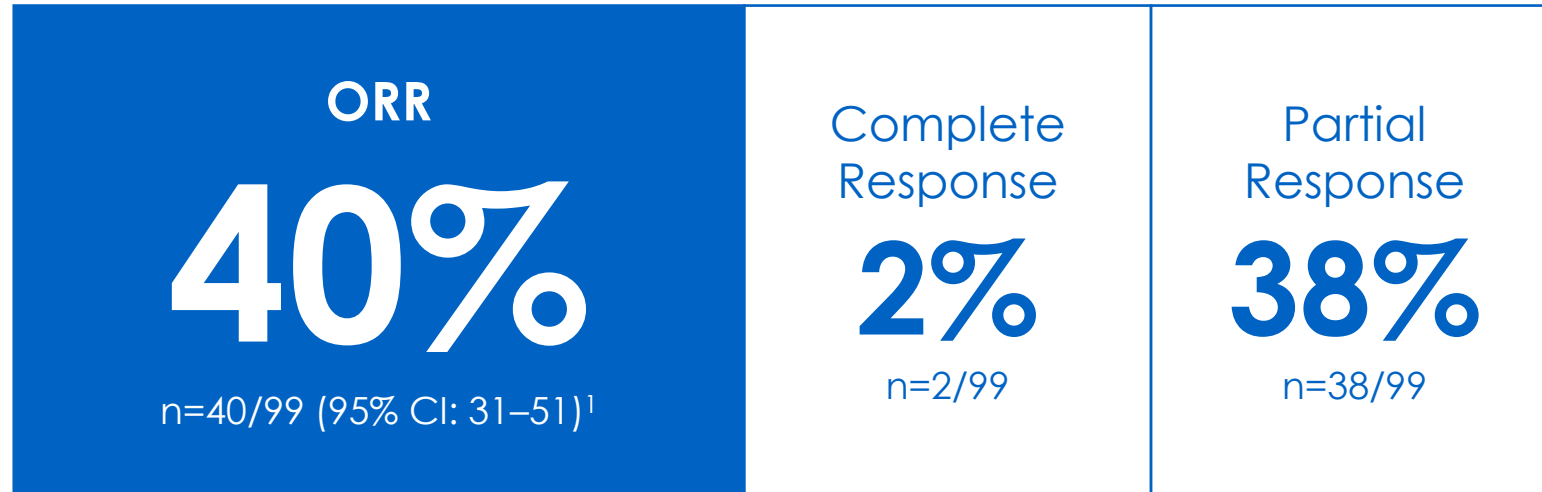
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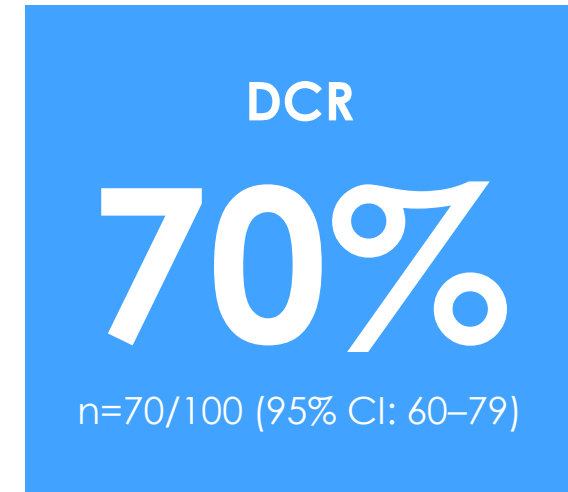
# IMDELLTRA™ Showed Durable Efficacy in Patients with ES-SCLC<sup>1</sup>

## Primary Endpoint: ORR<sup>1,2,\*,†</sup>



Median time to objective response was 1.4 months (1.1–2.8 months)<sup>2,‡</sup>

## Secondary Endpoint: DCR<sup>2,‡</sup>



Median follow-up was 10.6 months<sup>2</sup>

BICR, blinded independent central review; CI, confidence interval; DCR, disease control rate; ES-SCLC, extensive-stage small cell lung cancer; ORR, overall response rate.

\*Assessed by BICR.<sup>1</sup> †Based on 99 patients in the DeLLphi-301 study who received at least 1 dose of IMDELLTRA™ 10 mg and had measurable disease at baseline per BICR.<sup>1</sup>

‡Based on 100 patients who were assigned to receive IMDELLTRA™ 10 mg in the DeLLphi-301 study (intention-to-treat population).<sup>2</sup>

**1.** IMDELLTRA™ (tarlatamab-dlle) prescribing information, Amgen. **2.** Ahn M-J, et al. *N Engl J Med.* 2023;389:2063-2075.

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# IMDELLTRA™, the Majority of Patients (68%) Responded for ≥ 6 Months, and 40% Were Still Responding at 1 Year<sup>1,\*,\dagger</sup>

Secondary endpoint: mDOR<sup>1,2,\*,\dagger,\S</sup>

**Median DOR (mDOR)**  
**9.7 months**  
(2.7–20.7+ months)

Patients whose response continued at:

≥ 6 months **68%<sup>\dagger</sup>**

≥ 12 months **40%<sup>\dagger</sup>**

BICR, blinded independent central review; DOR, duration of response.

\*Based on 40 patients in the DeLLphi-301 study who received at least 1 dose of IMDELLTRA™ 10 mg, had measurable disease at baseline per BICR, and responded to treatment.<sup>1</sup>

<sup>\dagger</sup>Based on observed duration of response.<sup>1</sup> <sup>\S</sup>Assessed by BICR.<sup>1</sup> <sup>\S</sup>Based on Kaplan-Meier estimate.<sup>1</sup>

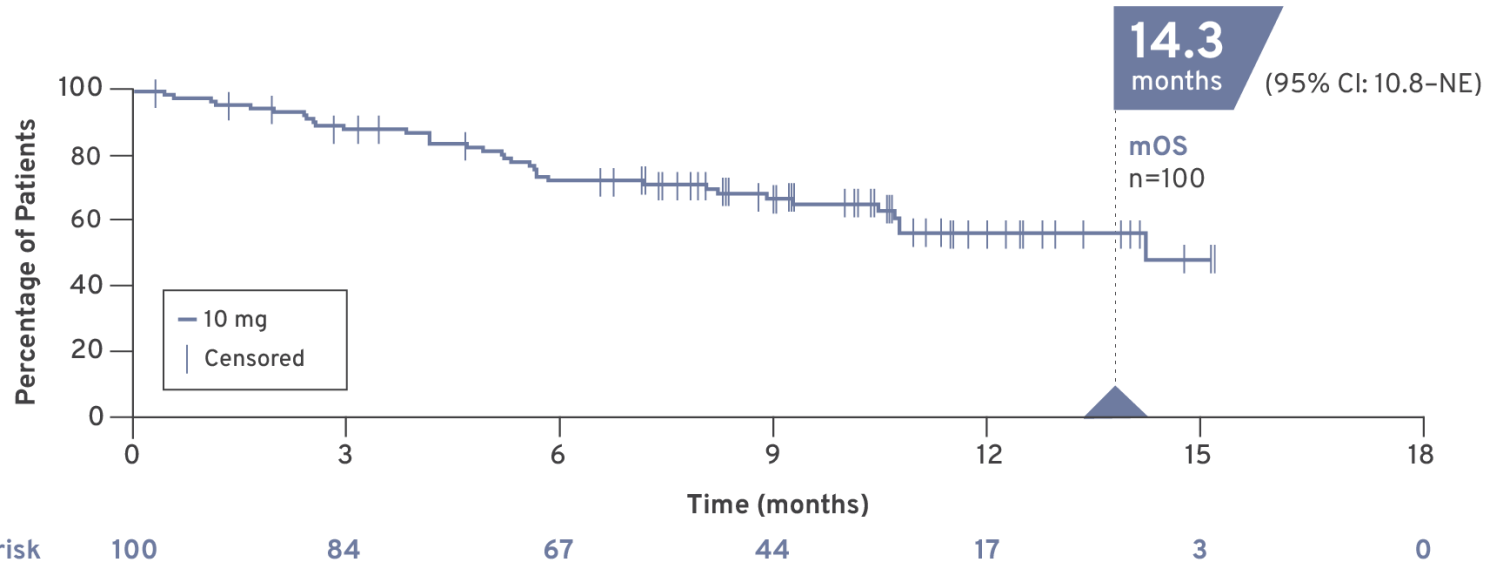
<sup>1</sup> IMDELLTRA™ (tarlatamab-dlle) prescribing information, Amgen. <sup>2</sup> Ahn M-J, et al. *N Engl J Med.* 2023;389(suppl):2063-2075.

<sup>1,2</sup> Provided May 20, 2024, as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.



# Median OS was 14.3 Months with IMDELLTRA™

## Secondary endpoint: Median OS\*



Median follow-up was 10.6 months

Patients received IMDELLTRA™ 1 mg on Day 1 followed by 10 mg thereafter.

**Treatment effects for this study on time-based endpoints, such as PFS and OS, can be difficult to interpret in the absence of a comparator arm.**

CI, confidence interval; mOS, median overall survival; NE, not evaluable; OS, overall survival; PFS, progression-free survival.

\*Based on 100 patients who were assigned to receive IMDELLTRA™ 10 mg in the DeLLphi-301 study (intention-to-treat population).

Ahn M-J, et al. *N Engl J Med.* 2023;389:2063-2075.

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# IMDELLTRA™ Safety and Tolerability was Evaluated in 187 Patients with ES-SCLC\*

## Adverse reactions occurring in ≥ 15% of patients†

Adverse Reaction	IMDELLTRA™ (n=187)	
	Any Grade (%)	Grade 3 or 4 (%)
CRS‡	55.0	1.6
Fatigue§	51.0	10.0
Pyrexia	36.0	0.0
Dysgeusia	36.0	0.0
Decreased appetite	34.0	2.7
Musculoskeletal pain**	30.0	1.1
Constipation	30.0	0.5
Anemia	27.0	6.0
Nausea	22.0	1.6
Dyspnea††	17.0	2.1
Cough	17.0	0.0

- The most common adverse reactions in patients (> 20%) were CRS, fatigue, pyrexia, dysgeusia, decreased appetite, musculoskeletal pain, constipation, anemia, and nausea\*
- Permanent discontinuation of IMDELLTRA™ due to adverse reactions occurred in 7% of patients\*
- Dosage interruptions of IMDELLTRA™ due to adverse reactions occurred in 27% of patients. Adverse reactions that required dosage interruptions in ≥ 2% of patients included fatigue (3.2%), CRS (2.7%), and respiratory tract infection (2.1%)\*

CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; ES-SCLC, extensive-stage small cell lung cancer; Q2W, every 2 weeks.

\*Based on the pooled safety population of 187 patients enrolled in DeLLphi-300 and DeLLphi-301 who received IMDELLTRA™ 1 mg on Cycle 1 Day 1 followed by 10 mg on Days 8, 15, and then Q2W until disease progression or intolerable toxicity. †Graded using CTCAE Version 4.0 and Version 5.0. ‡Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019. §Includes fatigue and asthenia. \*\*Includes myalgia, arthralgia, back pain, pain in extremity, neck pain, musculoskeletal chest pain, non-cardiac chest pain, and bone pain. ††Includes dyspnea and exertional dyspnea.

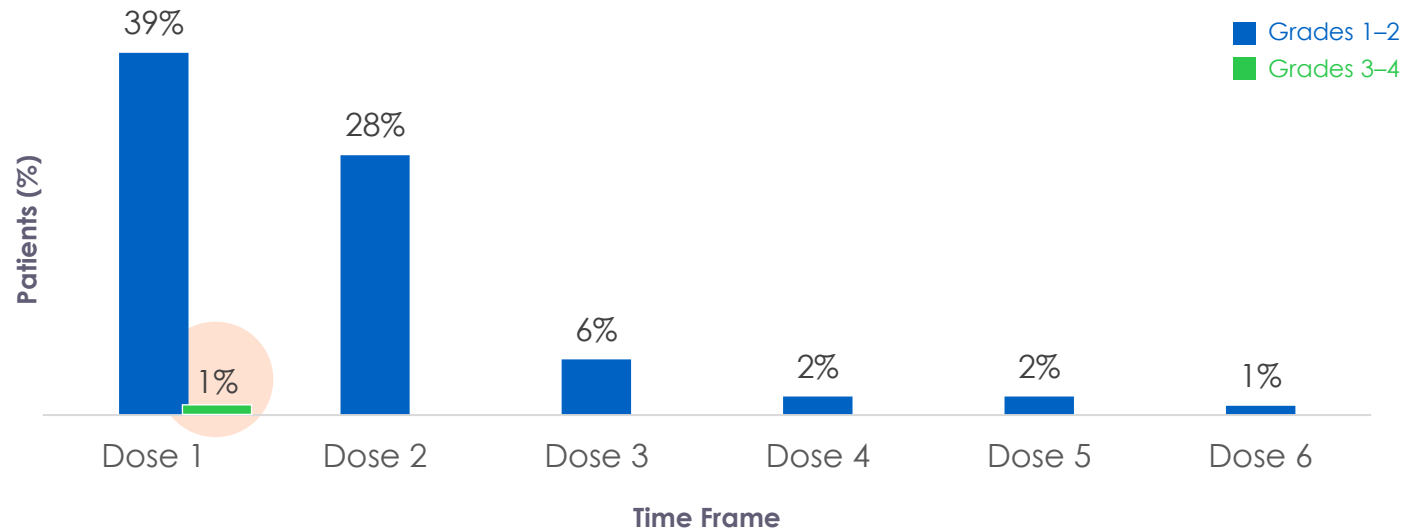
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# IMDELLTRA™<sup>1\*</sup>, Less than 1% Grade 3–4 CRS Mainly Associated with First Dose

CRS events across treatment doses in the DeLLphi-301 study<sup>2,†</sup>



In the DeLLphi-300 and DeLLphi-301 pooled safety population, most events (43%) of CRS occurred after the first dose, with 29% of patients experiencing any Grade CRS after the second dose and 9% following the third dose or later. Following the Day 1, Day 8, and Day 15 infusions, 16%, 4.3%, and 2.1% of patients experienced  $\geq$  Grade 2 CRS, respectively.<sup>1,\*</sup>

## Pooled Safety Analysis:

- 34% (n=64/187), 19% (n=36/187), 1.1% (n=2/187), and 0.5% (n=1/187) of patients experienced Grade 1, 2, 3, and 4 CRS, respectively<sup>1,\*</sup>
- Recurrent CRS occurred in 24% of patients treated with IMDELLTRA™, including 18% Grade 1 and 6% Grade 2<sup>1,\*</sup>

CRS, cytokine release syndrome; Q2W, every 2 weeks.

\*Based on the pooled safety population of 187 patients enrolled in DeLLphi-300 and DeLLphi-301 who received IMDELLTRA™ 1 mg on Cycle 1 Day 1 followed by 10 mg on Days 8, 15, and then Q2W until disease progression or intolerable toxicity.<sup>1</sup> †Based on 133 patients who received IMDELLTRA™ 10 mg in the DeLLphi-301 study.<sup>2</sup>

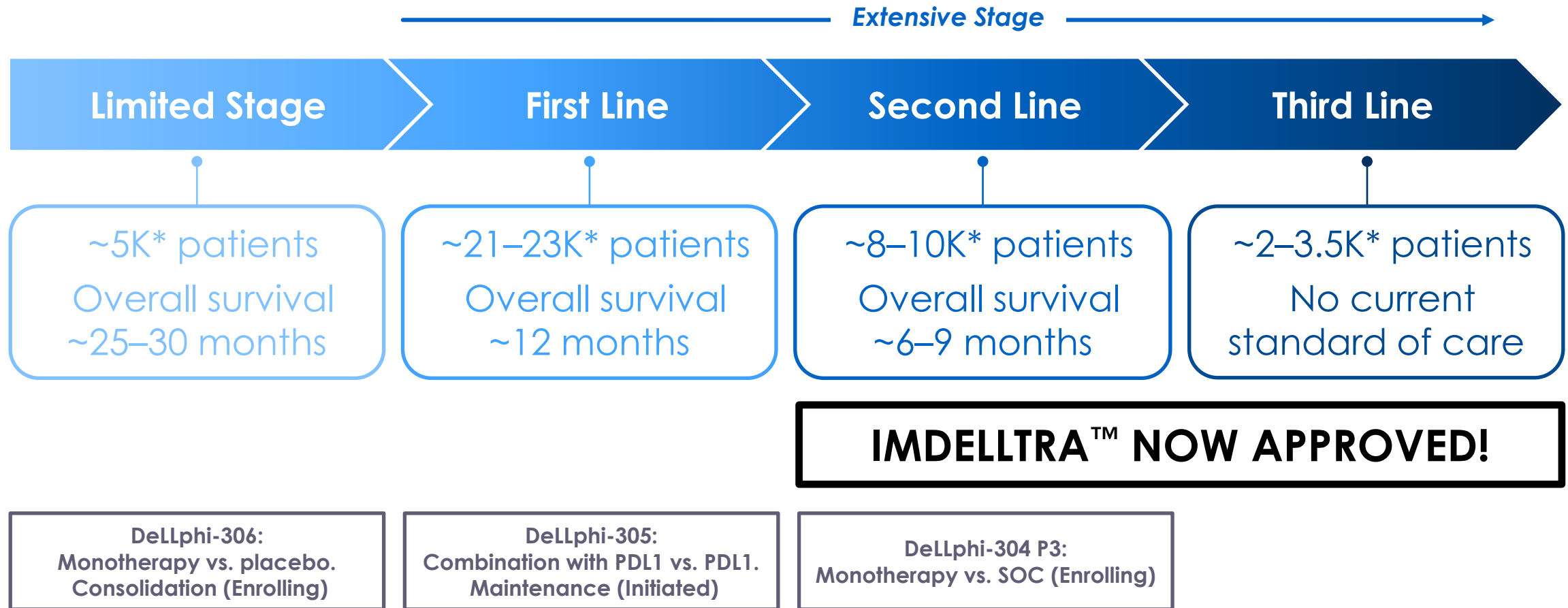
1. IMDELLTRA™ (tarlatamab-dlle) prescribing information, Amgen. 2. Ahn M-J, et al. *N Engl J Med*. 2023. doi:10.1056/NEJMoa2307980.

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# Rapidly Advancing IMDELLTRA™ into Earlier SCLC Treatment Lines through Ongoing Clinical Development Program



SCLC, small cell lung cancer; PDL1, programmed death-ligand 1; SOC standard of care.  
\*U.S. Drug treated population

Drug Treated Patient share source: US new patient share based on IQVIA LAAD (Full year 2022); Treated: Envida.  
Based on Drug Tx rate ~80% from Cerner (CfOR 2023) – A proportion of patients undergo surgery, radiotherapy.  
Source: CfOR Epi Forecast for CTRS, 2020 | Tx Rate (2022 → 2030): 1L: 75% → 85%; 2L: 75% → 85%; 3L: 65% → 70%.



# Advancing IMDELLTRA™ Into Community Centers will Provide Broad Access to Patients with SCLC

Early Adoption and Focus on Academic/Regional Centers;  
Rapidly Scale BiTE® Capability for Adoption in the Community



**ACADEMIC/REGIONAL CENTERS**



**COMMUNITY CENTERS**

**% of SCLC Patients Treated Today**

30%

70%

**Level of Experience with Novel Therapies**

High

Low

**Adoption**

More Rapid

More Gradual

Drive broad clinical conviction, provide education to build confidence with the safety profile, and provide operational support to adopt IMDELLTRA™

SCLC, small cell lung cancer; BiTE®, bispecific T-cell engager.

Sources: 1. Sabari JK, et al. Nat Rev Clin Oncol. 2017;14:549-561. 2. Cerner Enviza – CancerMPact® Report | CfOR 2021 validated epidemiology for US. 3. National Cancer Institute SEER Cancer Statistics Review (CSR) 1975-2017, Based on SEER 9 in patients with invasive small cell cancer of the lung and bronchus. 4. 5-year relative survival for patients with invasive small cell cancer of the lung and bronchus diagnosed from 2010 to 2016. Based on SEER 9 in patients with invasive small cell cancer of the lung and bronchus.

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- First medicine with clinically meaningful and unprecedented efficacy in advanced ES-SCLC\*
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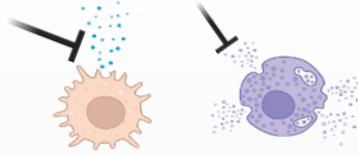
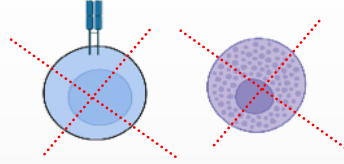
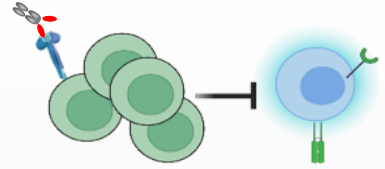
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# Inflammation Strategy

# We are Building Our Early Portfolio through a Differentiated Discovery Research Strategy Built on Four Dimensions





	<b>REPAIR/REMODEL</b> Epithelial barriers	<b>BLOCK</b> Cytokines, monoamines	<b>DEplete</b> Pathogenic cells	<b>TOLerize</b> Expand Tregs
				
<b>OBJECTIVE</b>	Promote epithelial repair and remodeling	Block key signaling pathways driving inflammation	Selectively eliminate pathogenic cells and achieve sustained immune suppression	Expand regulatory T-cells for immune suppression and a curative therapy
<b>APPROACH</b>	Combine immune-suppression and regenerative therapies	Transcription factor degraders	Bispecific antibodies for increased precision	Unique tolerance platforms

# We are Focusing on Difficult-to-treat Diseases with High Unmet Need

	<b>Respiratory</b>	Asthma	Chronic Obstructive Pulmonary Disease	Chronic Rhinosinusitis with Nasal Polyps	
	<b>Dermatology</b>	Psoriasis	Atopic Dermatitis	Prurigo Nodularis	Palmoplantar Pustulosis
	<b>Gastroenterology</b>	Ulcerative Colitis	Eosinophilic Esophagitis	Non-responsive Celiac Disease	
	<b>Rheumatology</b>	Psoriatic Arthritis	Rheumatoid Arthritis	Behçet's Disease	

# Broad Portfolio of Inflammation Products\*

 Today's Focus

	Phase 1	Phase 2	Phase 3	Pre-launch	Launched
RESP	<p><b>AMG 104</b> (anti-TSLP inhaled Fab) P2 trial initiation expected in 2024</p>	<p><b>TEZSPIRE® (anti-TSLP mAb)</b> Chronic obstructive pulmonary disease (COPD)</p> <p><b>Rocatinlimab (anti-OX40 mAb)</b> Asthma P2 trial initiated</p>	<p><b>TEZSPIRE® (anti-TSLP mAb)</b> Chronic rhinosinusitis with nasal polyps Data expected in H2'24</p>		 <p><b>TEZSPIRE®</b> (tezepelumab-ekko) Subcutaneous injection 210 mg</p>
DERM			<p><b>Rocatinlimab (anti-OX40 mAb)</b> Atopic dermatitis ongoing Prurigo nodularis P3 planned '24</p> <p><b>Otezla® (apremilast, PDE4i)</b> Palmoplantar pustulosis Pediatric indications<sup>2</sup></p>	<p><b>WEZLANA™<sup>1</sup></b> (anti-IL-12/IL-23 mAb) Interchangeability</p> <p><b>AMJEVITA® (anti-TNF mAb)</b> Interchangeability</p>	 <p><b>Enbrel</b> (etanercept) <b>AMGEVITA™</b> (adalimumab) <b>Otezla®</b> (apremilast) 30mg tablets <b>AVSOLA™</b> (infliximab-axxq) For injection 100mg/5mL</p>
GI		<p><b>Efavaleukin alfa (IL-2 mutein)</b> Ulcerative colitis</p> <p><b>Ordesekimab (anti-IL-15 mAb)</b> Non-responsive celiac disease</p>	<p><b>TEZSPIRE® (anti-TSLP mAb)</b> Eosinophilic esophagitis</p>	<p><b>WEZLANA™<sup>1</sup></b> (anti-IL-12/IL-23 mAb) Interchangeability</p> <p><b>AMJEVITA® (anti-TNF mAb)</b> Interchangeability</p>	 <p><b>AMGEVITA™</b> (adalimumab) <b>AVSOLA™</b> (infliximab-axxq) For injection 100mg/5mL</p>
RHEUM				<p><b>WEZLANA™<sup>1</sup></b> (anti-IL-12/IL-23 mAb) Interchangeability</p> <p><b>AMJEVITA® (anti-TNF mAb)</b> Interchangeability</p>	 <p><b>Enbrel</b> (etanercept) <b>AMGEVITA™</b> (adalimumab) <b>RIABNI</b> (infliximab-arrx) For injection 100mg/5mL <b>Otezla®</b> (apremilast) 30mg tablets <b>AVSOLA™</b> (infliximab-axxq) For injection 100mg/5mL</p>

TEZSPIRE® and AMG 104 (also known as AZD8630) are also being developed in collaboration with AstraZeneca. Rocatinlimab, formerly AMG 451/KHK4083, is being developed in collaboration with Kyowa Kirin. Ordesekimab is being developed in collaboration with Provention Bio, a Sanofi Company. For the purposes of the collaboration, Provention Bio conducts a clinical trial and leads certain development and regulatory activities for the program.

1. The FDA approved WEZLANA™ on 31 October 2023.

2. Includes pediatric indications in juvenile psoriatic arthritis and Behcet's disease.

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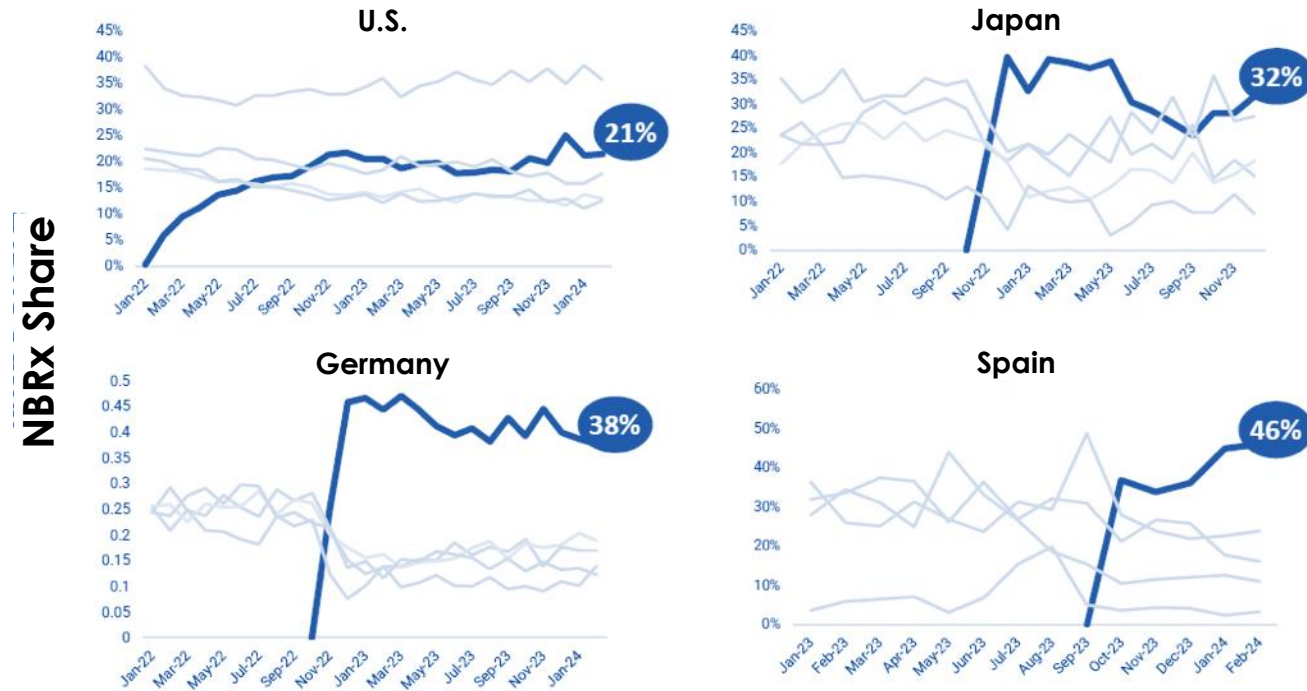




TEZSPIRE® For Chronic Obstructive  
Pulmonary Disease (COPD)

# Strong TEZSPIRE® Launch and Set to Lead in Severe Uncontrolled Asthma

Early launch success supports establishing TEZSPIRE® leadership in severe uncontrolled asthma



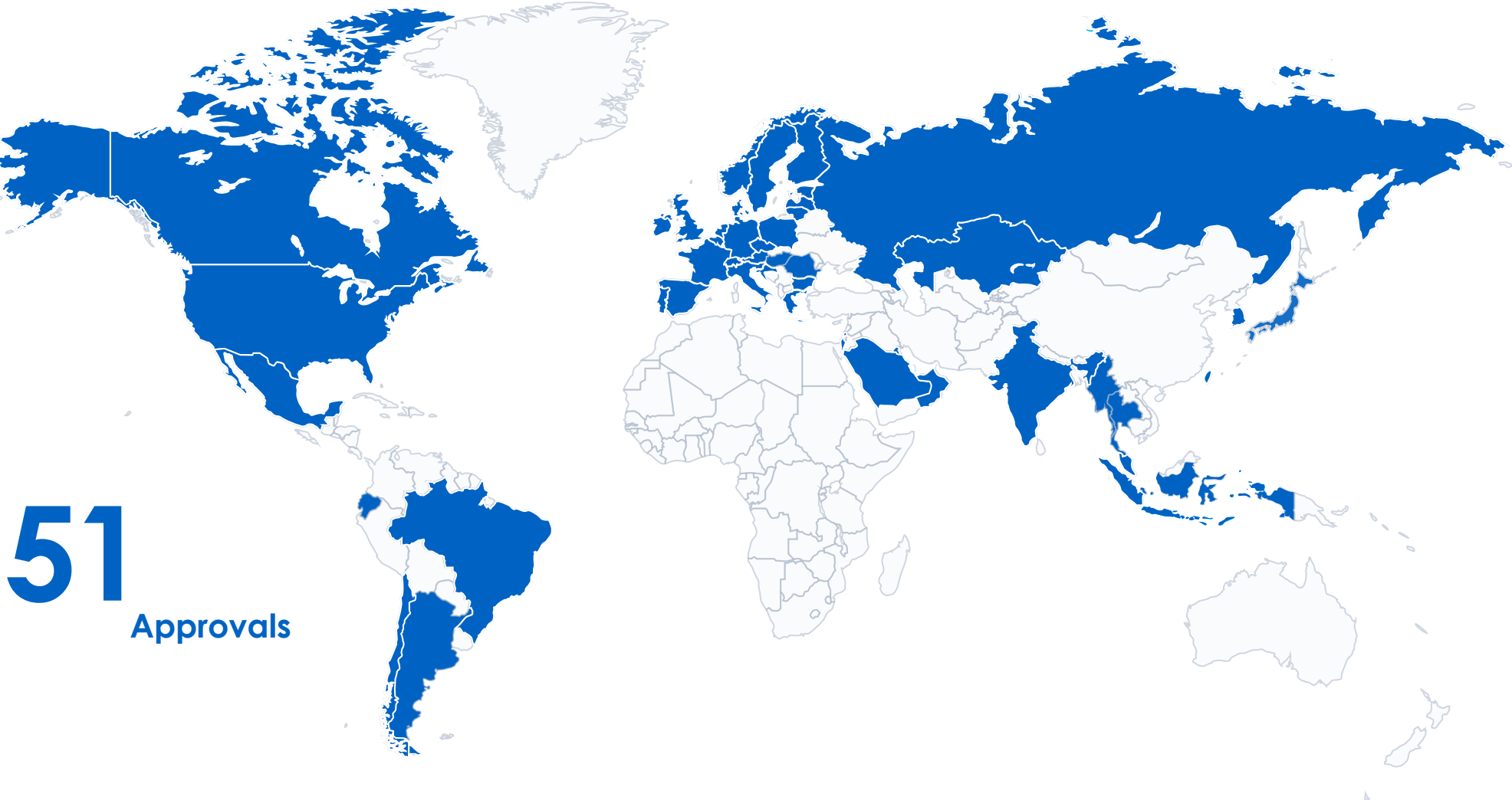
Expansion into new indications provides additional opportunities

Phase 3 Trials	Anticipated Data Readout
CRSwNP WAYPoint Ph3	2H '24
EoE CROSSING Ph3	2025+
COPD Pending Ph3	In Planning

NBRx, New-to-brand prescription; CRSwNP, chronic rhinosinusitis with nasal polyps; EoE, eosinophilic esophagitis; COPD, chronic obstructive pulmonary disease. TEZSPIRE® is being developed in collaboration with AstraZeneca. US: IQVIA Custom SOB, monthly NBRx share Jan 2024; Japan: IQVIA MDV, Nov 23; Germany: IQVIA LRx data 1/24 with AZ hospital up-projection; Spain: Telomera NBRx Jan 2024. 24 Provided May 20, 2024, as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.



# TEZSPIRE® is Reaching Patients Across the Globe



**51**  
Approvals

TEZSPIRE® is being developed in collaboration with AstraZeneca.  
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# High Disease Prevalence & Unmet Need in COPD

## Epidemiology

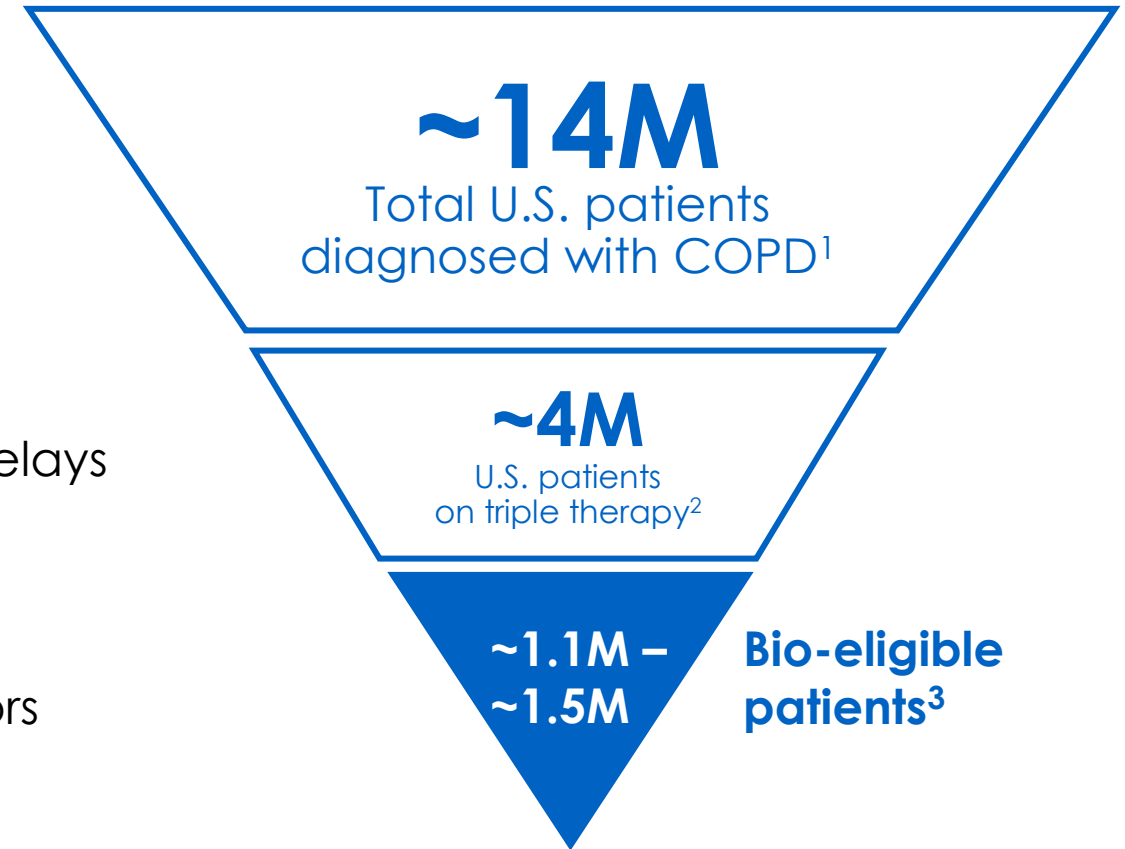
- COPD is the world's **third** leading cause of death
- **~65%** of bio-eligible patients have a BEC >150

## Patient Burden

- Severe symptoms, limited activities, long diagnostic delays

## Unmet Need

- Current SOC is focused on steroids and bronchodilators
- No approved biologic options



COPD, chronic obstructive pulmonary disease; BEC, blood eosinophil count; SOC, standard of care.

TEZSPIRE® is being developed in collaboration with AstraZeneca.

1. Source: CDC ([https://www.cdc.gov/mmwr/volumes/72/wr/mm7246a1.htm#:~:text=An%20estimated%2014.2%20million%20\(6.5.prevalence%20remained%20unchanged%20since%202011\)](https://www.cdc.gov/mmwr/volumes/72/wr/mm7246a1.htm#:~:text=An%20estimated%2014.2%20million%20(6.5.prevalence%20remained%20unchanged%20since%202011),)).

2. Source: Criner G et al. JHEOR. 2023;10(1):20-27.

3. Amgen internal estimate.

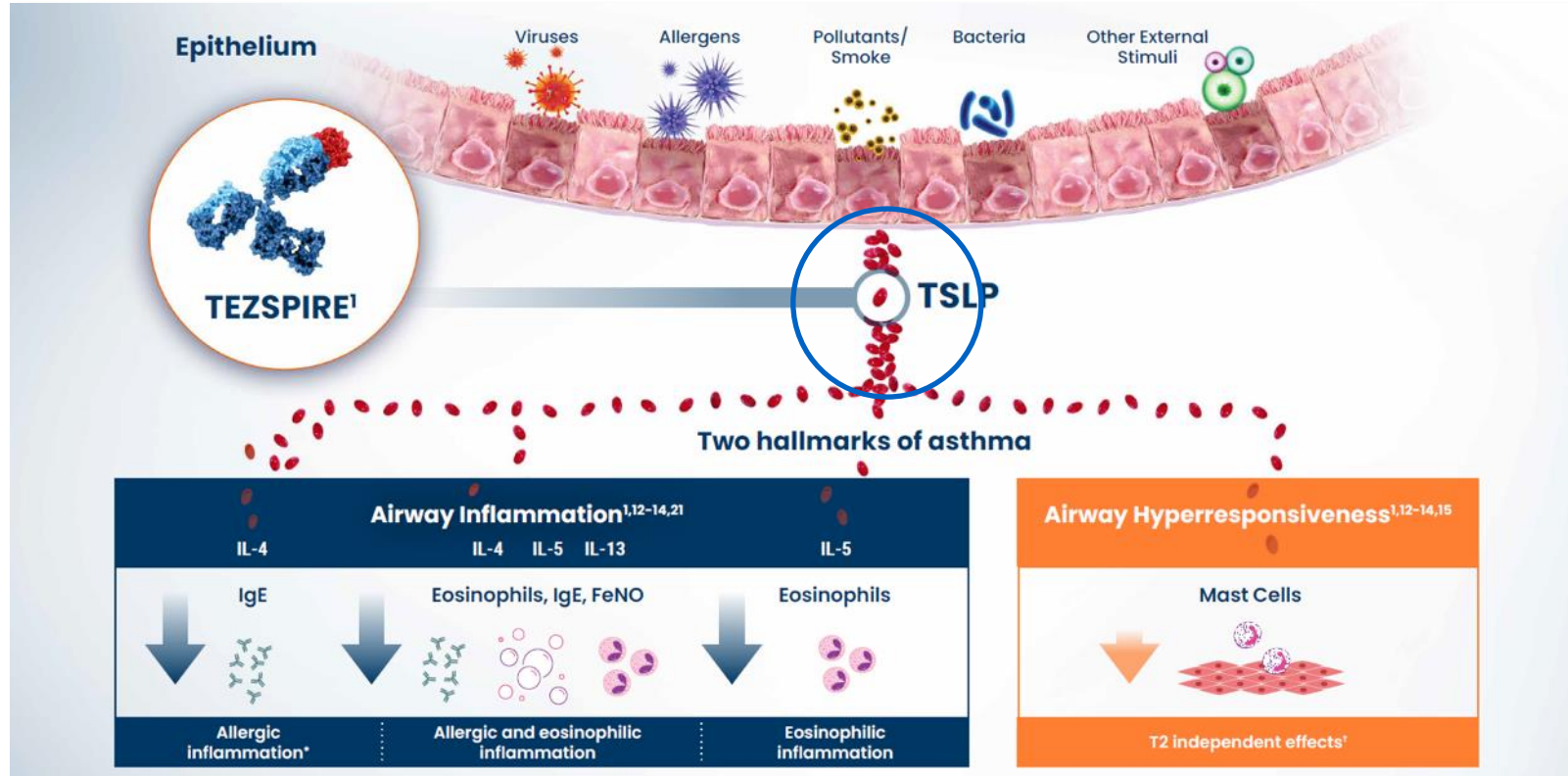
26 Provided May 20, 2024, as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.

**AMGEN**

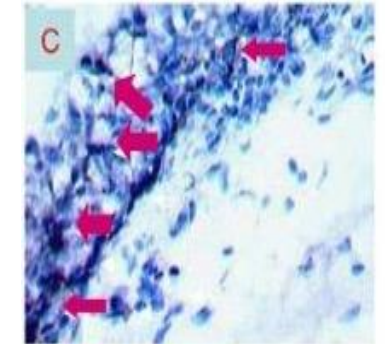
# Multiple Drivers and Triggers in Asthma are Similar to those in Chronic Obstructive Pulmonary Disease

Increased TSLP expression is reported in the airway of patients with COPD

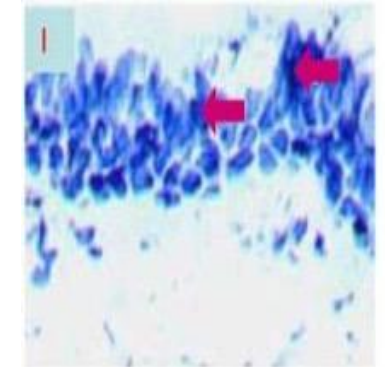
TSLP expression in bronchial biopsy sections



COPD



Normal



Ying et al, 2008. JI:181;2790

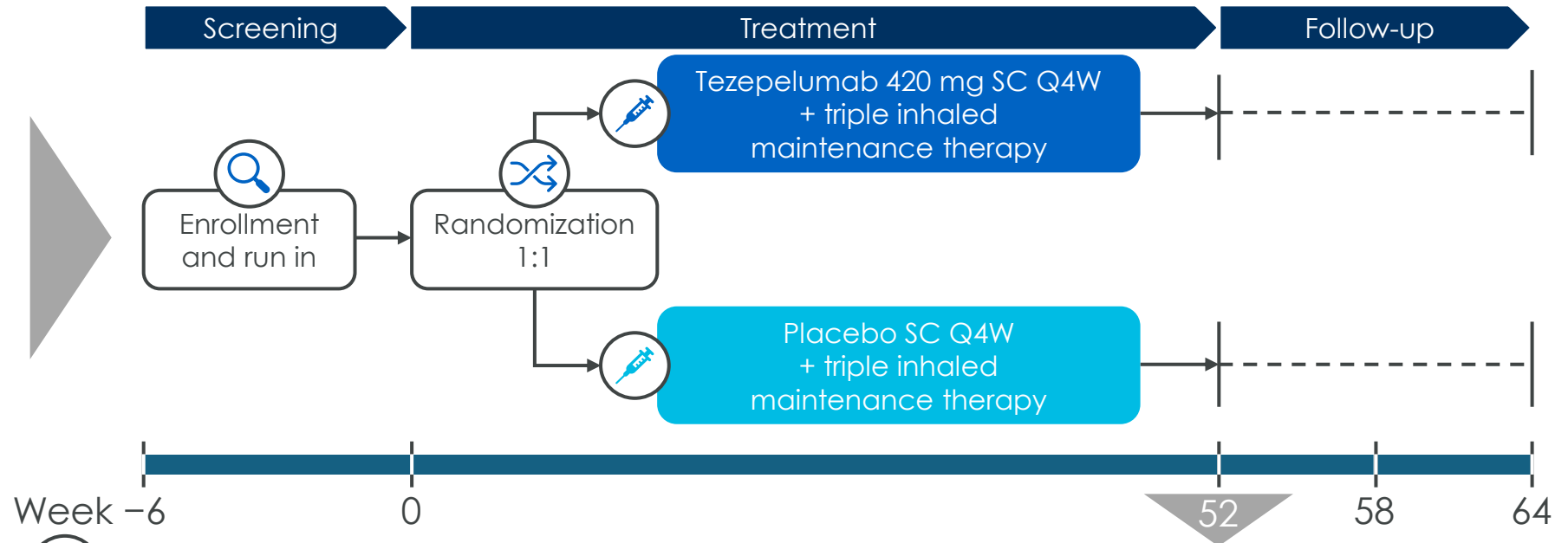
TSLP, thymic stromal lymphopoietin; COPD, chronic obstructive pulmonary disease; IL-4, interleukin 4; IL-5, interleukin 5; IL-13, interleukin 13; IgE, allergen-specific immunoglobulin E; FeNO, fractional exhaled nitric oxide; T2, type 2.

TEZSPIRE<sup>®</sup> is being developed in collaboration with AstraZeneca.

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# COURSE was a Phase 2a, Multicentre, Randomized, Double-blind, Placebo-controlled, 52-week Study

- Patients 40–80 years old
- Patients with COPD on triple inhaled therapy<sup>a</sup> and ≥ 2 exacerbations in the 12 months before enrollment
- Patients with a current diagnosis of asthma, or a history of asthma, including pediatric asthma or asthma–COPD overlap syndrome, were excluded
- No patients were excluded based on BEC, chronic bronchitis or emphysema during enrollment



**Primary endpoint**

- The annualized rate of moderate or severe COPD exacerbations over 52 weeks

**Secondary endpoints**

- The annualized rate of severe COPD exacerbations over 52 weeks
- Change from baseline to week 52 in:
  - pre-bronchodilator FEV<sub>1</sub>
  - SGRQ total score
  - CAT total score
- Safety

COPD, chronic obstructive pulmonary disease; SC, subcutaneously; Q4W, every 4 weeks; FEV<sub>1</sub>, forced expiratory volume in 1 second; SGRQ, St George's Respiratory Questionnaire; CAT, COPD assessment test. TEZSPIRE® is being developed in collaboration with AstraZeneca.

<sup>a</sup>Documented use of inhaled corticosteroids, a long-acting β-agonist and a long-acting muscarinic antagonist. <sup>b</sup>Patients with a history of pediatric asthma or asthma–COPD overlap syndrome were excluded. 28 Provided May 20, 2024, as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.



# Baseline Demographics and Characteristics were Generally Balanced between Treatment Groups

	Tezepelumab 420 mg SC Q4W (n = 165)	Placebo (n = 168)	Overall (n = 333)
Age, years, mean (SD)	67.4 (6.75)	67.1 (7.24)	67.2 (7.00)
Female, % (n)	46.7 (77)	40.5 (68)	43.5 (145)
BMI, kg/m <sup>2</sup> , mean (SD)	27.3 (5.72)	27.4 (6.43)	27.3 (6.08)
<b>Smoking status, % (n)</b>			
Former	66.7 (110)	69.6 (117)	68.2 (227)
Current	33.3 (55)	30.4 (51)	31.8 (106)
Smoking pack-years, mean (SD)	52.0 (25.40)	50.6 (23.11)	51.3 (24.25)
Pre-BD FEV <sub>1</sub> , L, mean (SD)	0.982 (0.3549)	0.991 (0.3593)	0.987 (0.3566)
FEV <sub>1</sub> reversibility, %, mean (SD)	11.0 (12.13)	9.4 (11.09)	10.2 (11.63)
Number of moderate or severe COPD exacerbations in the past 12 months, % (n)			
2	59.4 (98)	58.3 (98)	58.9 (196)
≥ 3	40.6 (67)	41.7 (70)	41.1 (137)
Historical COPD exacerbations requiring hospitalization, % (n)	20.0 (33)	21.4 (36)	20.7 (69)
FeNO level, ppb, mean (SD)/median (min, max)	17.7 (13.35)/14 (5, 81)	19.0 (14.40)/15 (5, 112)	18.3 (13.87)/15.0 (5, 112)
FeNO group, ppb, % (n)			
< 25	81.8 (117)	76.8 (109)	79.3 (226)
≥ 25	18.2 (26)	23.2 (33)	20.7 (59)
<b>BEC, cells/μL, mean (SD)/median (min, max)</b>	<b>195 (133)/150 (40, 890)</b>	<b>215 (162)/180 (30, 1290)</b>	<b>205 (148)/170 (30, 1290)</b>
<b>BEC group, cells/μL, % (n)</b>			
< 150	44.2 (73)	38.1 (64)	41.1 (137)
≥ 150	55.8 (92)	61.9 (104)	58.9 (196)
≥ 150 to < 300	41.2 (68)	42.9 (72)	42.0 (140)
≥ 300	14.5 (24)	19.0 (32)	16.8 (56)
Chronic bronchitis, % (n) <sup>a</sup>	51.5 (85)	59.5 (100)	55.6 (185)
Emphysema, % (n) <sup>a</sup>	55.2 (91)	60.1 (101)	57.7 (192)

SD, standard deviation; n, number; BMI, body mass index; FEV<sub>1</sub>, forced expiratory volume in 1 second; COPD, chronic obstructive pulmonary disease; FeNO, fractional exhaled nitric oxide; ppb, parts per billion; BEC, blood eosinophil count; SC subcutaneous administration; Q4W every 4-weeks.

TEZSPIRE® is being developed in collaboration with AstraZeneca.

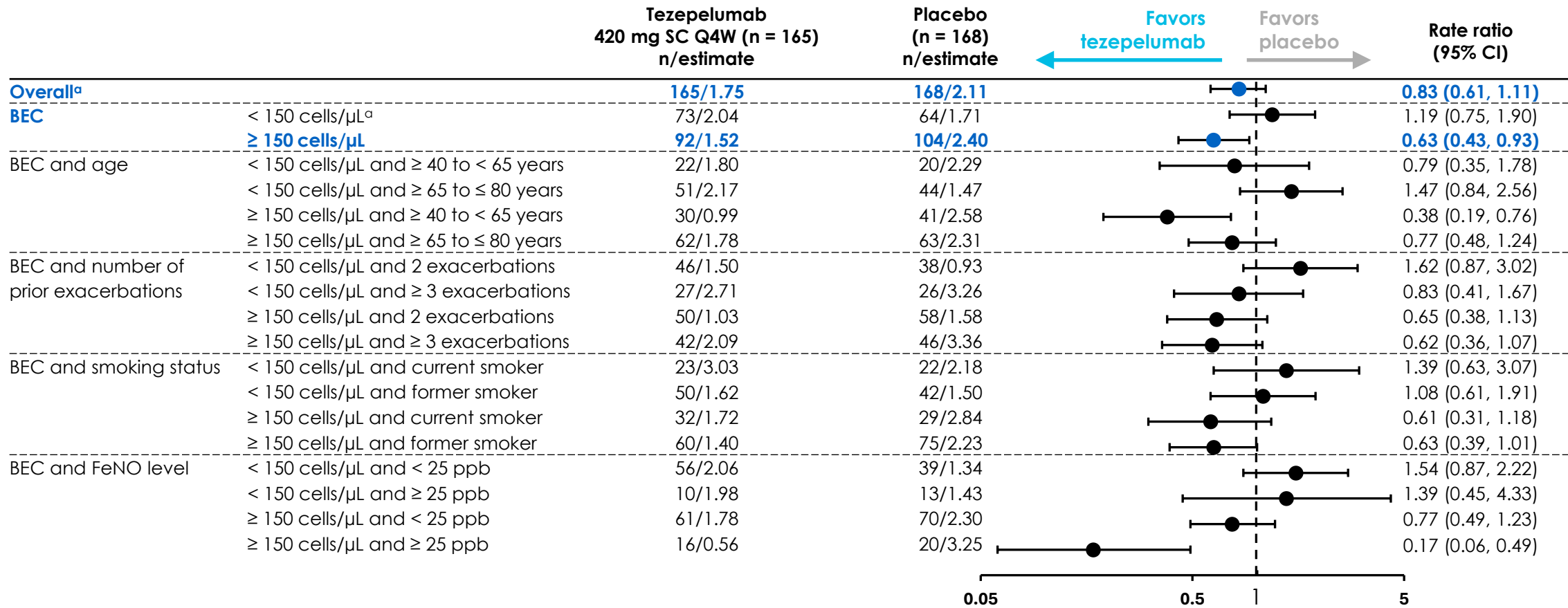
<sup>a</sup>Documented use of inhaled corticosteroids, a long-acting β-agonist and a long-acting muscarinic antagonist. <sup>b</sup>Patients with a history of pediatric asthma or asthma-COPD overlap syndrome were excluded.

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# Post hoc Analysis Showed Greater Reductions in the Annualized Rate of Moderate or Severe COPD Exacerbations in Patients with a Baseline BEC of $\geq 150$ cells/ $\mu\text{L}$ vs. the Overall Population



BEC, blood eosinophil count; CI, confidence interval; FeNO, fractional exhaled nitric oxide; Q4W, every 4 weeks; SC, subcutaneous administration.

TEZSPIRE® is being developed in collaboration with AstraZeneca.

<sup>a</sup>These analyses are prespecified, all other subgroup analyses presented were post hoc.

Unless otherwise stated, all demographics and clinical characteristics are those at baseline.

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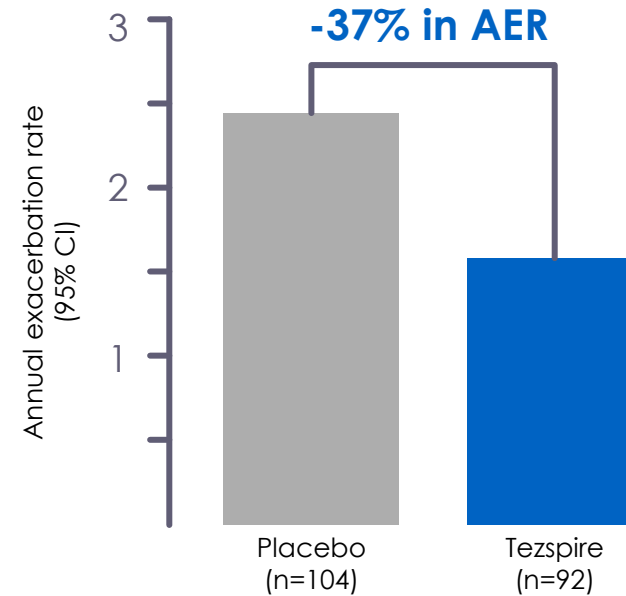


# COURSE COPD Data Indicates Potential in a Broader Group of Patients

## Significant Opportunity in COPD<sup>1</sup>

- Benralizumab, dupilumab, and mepolizumab studied in high-EOS COPD (EOS  $\geq 300$  cells/ $\mu\text{L}$ ) [ $\sim 30\%$  of market]
- TEZSPIRE<sup>®</sup> showed nominally significant 37% reduction with EOS  $\geq 150$  [65% of market]
- TEZSPIRE<sup>®</sup> showed 46% numerical reduction in mod-severe exacerbations in high-EOS (EOS $\geq 300$ )

## TEZSPIRE<sup>®</sup> Phase 2 COURSE Data in COPD<sup>2</sup>



**Primary subgroup analysis:  
EOS >150 cells/ $\mu\text{L}$**

Missed primary endpoint of annual rate of moderate or severe exacerbations in ITT population (all-comers; 17% reduction vs. placebo)

37% reduction in AER (EOS>150, CI 7, 57); nominal p=0.0212

COPD, chronic obstructive pulmonary disease; EOS, eosinophil; AER, asthma exacerbation risk; CI, confidence interval. TEZSPIRE<sup>®</sup> is being developed in collaboration with AstraZeneca.

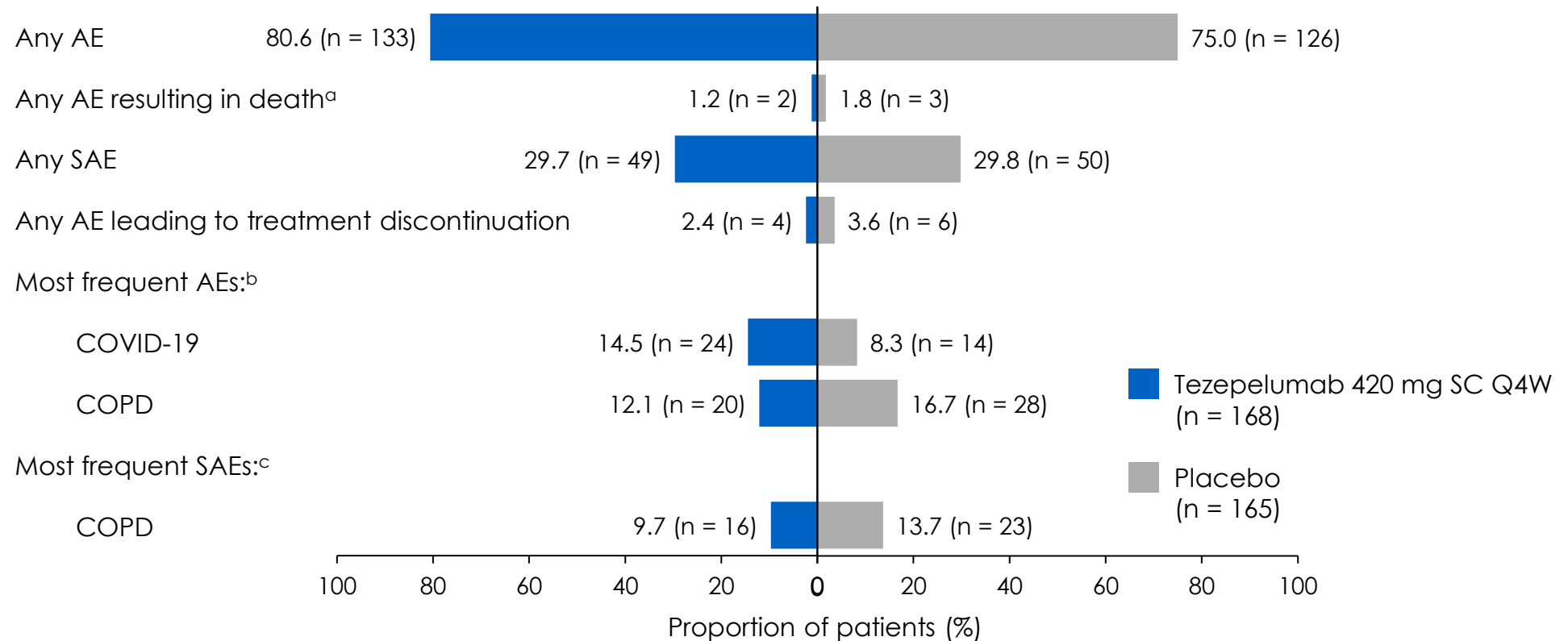
1. Internal AZ Claims Analysis, Optum Clinformatics Datamart triangulated with secondary literature.

2: Singh et al, "Tezepelumab in adults with moderate to very severe chronic obstructive pulmonary, disease (COPD): efficacy and safety from the phase 2a COURSE study," American Thoracic Society International Conference, 2024.

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# Incidences of On-Treatment AEs and SAEs were Generally Similar Between Treatment Groups



Safety findings were consistent with what has previously been reported for tezepelumab

AE, adverse event; SAE, serious adverse event; COVID-19, coronavirus disease 2019; COPD, chronic obstructive pulmonary disease.

TEZSPIRE® is being developed in collaboration with AstraZeneca.

<sup>a</sup>No deaths were determined to be causally related to treatment by the investigator. <sup>b</sup>AEs by preferred term that occurred in ≥ 10% of patients in any treatment group, irrespective of causality.

<sup>c</sup>SAEs by preferred term that occurred in ≥ 5% of patients in any treatment group, irrespective of causality.

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# TEZSPIRE® Reduced COPD Exacerbations by 37% in Patients with BEC $\geq 150$ , Actively Planning Phase 3 Program



TEZSPIRE® numerically reduced the annualized rate of moderate or severe COPD exacerbations in patients with moderate-to-very severe COPD



Magnitude of effect increased with increasing baseline BEC; this trend was also observed with pre-bronchodilator FEV<sub>1</sub> and SGRQ total score



Actively planning a Phase 3 clinical program in patients with COPD

COPD, chronic obstructive pulmonary disease; EOS, eosinophil; BEC, blood eosinophil count; FEV<sub>1</sub> forced expiratory volume in 1 second; SGRQ, St George's Respiratory Questionnaire. TEZSPIRE® is being developed in collaboration with AstraZeneca.

1 AstraZeneca. Tezepelumab (TEZSPIRE) prescribing information. 2021. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/761224s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761224s000lbl.pdf) (accessed April 25, 2024).

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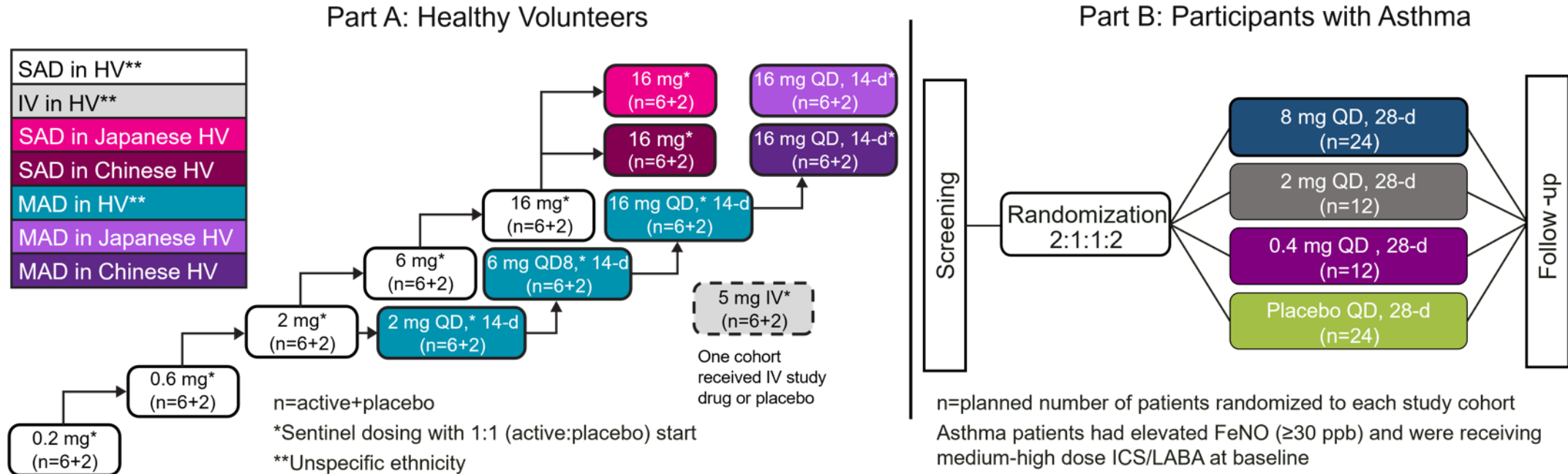
AMG 104

# AMG 104 is a Fragment Antibody (Fab) Against Thymic Stromal Lymphopoietin (TSLP)

- Formulated for delivery as a dry powder inhaler
- Being developed as a treatment for patients with uncontrolled asthma
- Potentially offers TEZSPIRE® like efficacy via the inhaled route
- If successful, expands potential of the TSLP franchise to patients who do not have access to systemic biologics



# Initial Phase 1 Study Evaluated Safety and Efficacy of Inhaled AMG 104 Administered Once Daily



**Part A evaluated 96 healthy subjects for up to 14 days.**

**Part B evaluated 77 patients with moderate-to-severe asthma and elevated FeNO (≥ 30ppb).**

SAD, single ascending dose; HV, healthy volunteers; IV, intravenous; MAD, multiple ascending dose; QD, once a day; FeNO, fractionated exhaled nitric oxide; ICS, inhaled corticosteroids; LABA, long-acting beta agonist; ppb, parts per million.

AMG 104 (also known as AZD8630) is being developed in collaboration with AstraZeneca.

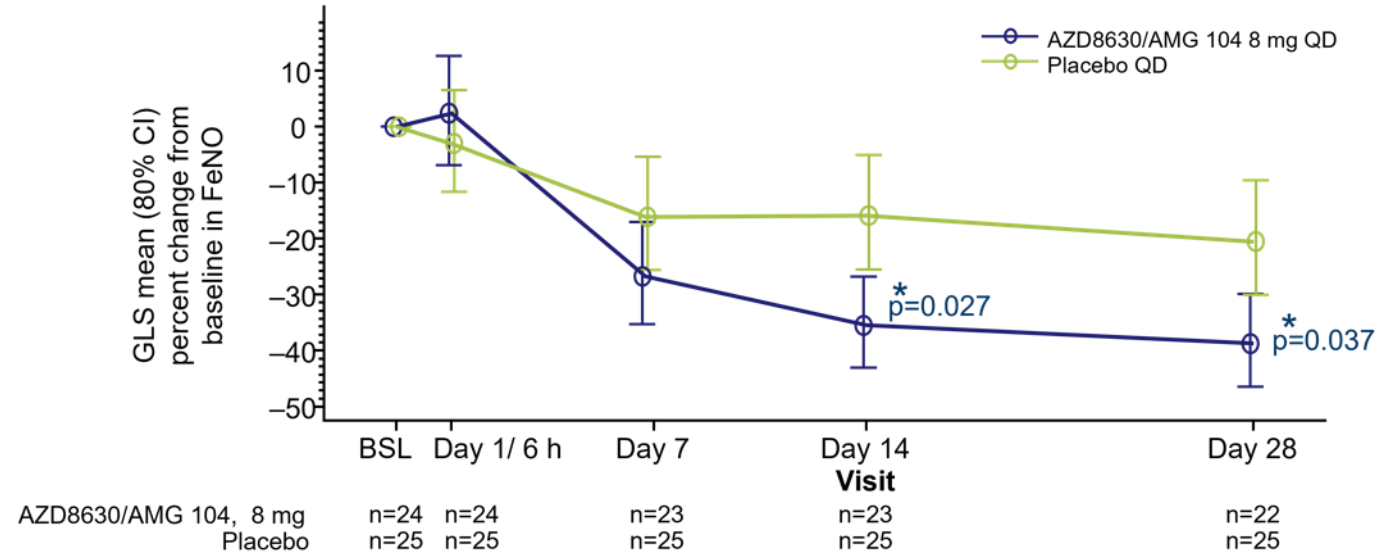
1. Doffman S, et al. "Phase 1 safety and efficacy of AZD8630/AMG 104 inhaled anti-TSLP in healthy volunteers and patients with asthma on medium-high dose inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) with elevated baseline fractional exhaled nitric oxide (FeNO)," American Thoracic Society International Conference 2024.

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# AMG 104 Demonstrated a 23% Reduction in FeNO in Patients with Moderate-to-severe Asthma and Elevated FeNO

- Reduction in FeNO was observed for all AMG 104 dose groups compared to placebo
- At the highest dose: 23% reduction in FeNO at day 14 maintained at day 28
  - Comparable to 25% reduction in TEZSPIRE® Ph2b PATHWAY trial<sup>2</sup> in asthma at same timepoint (28 days)



**AMG 104 was safe and well tolerated**  
**Phase 2 trial initiation anticipated in 2024**

FeNO, fractionated exhaled nitric oxide; QD, once a day; GLS, global longitudinal strain; BSL baseline.  
AMG 104 (also known as AZD8630) is being developed in collaboration with AstraZeneca.

1. Doffman S, et al. "Phase 1 safety and efficacy of AZD8630/AMG 104 inhaled anti-TSLP in healthy volunteers and patients with asthma on medium-high dose inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) with elevated baseline fractional exhaled nitric oxide (FeNO)," American Thoracic Society International Conference 2024.

2. Corren et al, "Tezepelumab in Adults with Uncontrolled Asthma" (PATHWAY), New England Journal of Medicine, 2017.

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Rocatinlimab

# Atopic Dermatitis (AD) Impacts Over 30 Million Individuals Globally

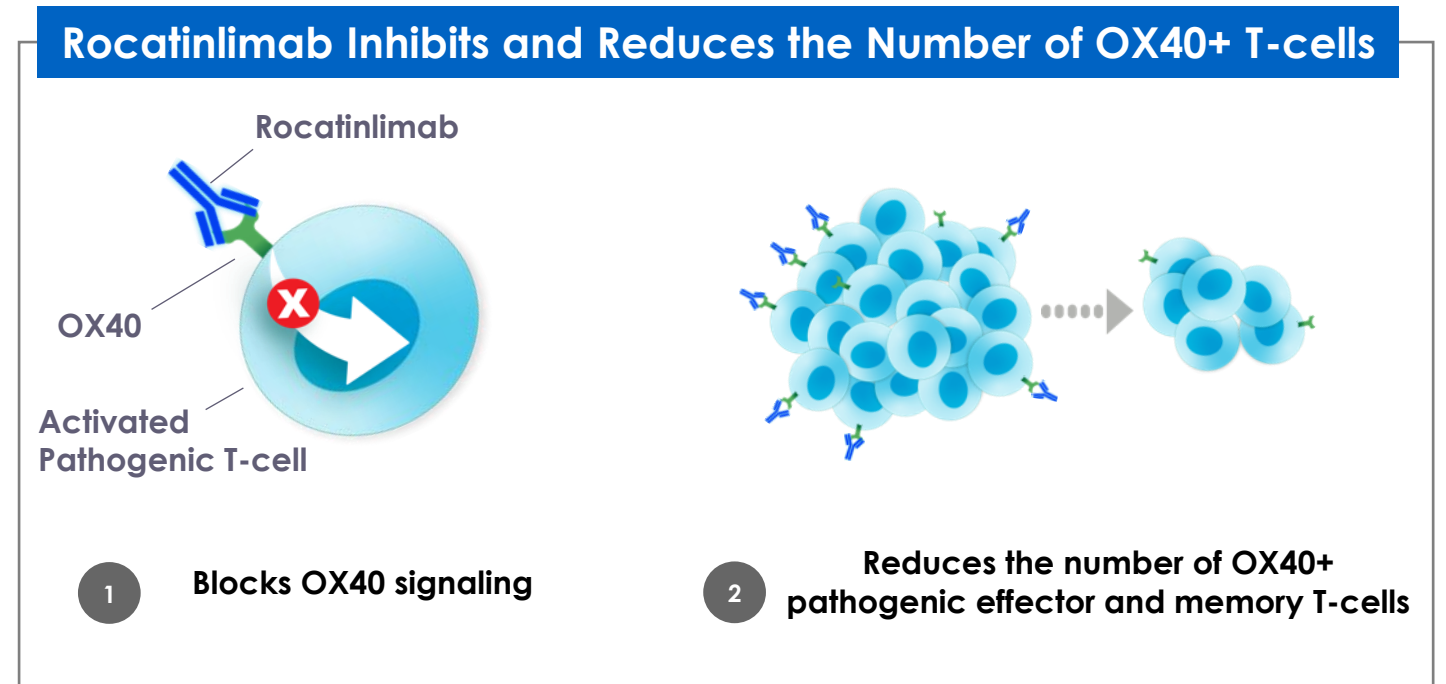
- AD affects over 30 million people in major global markets
  - Affects ~15–20% of children and up to 10% of adults in the U.S.
  - Global prevalence with approximately 1 in 3 affected people with moderate-to-severe disease
- Over half of patients with moderate-to-severe have inadequately controlled disease with current therapies including existing biologics



AD is complex and heterogenous with a broad range of clinical presentations that impact patient's quality of life.

# Rocatinlimab Directly Targets OX40 Receptor and Reduces Activated Pathogenic T-cells, Root Cause of Inflammation

- Reduces activated pathogenic T-cells, a key driver of inflammation
- Directly targeting the OX40 receptor provides an opportunity to achieve durable efficacy
  - Does not target naïve or resting T-cells that do not express OX40
- Potential to treat a spectrum of inflammatory diseases



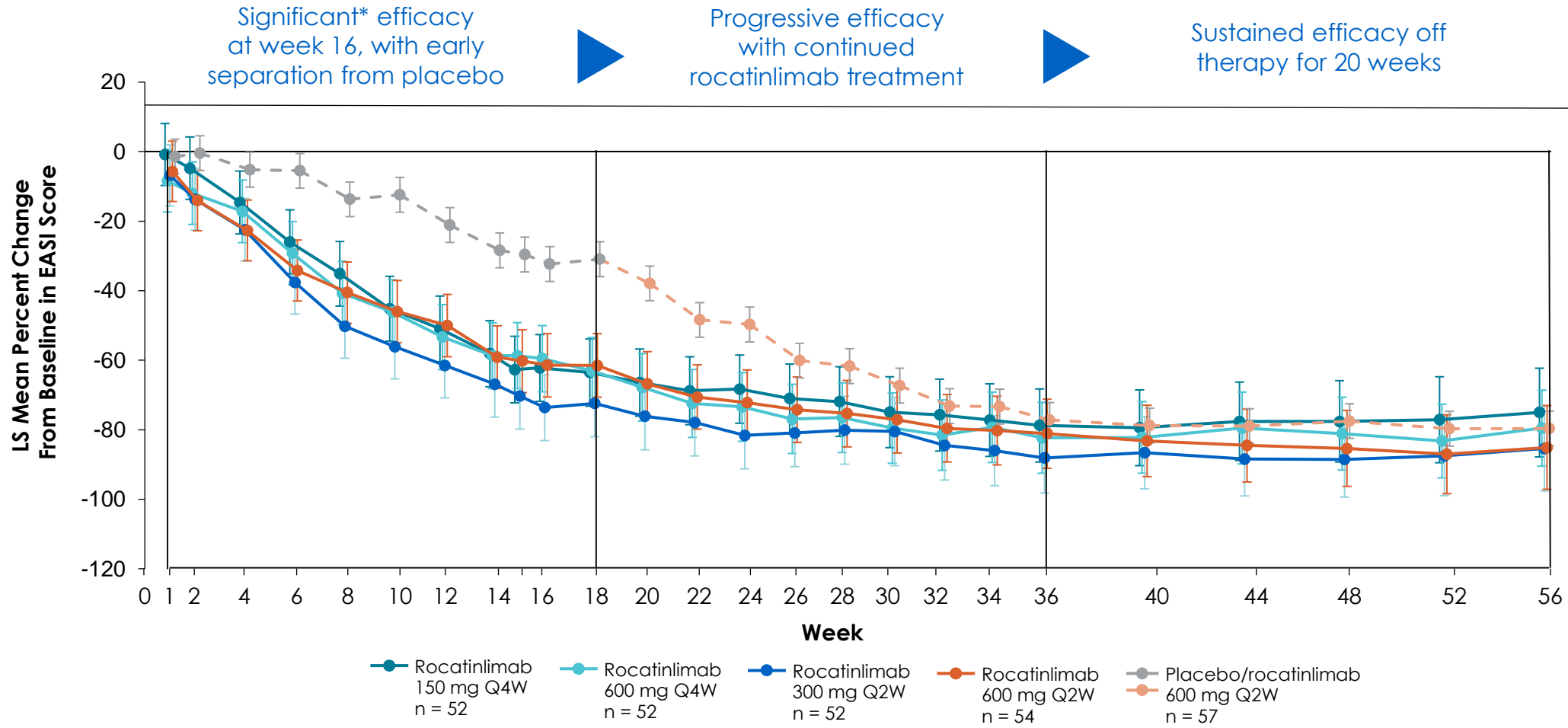
**Rocatinlimab is a potentially first- and best-in-class anti-OX40 mAb with the potential to reduce inflammation and achieve a durable response**

mAb monoclonal antibody..

Rocatinlimab, formerly AMG 451/KHK4083, is being developed in collaboration with Kyowa Kirin.  
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**AMGEN**

# Rocatinlimab Demonstrated Progressive and Sustained Efficacy in Moderate to Severe Atopic Dermatitis in a Phase 2b Study



\*LS mean percent change in EASI score was statistically significant for all doses compared with placebo (all doses vs placebo,  $P < 0.001$ ). Efficacy assessments were analyzed in the full analysis set. For percent change from baseline in EASI score, error bars represent 95% confidence intervals. A mixed-effects model with repeated measures was used for LS mean percent change in EASI score. EASI, Eczema Area and Severity Index; LS, least-squares; Q2W, every 2 weeks; Q4W, every 4 weeks. Rocatinlimab, formerly AMG 451/KHK4083, is being developed in collaboration with Kyowa Kirin. Guttman-Yassky E, et al. Lancet. 2023;401:204-214.



# Rocatinlimab Demonstrated a Favorable Safety Profile in Clinical Trials in the Phase 2b

- Fever and chills observed primarily after the first administration of rocatinlimab, did not lead to discontinuation
- Aphthous ulcers observed were mild-to-moderate in intensity
- No signs of immunosuppression or immune dysregulation observed

**Most Common AEs in ≥5% of Patients Through Week 18**

	<b>Total Rocatinlimab (Total n = 216)</b>	<b>Placebo (Total n = 57)</b>
<b>Preferred Term</b>	<b>n (%)</b>	<b>n (%)</b>
Pyrexia	36 (17)	2 (4)
Nasopharyngitis	30 (14)	9 (16)
Chills	24 (11)	0
Headache	19 (9)	1 (2)
Aphthous ulcer	15 (7)	0
Nausea	13 (6)	1 (2)

AE, adverse event; Q2W, every 2 weeks; Q4W, every 4 weeks.

Rocatinlimab, formerly AMG 451/KHK4083, is being developed in collaboration with Kyowa Kirin.

Guttman-Yassky E, et al. Lancet. 2023;401:204-214.

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# ROCKET Phase 3 Program in Atopic Dermatitis Well Underway with First Data Read-out Expected in H2 2024, Potential in other Diseases



Moderate to Severe  
**ATOPIC DERMATITIS**

Phase 3

**Adult**

**IGNITE:** placebo-controlled monotherapy evaluating two rocatinlimab doses (N=770)

**HORIZON:** placebo-controlled monotherapy rocatinlimab (N=726)

**SHUTTLE:** placebo-controlled evaluating two rocatinlimab doses with topical therapy (N=746)

**VOYAGER:** placebo-controlled trial assessing vaccine antibody response while on rocatinlimab (N=221)

**Adolescent**

**ASTRO:** 52-week study evaluating two rocatinlimab doses (N=500)

**ORBIT:** 52-week adolescent open-label study (N=187)

**Adult &  
Adolescent**

**ASCEND:** Maintenance Study with Re-randomized Withdrawal & Extension Cohorts

**OUTPOST:** 52-week open label trial of self-administered rocatinlimab (N=100)

**PRURIGO NODULARIS**

Phase 3

**Adult &  
Adolescent**

Phase 3 study in Prurigo Nodularis will be initiated in H2 2024

**ASTHMA**

Phase 2

**Adult &  
Adolescent**

Phase 2 study in moderate-to-severe asthma initiated

# Conclusion

# Four Therapeutic Area Pillars Driving Long-term Growth

GENERAL  
MEDICINE



ONCOLOGY



INFLAMMATION



RARE DISEASE



Marketed Products  
Innovative Pipeline  
Biosimilars





Q&A