## Regeneron Corporate Presentation

APRIL 2025

**REGENERON®** 

### Note regarding forward-looking statements and non-GAAP financial measures

This presentation includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate." "expect." "intend." "plan." "believe." "seek." "estimate." variations of such words, and similar expressions are intended to identify such forwardlooking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, competing drugs and product candidates that may be superior to, or more cost effective than products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") (including biosimilar versions of Regeneron's Products); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties or other factors beyond Regeneron's control on the commercial success of Regeneron's Products and Regeneron's Product Candidates; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's Product Candidates and research and clinical programs now underway or planned, including without limitation EYLEA HD® (aflibercept) Injection, 8 mg. EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Libtavo® (cemiplimab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, Evkeeza® (evinacumab) Injection, Veopoz™ (pozelimab) Injection, Ordspono™ (odronextamab), Lynozyfic™ (linvoseltamab), Lynozyfic fianlimab, garetosmab, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), REGN5713-5715, nexiguran ziclumeran (nex-z, NTLA-2001), REGN1908-1909, mibayademab, Regeneron's and its collaborators' earlier-stage programs and the use of human genetics in Regeneron's research programs: the likelihood and timing of achieving any of the anticipated milestones discussed or referenced in this presentation; safety issues resulting from the administration of Regeneron's Product and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Product Candidates in patients. trials: the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, such as those listed above; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Product and Regeneron's Product Candidates; Regeneron's ability to manufacture and manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products from third-party payors and other third parties, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payors and other third parties and new policies and new policies and procedures adopted by such payors and other third parties; changes in laws, regulations, and policies affecting the healthcare industry; unanticipated expenses; the costs of developing, producing, and selling products: Regeneron's ability to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; Regeneron's estimates of market opportunities for Regeneron's Products and Regeneron's Product Candidates: the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's fillings with the U.S. Securities and Exchange Commission. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron, Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise,

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# Driven by science and innovation



Differentiated technology platforms have delivered 4 'blockbuster' products discovered by Regeneron









Unprecedented research and discovery capabilities drive bestin-class pipeline of ~45 product candidates

- Includes near-term opportunities with potential to address therapeutic categories expected to exceed an aggregate of \$220 billion in 2030
- Regeneron Genetics Center® has created the world's largest DNA sequence-linked healthcare database to improve drug discovery and development as well as healthcare analytics and management

Balanced approach to capital allocation, prioritizing internal R&D investment while returning capital to shareholders through share repurchases and newly initiated dividend program

### Q1 2025 Financial Performance and **Pipeline Developments**





**1025 Total Revenues** 

\$3.03B

1Q25 Non-GAAP EPS\*

\$8.22

#### **Notable R&D Pipeline Advancements**



sBLA submission accepted for RVO and every four-week dosing (PDUFA Aug 19)



- Approved in CSU in U.S. and in COPD in Japan
- sBLA for BP accepted (PDUFA June 20), late-breaking data presented at American Academy of Dermatology Annual Meeting
- Libtayo U.S. and EU regulatory filings submitted for adjuvant CSCC
- Interim analysis of POC Phase 2 trials for Fianlimab + Libtayo in 1L advanced NSCLC conducted: trials to continue until data mature
- Linvoseltamab BLA resubmission for R/R multiple myeloma accepted (PDUFA July 10); now approved in Europe
- Odronextamab BLA resubmission in R/R follicular lymphoma accepted (PDUFA July 30)
- Phase 3 program for itepekimab in CRSwNP initiated; Phase 2 POC study in NCFB fully enrolled
- Updated DB-OTO results presented at Association for Research in Otolaryngology's 48th Annual MidWinter Meeting demonstrated clinically meaningful improvements in nearly all children with profound genetic hearing deficit



### Continued growth and expansion in multiple Type 2 indications

1Q 2025 Dupixent global net sales of \$3.7B (+20% YoY\*)

## ~1.2 million patients on therapy globally

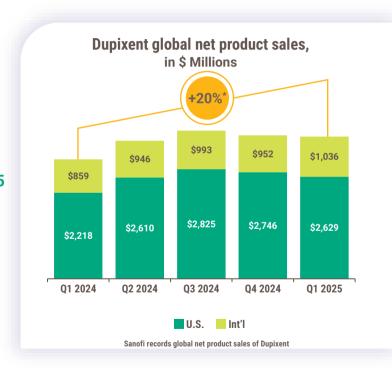
Approved in **SEVEN** indications globally

Chronic spontaneous urticaria (CSU) approved in U.S. in April 2025

Chronic obstructive pulmonary disease (COPD) approved in Japan in 1Q25

**Bullous pemphigoid sBLA accepted in 1Q25** (PDUFA June 20)

Driving growth through increased penetration in established indications and launches in new indications

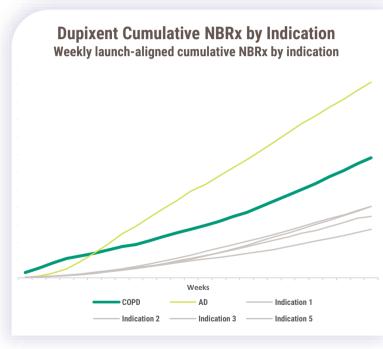




### COPD launch underway in U.S.

Dupixent approved by FDA in late September 2024 as an add-on maintenance treatment of adult patients with inadequately controlled COPD and an eosinophilic phenotype

- Potential to address ~300,000 patients in the U.S.
- Top commercial and Medicare payors authorized Dupixent coverage "to label" within first 90 days of approval
- 2025 Global initiative for Chronic Obstructive Lung Disease (GOLD)
  guidelines include Dupixent as the only biologic recommended as
  treatment for certain COPD patients who continue to experience
  exacerbations after optimized inhaled therapy
- Launch efforts (including DTC campaign) focused on increasing awareness of Type 2 inflammation in COPD among physicians and patients to drive momentum in 2025

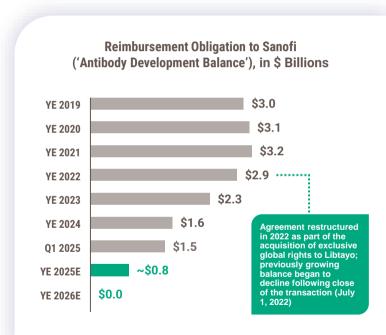


Data Source IQVIA Weekly NSOB

### Full reimbursement of Sanofi development balance anticipated in 2026; Expected to drive significant growth in collaboration revenue & cash flow

- The 'development balance' represents development costs funded by Sanofi under the companies' antibody collaboration for certain antibodies, including Dupixent, Kevzara and itepekimab, for which Regeneron is required to pay 50%
- Reimbursement of the balance is primarily recorded as a reduction to Regeneron's share of antibody profits within Sanofi Collaboration Revenue
- In Q1 2025, development balance reduced by ~\$180 million
- Balance anticipated to be fully reimbursed by the end of 2026
- Development Balance as of 3/31/25: ~\$1.5 billion

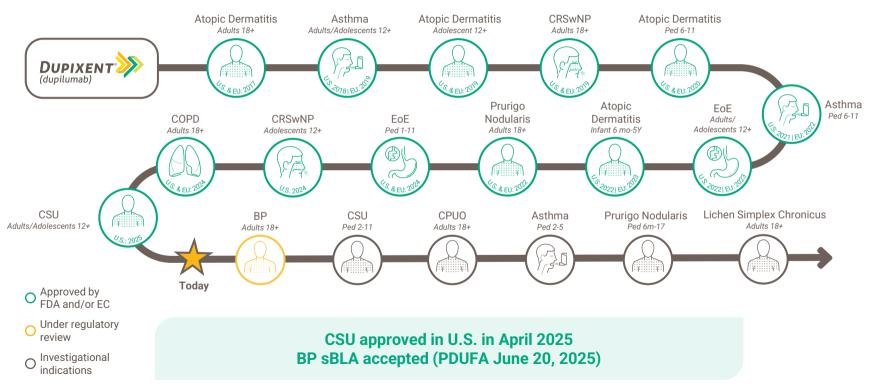
Reimbursement expected to average ~\$800 million per year in 2025 and 2026; upon full reimbursement of the balance, Regeneron's share of antibody profits will immediately inflect, leading to a significant increase in collaboration revenue and cash flow





### Delivering on Dupixent's "pipeline in a product" potential

Dupixent clinical trials have repeatedly demonstrated that IL-4 and IL-13 are key drivers of multiple Type 2 allergic diseases



#### **EYLEA HD + EYLEA in the U.S.**

EYLEA HD + EYLEA remain the U.S. anti-VEGF category leaders

## Goal to establish EYLEA HD as new standard of care for retinal diseases



 Q1 2025 U.S. net product sales of \$307M comprised 29% of Q1 2025 EYLEA + EYLEA HD net sales

## EYLEA remains #1 anti-VEGF treatment for retinal diseases

- (aflibercept) Injection
- Q1 2025 U.S. net product sales of \$736M
- Quarter results impacted by:
  - Lower inventory
  - Increased competition
  - Category shift to off-label use of compounded Avastin
  - Patient affordability constraints

~41% category share for EYLEA HD and EYLEA in Q1 2025\*

#### U.S. Net Product Sales, in \$ Millions





### Key growth driver and foundational to oncology portfolio

LIBTAYO has become Regeneron's latest internally-discovered drug to reach >\$1B in annual net sales

#### Strong and consistent growth

- Q1 2025 WW net sales of \$285M (+8% YoY\*)
  - U.S. net sales of \$193M (+21% YoY)
- Expanding global commercial footprint



- One of two PD-1 antibodies FDA-approved for use in combination with chemotherapy irrespective of histology or PD-L1 expression levels
- Continuing to grow market share in monotherapy and in combination with chemotherapy



Leading anti-PD-1/L1 therapy in advanced CSCC and BCC



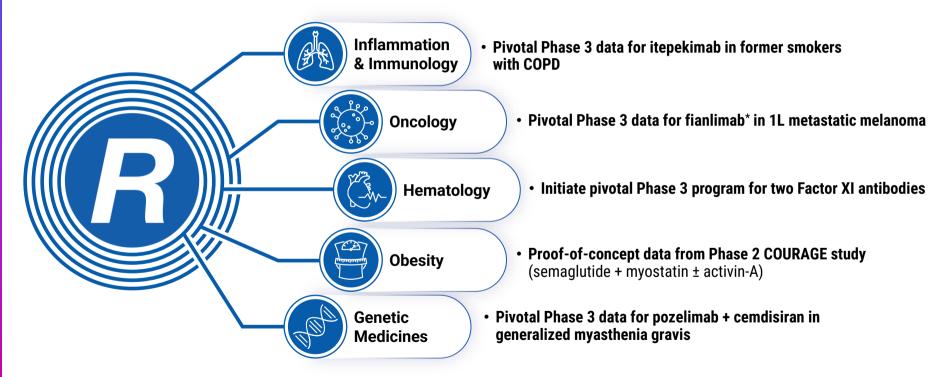
First and only immunotherapy to show statistically significant DFS benefit in high-risk adjuvant CSCC

U.S. & EU regulatory filings submitted



### Key 2025 clinical milestones to drive long-term shareholder value

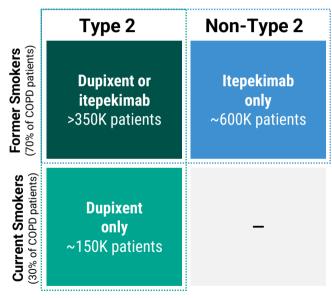
Opportunity to address areas of high unmet need in large commercial categories



## Dupixent & itepekimab<sup>†</sup>: Two opportunities to address high unmet need in COPD



- Addressing COPD with an eosinophilic phenotype (eos ≥300/µl) in both current and former smokers
- First and only biologic to achieve clinically meaningful and statistically significant reduction in COPD exacerbations and improvement in lung function vs. placebo\*
- Approved in 45 countries, including the U.S., EU, Japan, and China



Current U.S., EU and Japan addressable patient estimates

## Itepekimab

(anti IL-33)

- Potential to address COPD in former smokers, regardless of eosinophilic phenotype
- Includes patients with both high and low eosinophil counts
- Two Phase 3 studies ongoing:
  - AERIFY-1
  - **⊘** AERIFY-2
- AERIFY studies passed interim futility analysis in 2023
- Enrollment complete, results expected in mid-2025

<sup>\*</sup>Patients were randomized to receive Dupixent or placebo added to maximal standard-of-care inhaled triple therapy (LABA+LAMA+ICS)
†Itepekimab is not approved by any regulatory authority

## Itepekimab (IL-33): Regeneron's next innovation in COPD with pivotal results anticipated in mid-2025

Building upon Dupixent's clinical success, potential for benefit in broader COPD population

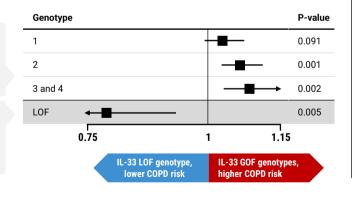


The RGC found that IL-33 is genetically linked to COPD and asthma via risk-increasing variants and protective loss-of-function variants

IL-33 loss-of-function protects from COPD (~20% decreased risk) and gain of function increases risk (up to ~10% increased risk)

GOF genotypes that increase IL-33 signaling are associated with higher risk of COPD

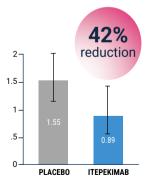
LOF genotype that decreases IL-33 signaling is associated with lower risk of COPD



Phase 2 study showed overall reduction in exacerbations; post-hoc analysis informed Phase 3 trial design

Phase 3 AERIFY studies passed interim futility analysis in 2023; results expected in mid-2025

- Itepekimab showed overall reduction in exacerbations and improvement in lung function
- Driven by 42% reduction in exacerbations in former smokers vs placebo
- Itepekimab was generally well tolerated, with an acceptable safety profile
- Also being evaluated in CRSwNP, CRSsNP, NCFB

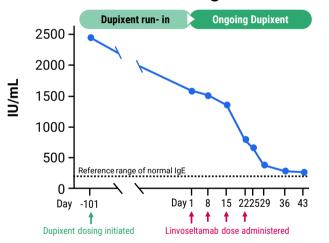


## Novel treatment approach for potentially reversing severe allergy: Linvoseltamab (BCMAxCD3) plus Dupixent (anti-IL4Rα)

Linvoseltamab and Dupixent regimen has the potential to eliminate IgE: potential groundbreaking approach for controlling severe allergy

- Initial Data: A 20-year-old male with mild asthma, allergic rhinitis, atopic dermatitis and multiple severe IgE-mediated food allergies with documented recurrent anaphylaxis, ER visits and hospitalizations, which have significantly impacted his quality of life
- Safety: no unexpected adverse events to-date

~90% reduction in IgE levels in Severe Food-Allergic Patient #1



Induction with short course (4 doses) of low-dose linvoseltamab led to rapid and profound (~90%) reduction in IgE with combined approach

Immunoglobulin E (IgE) is the key driver of allergic reactions, such as food allergies; long-lived plasma cells consistently produce IgE

Clinical trial with the two-drug regimen in patients with severe food allergies is ongoing;

Additional patients enrolled with data updates anticipated in 2025

## Regeneron's oncology strategy: using the immune system to defeat cancer with 5 classes of immunomodulatory agents

Regeneron has clinically validated these first 3 classes, several with potentially best-in-class clinical efficacy



Designed to overcome T cell suppression



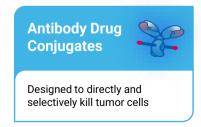
Designed to link killer T cells with cancer cells



Activating killer T cells via costimulation

#### **Earlier-stage Programs**





#### **Indication areas of focus**

#### Hematological

Lymphomas, Myelomas, Myeloid malignancy

#### **Lung Cancer**

NSCLC

#### **Dermato-Oncology**

CSCC; BCC; Melanoma

#### Genitourinary

Prostate; RCC

#### **Gyn-Onc**

Ovarian; endometrial; cervical

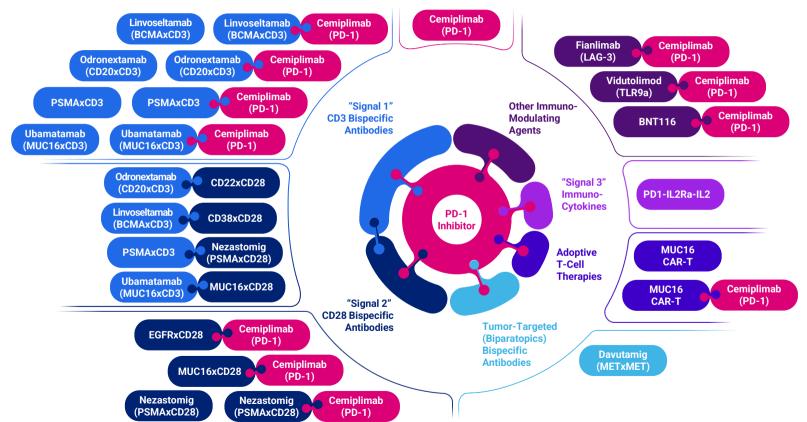
#### GI

CRC; esophageal / gastric; HCC

**HNSCC** 

✓ Can be used across multiple tumor types and in combination

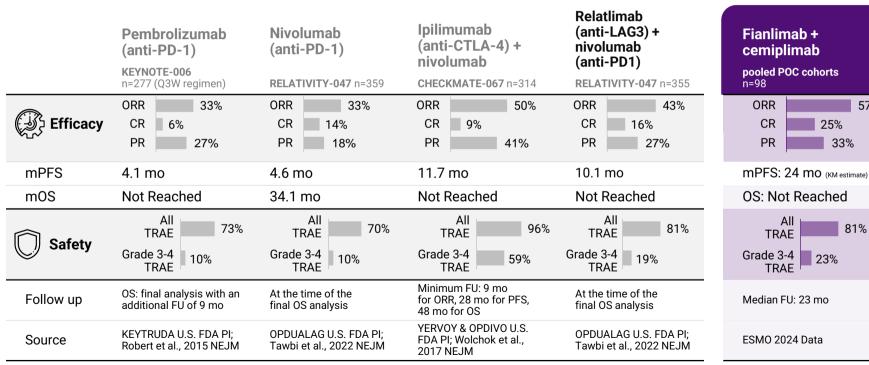
## Unique flexibility of internally-developed oncology pipeline drives potential for novel and differentiated combinations



### Combining two potentially best-in-class checkpoint inhibitors: Fianlimab (anti-Lag3) & LIBTAYO (anti-PD1) in 1L metastatic melanoma\*

Emerging as potentially differentiated treatment option for 1L metastatic melanoma

Table depicts randomized Phase 3 data for four FDA-approved treatments as well as pooled, post-hoc data from three independent cohorts from initial trial of fianlimab + cemiplimab; there are no randomized, head-to-head clinical trials between these products. Study data being provided for descriptive purposes only. Caution is advised when drawing conclusions based on cross-trial comparisons.



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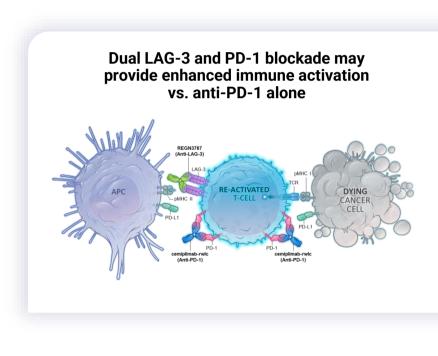
57%

81%

## Advancing Fianlimab (anti-Lag3) & LIBTAYO (anti-PD1) combination in melanoma and across several solid tumor cancers

Combining two potentially "best-in-class" checkpoint inhibitors: Fianlimab (anti-LAG-3) & LIBTAYO (cemiplimab, anti-PD-1) – potential for differentiated efficacy and safety vs. current standard-of-care

		Phase 1	Phase 2	Phase 3
	1L Metastatic Melanoma (vs. pembrolizumab)	Enrolling – P	ivotal data in 2	H 2025
Melanoma	1L Metastatic Melanoma (vs. nivolumab+relatlimab)	Enrolling		
	Adjuvant Melanoma	Enrollment co	omplete	
	Perioperative Melanoma	Enrolling		
NSCLC	Advanced NSCLC	Enrolling – N	lext analysis n 1Q26	
NSOLU	Perioperative NSCLC	Enrolling		
	Perioperative HCC	Enrolling		
Other solid tumors	1L HNSCC (PD-L1+; HPV+ and HPV-)	Initiating 202	5	
	Perioperative HNSCC	Initiating 202	5	

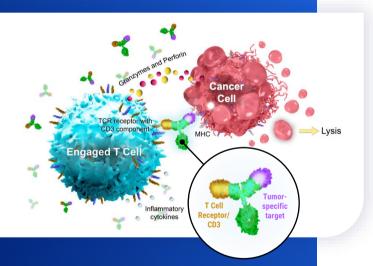


## Pipeline of CD28 costimulatory bispecifics progressing

						Collibi	nea with:
_		Dose Escalation	Proof-of- Mechanism	Dose Expansion	Status / Next Steps	Checkpoint Inhibitors	xCD3 bispecifics
	Nezastomig (PSMAxCD28) Prostate Cancer; RCC	Data <sub>l</sub>	poster at AA(	CR	Enrolling monotherapy and combination cohorts	Cemiplimab	PSMAxCD3
	EGFRxCD28 Solid Tumors	Data e	xpected in 2H	H25	Expansion cohorts (NSCLC, HNSCC, CSCC, CRC) in combination with cemiplimab and with chemotherapy now enrolling	Cemiplimab	
To the second	MUC16xCD28 Ovarian Cancer				Expansion cohorts in combination with cemiplimab expected to initiate in 2025; enrolling dose escalation with ubamatamab	Cemiplimab	Ubamatamab (MUC16xCD3)
÷0.	CD22xCD28 DLBCL				Enrolling dose escalation cohorts		Odronextamab (CD20xCD3)
00	CD38xCD28 MM				Enrolling dose escalation cohorts		Linvoseltamab (BCMAxCD3)

Combined with

# Regeneron's differentiated CD3 bispecifics



#### **ORDSPONO™**

(odronextamab, CD20xCD3)

Non-Hodgkin lymphoma (NHL)

Regeneron's first approved bispecific antibody (in EU) in relapsed/refractory (R/R) follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL)

80% ORR / 73% CR in r/r FL

Highest response rate observed in the class in this late-line setting

**Approved in Europe in 2024** 

BLA resubmitted for r/r FL: PDUFA July 30, 2025

#### **LYNOZYFIC™**

(linvoseltamab, BCMAxCD3)

Multiple myeloma (MM)

Linvoseltamab has the potential to be the best-in-class BCMAxCD3 bispecific with its differentiated clinical profile, dosing, and administration

71% ORR / 50% CR in r/r MM<sup>+</sup>

Nearly double the CR rate of other bispecifics at similar follow-up\*

BLA resubmitted for r/r MM: PDUFA July 10, 2025

**Now approved in Europe** 

Differentiated Phase 3 programs in earlier lines of therapy using monotherapy and novel combinations underway for both odronextamab and linvoseltamab

† Median follow up of 14 months

\*There are no randomized, head-to-head clinical trials between these products. Study data being provided for descriptive purposes only. Caution is advised when drawing conclusions based on cross-trial comparisons.

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## Broad odronextamab phase 3 program currently enrolling patients, including in earlier lines of FL and DLBCL

Monotherapy efficacy in late lines supports differentiated approach using monotherapy and novel combinations in earlier lines

	<b>Line of therapy</b> U.S. treated population	Study	Phase 1	Phase 2	Phase 3	
	Third line+ ~1,900	ELM-2* (odro mono, pivotal)	Phase 2			
Follicular Lymphoma	Second line ~4,100	<b>OLYMPIA-5*</b> (odro-lenalidomide vs. rituximab-lenalidomide)	Phase 3			Now approved in Europe
Incidence: U.S. ~13,100	<b>-</b>	<b>OLYMPIA-1</b> (odro mono vs. R-CHOP)	Phase 3			for R/R FL and DLBCL
WW ~120,000	OLYMPIA 2 (odro chomo	Phase 3			BLA for R/R FL resubmitted; PDUFA July 30, 2025	
		ELM-2* (odro mono, pivotal)	Phase 2			
DLBCL	<b>Third line+</b> ~3,600	ATHENA-1 (odro-CD22xCD28)	FIH, Phase 1			Exploring differentiated combinations (with CD22xCD28)
Incidence: U.S. ~31,000		CLIO-1 (odro-cemiplimab)	Phase 1			Combinations (with CD22xCD26)
WW ~163,000	Second line ~8,600	OLYMPIA-4 (odro vs. SOC)	Phase 3			
	First line ~27,000	OLYMPIA-3 (odro-CHOP vs. R-CHOP)	Phase 3			Advancing to earlier lines of therapy

Incidence – new cases diagnosed annually.

\* Also investigating patients with marginal zone lymphoma (MZL)



### Broad linvoseltamab development program to evaluate monotherapy and simplified combinations in earlier stages of disease

Unprecedented late-line responses rates provide confidence to explore monotherapy and novel combinations in earlier disease settings to simplify treatment approaches

	<b>Line of therapy</b> U.S. treated population	Study	Phase 1	Phase 2	Phase 3	
	-1.11	LINKER-MM3 <sup>§</sup> (Linvo vs. EPd)	Phase 3 - r	now fully enro	lled	
	Third line+ ~4,000 in 4L+/ ~8.000 in 3L	LINKER-MM1 (Linvo mono)	FIH/Phase	1/2		
Multiple Myeloma	,,,,,	(Linvo + CD38xCD28)	FIH/Phase	1/2		
Incidence: U.S. ~35,000 WW >176,000	Second line ~16,000	LINKER-MM2 (cohorts of Linvo + SOC / novel therapies)	Phase 1			
	First line	LINKER-MM4 (Linvo mono)	Phase 1/2			
	~30,000		Studies in maintenance, transplant ineligible, transplant eligible	Phase 3s pl	anned	
Multiple Myeloma	High Risk (HR) Smoldering MM	Study 2256 (Linvo mono)	Phase 2			
Precursor Conditions	HR MGUS / non-HR Smoldering MM	LINKER-MGUS1 (Linvo mono)	Phase 2			
AL Amyloidosis	Second line+	LINKER-AL2 (Linvo mono)	Phase 1/2			
U.S. ~4,500	333	)	Titude 1/2			

**BLA resubmitted. PDUFA July 10.** 2025; now approved in Europe

**Exploring differentiated** combinations (with CD38xCD28)

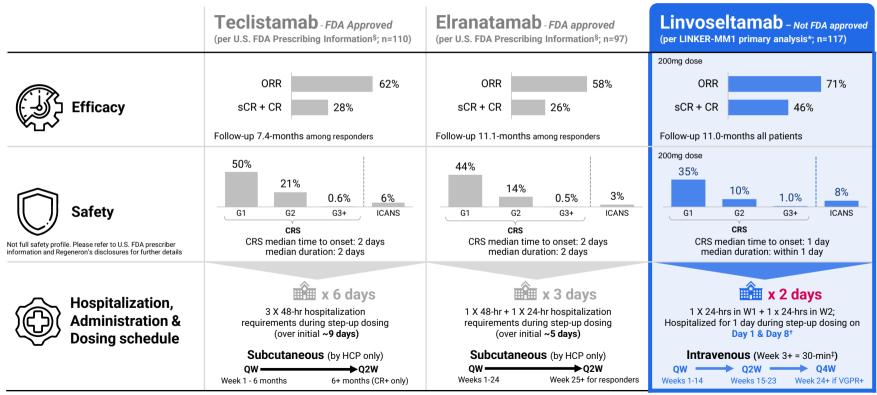
Advancing to earlier lines of therapy

**U.S. Epidemiology MM Precursor Conditions** (clinically detected cases only, actual population may be higher; estimates not as well-characterized as MM)

HR SMM, incidence:	1,200 - 1,600
Non-HR SMM, incidence:	3,000 - 3,500
HR MGUS, prevalence*:	11,000 - 19,000

## Within the BCMA bispecific class, linvoseltamab emerging with differentiated and compelling clinical profile in r/r multiple myeloma

There are no randomized, head-to-head clinical trials between these products. Study data being provided for descriptive purposes only. Caution is advised when drawing conclusions based on cross-trial comparisons.



<sup>\*</sup> Data source: Jagannath, S. Linvoseltamab, a B-cell maturation antigen-targeted T-cell-engaging bispecific antibody in patients with relapsed or refractory multiple myeloma, including difficult-to-treat subgroups, AACR 2024 \$ US PI as of April 2024 Per Protocol. \$ 30-min as long as patient tolerability allows; discretion at Day 8.

## Two-pronged approach to anticoagulation offers potential for improved blood clot prevention and lower bleeding risk

Two Factor XI antibodies advancing to pivotal trials in 2025: REGN7508 (catalytic domain) and REGN9933 (A2 domain)

## **Current market for thrombosis disorders:**

- Existing SoC includes LMWH, DOAC's and aspirin, including \$20 billion SPAF market
- Challenges with existing SoC include:
  - Factor Xa effectively reduce thrombotic events, but carry elevated risk of bleeding
  - Utilization rate for DOAC's in SPAF is only ~50%, mainly due to bleeding risk

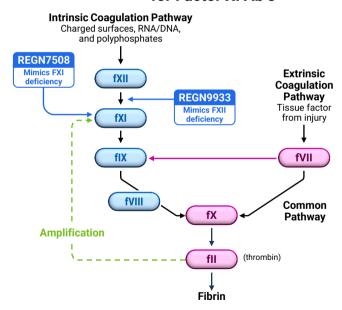
#### **Future vision: Factor XI Ab's**

- More specific inhibition of the intrinsic coagulation pathway
- Two FXI antibodies may address unmet need in thrombosis prevention, with unique profiles<sup>1</sup>:
  - REGN7508 mimics FXI deficiency: improved anticoagulation vs. SoC
  - REGN9933 mimics FXII deficiency: low bleeding risk may enable broader usage

#### **Genetic data:**

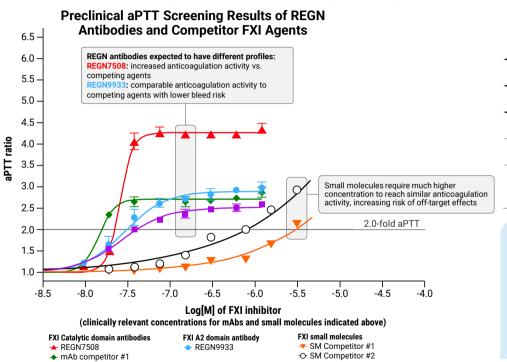
- FXI deficiency<sup>2</sup>: trend toward reduced risk of MI, stroke with minimal increased bleeding risk
- FXII deficiency: no increased bleeding risk

## Mechanism of Action for Factor XI Ab's



## Regeneron's Factor XI antibodies: Potential for maximal anti-coagulation with minimal bleeding

Positive proof-of-concept data for REGN7508 (catalytic) and REGN9933 (A2) announced in December 2024



Therapy	Target	VTE Rate*	Initiation of dosing (hrs)
REGN7508	FXI (catalytic)	7%	12-24 postop
REGN9933	FXI (A2)	17%	12-24 postop
Enoxaparin	Multiple	21%	12-24 postop
Apixaban	FXa	12%	12-24 postop
Historical Control (pbo)	N/A	48%1	N/A

PoC data support advancing both antibodies into a broad Phase 3 development program in multiple coagulation disorders and in patients with different risk factors for bleeding

Phase 3 trials expected to initiate in 2025

mAb competitor #2

<sup>\*</sup>Results from ROXI-VTE I (REGN9933, apixaban) and ROXI-VTE II (REGN7508); enoxaparin VTE rate pooled across both studies

\*Fuji T, Fujita S, Tachibana S, Kawai Y. A dose-ranging study evaluating the oral factor Xa inhibitor edoxaban for the prevention of venous thromboembolism in patients undergoing total knee arthroplasty. J Thromb

Haemost. 2010 Nov:8(11):2458-68. doi: 10.1111/i.1538-7836.2010.04021.x. PMID: 20723033.

## Our differentiated siRNA + antibody approach has the potential to address multiple complement-mediated diseases

Despite competitive markets, there is opportunity to improve upon the current standard of care with prolonged and complete inhibition of complement protein C5 (for multiple diseases)

siRNA (cemdisiran) lowers C5 target burden, allowing antibody (pozelimab) to more effectively block C5 function



#### **Geographic Atrophy**

2025 U.S. Prevalence (patients): ~1.1M Worldwide market sales\* (2025e): ~\$1.0B Estimated market sales CAGR\* (2025-2030): ~34%



Phase 3 pivotal program initiated in 2H 2024



#### **Myasthenia Gravis**

2025 U.S. Prevalence (patients): ~90k Worldwide market sales\* (2025e): ~\$5.0B Estimated market sales CAGR\* (2025-2030): ~17%

- · Study fully enrolled
- Phase 3 results expected in 2H 2025



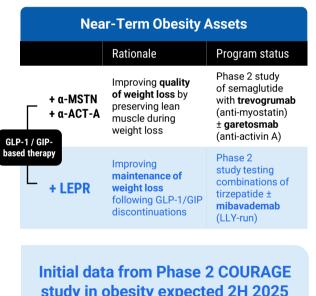
#### **Paroxysmal Nocturnal Hemoglobinuria**

2025 U.S. Prevalence (patients): ~6k
Worldwide market sales\* (2025e): ~\$2.0B
Estimated market sales CAGR\* (2025-2030): ~12%

- Cohort A (exploratory): Updated Phase 3 data reported at ASH 2024
- Cohort B (registrational): Study enrolling, data expected in 2026+

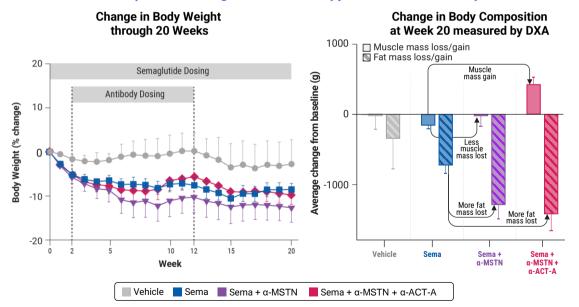
## Regeneron's approach to obesity: novel combinations with leading medicines aim to improve quality of weight loss

GLP-1 based therapies, such as semaglutide (sema) and tirzepatide, are emerging as standards of care for weight loss; however, up to 40% of weight loss from these agents is due to decreases in muscle mass<sup>1</sup>



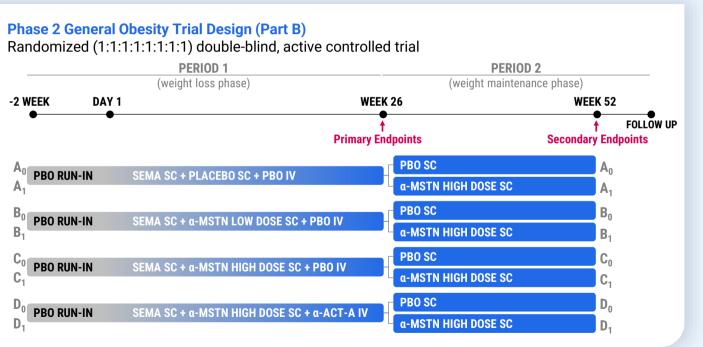
study in obesity expected 2H 2025

Adding myostatin blockade to semaglutide leads to greater fat loss and less muscle mass loss compared to semaglutide monotherapy in obese non-human primates<sup>2</sup>



## Phase 2 COURAGE study in obesity fully enrolled; primary analysis expected to read-out in 2H 2025

Phase 2 study to investigate if addition of trevogrumab (anti-myostatin) to semaglutide with and without garetosmab (anti-activin A) improves the quality of weight loss and/or improves maintenance of weight loss post semaglutide discontinuation



#### **Primary Endpoints:**

- % change in body weight from baseline at week 26
- % change in total fat mass from baseline at week 26

#### **Key Secondary Endpoint:**

 % change in muscle mass from baseline at week 26

## Leveraging decades of expertise to develop a robust pre-clinical obesity and cardiometabolic pipeline

Our **first wave** of therapeutics focuses on improving GLP1-based weight loss by preserving muscle

**Goal:** To provide the best suite of antibody + GLP1 combination therapies – either as coformulations or 'unimolecular' solutions – to improve quality of weight loss and long-term health outcomes

Our **next wave** of therapeutics focuses on GLP1-independent mechanisms and targeting muscle growth and improved metabolism

**Goal:** To bring next-generation muscle and/or neuro-targeted therapies (androgens, siRNAs, gene therapies) to patients as the next cornerstone of healthy weight management therapy

Opportunity to combine novel, first-in-class muscle and/or neuro-targeting agents with appropriate weight loss interventions to provide benefit to distinct patient populations

### World-class Regeneron Genetic Medicines (RGM) Program

RGM builds and utilizes 'turnkey' therapeutic platforms — customizing the choice of genetics technology (siRNA, CRISPR/Cas9, etc.) based on therapeutic application

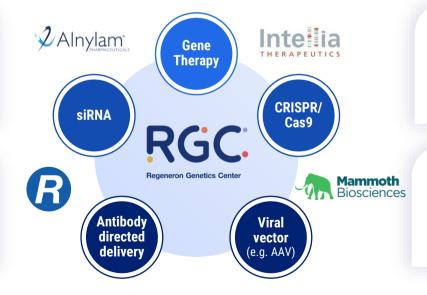
## Continuing to build in-house expertise and leverage groundbreaking industry collaborations



Alnylam: Exclusive siRNA collaboration in eye and CNS, with liver programs in MASH and additional RGC targets



In-House: Developing next-generation gene therapies combining novel payloads, viral vectors and antibodies to address difficult-to-treat diseases





Intellia: Exclusive CRISPR/Cas9 gene knockdown and gene insertion in the liver and ex vivo targets



#### **Mammoth Biosciences:**

Ultracompact CRISPR gene editing systems to advance *in vivo* programs in multiple tissue and cell types

## DB-OTO demonstrates the potential to provide hearing to deaf children (from infancy to adolescence)

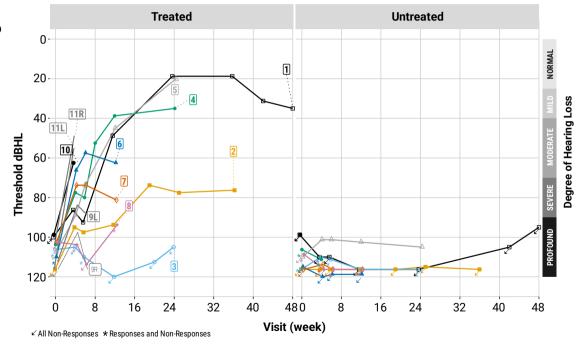
DB-OTO is an AAV-based dual-vector gene therapy delivered to the inner ear to enable hearing in children

#### Gene therapy for genetic hearing deficit

Potentially first-in-class, one-time treatment to enable hearing in patients born with profound deafness due to biallelic OTOF mutations

- Twelve patients between the ages of 10 months and 16 years have now been dosed with DB-OTO (3 bilaterally)
- 10 of 11 treated patients with at least one post treatment assessment have shown a notable response, with improved hearing at various dBHL thresholds
- No DB-OTO related adverse events have been recorded to date
- Updated data presented at Association for Research in Otolaryngology's 48th Annual MidWinter Meeting

Maturing data continues to demonstrate the potential of DB-OTO as a revolutionary treatment for children with genetic hearing deficit



Behavioral pure tone audiogram – a plot of softest sounds a patient can hear in an individual ear

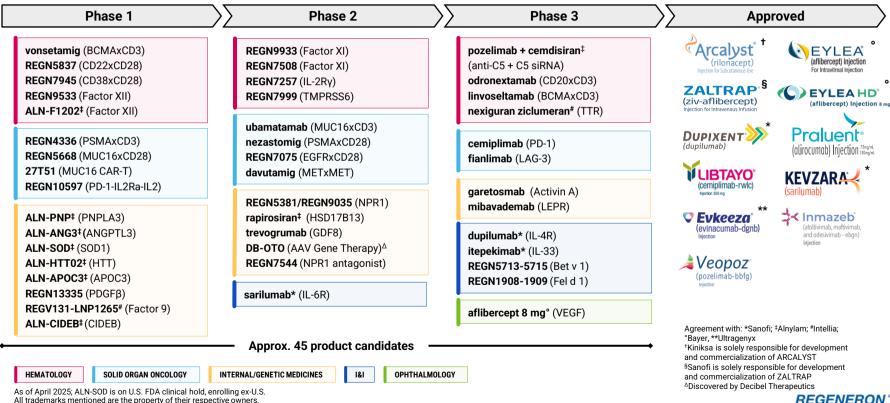
\*Arrows indicate no response at maximum level tested

\*\*REGEN\*\*

### Regeneron Genetic Medicines pipeline

Phase 1 **Select Pre-IND Candidates** Phase 2 Phase 3 ALN-SOD\* AI N-PNP\* Pozelimab + Cemdisiran\* Rapirosiran\* MAPT\* SNCA\* SOD1 siRNA PNPI Δ3 siRNΔ HSD17B13 C5 Antibody + C5 siRNA MAPT (Tau) siRNA SNCA (synuclein) SOD1 ALS NAFI D siRNA Myasthenia Gravis; Paroxysmal Neuro-degenerative siRNA Nocturnal Hemoglobinuria; diseases Parkinson's MASH AI N-ANG3\* **AI N-HTT02\*** Geographic Atrophy ANGPTL3 siRNA HTT siRNA Healthy Volunteers Huntington's Disease ALN-APOC3\* **ALN-CIDEB\*** APOC3 siRNA **CIDEB siRNA** People with MASH dvslipidemia **Nexiguran ziclumeran** Factor 9<sup>†</sup> **GAA**† (Nex-z. NTLA-2001) † GAA CRISPR + AAV F9 CRISPR + AAV CRISPR/Cas9 Hemophilia B Pompe Disease Transthyretin Amyloidosis with cardiomyopathy (ATTR-CM): Hereditary transthyretin amyloidosis with polyneuropathy (ATTRv-PN) GJB2 DB-OTO | OTOF AAV Dual Vector Gene Therapy **GJB2 AAV** OTOF-related Hearing Deficit (Phase 1/2) GJB2-related Hearing Loss

### Regeneron-discovered, approved and investigational medicines across a diverse set of diseases



As of April 2025; ALN-SOD is on U.S. FDA clinical hold, enrolling ex-U.S. All trademarks mentioned are the property of their respective owners.

## Differentiated pipeline opportunities to potentially address categories expected to exceed \$220 billion annually in 2030

Category	Product	Anticipated Launch Year	Indication(s)	Value Proposition
Eosinophilic COPD	Dupixent	2024	Eosinophilic COPD	First and only biologic approved for eosinophilic COPD
COPD in former smokers	itepekimab	2026	COPD in former smokers	Potential first-in class opportunity to address up to 1 million former smokers with COPD globally
Non-melanoma skin cancers	Libtayo	2025-2026	Adjuvant CSCC	First and only immunotherapy to show a statistically significant DFS benefit in high-risk adjuvant CSCC
Solid tumors	fianlimab + Libtayo	2026 (Melanoma)	Melanoma, NSCLC, HNSCC	Emerging as a potentially differentiated treatment option in multiple solid tumors
Myeloma	linvoseltamab	2025 (3L+ MM only)	Multiple myeloma & pre-cursor conditions	Potentially best-in-class BCMA bispecific to disrupt current treatment paradigm in earlier lines
Lymphoma	odronextamab	2025 (3L+ FL only)	FL, DLBCL	Potentially best-in-class CD20 bispecific (in FL) to disrupt current treatment paradigm in earlier lines
Complement- mediated diseases	pozelimab + cemdisiran	2027 (gMG)	gMG, PNH, GA	Complete inhibition of C5 has potential to improve efficacy and convenience
Anticoagulants	REGN7508 & REGN9933	2028	Coagulation disorders	Potential to improve efficacy and safety relative to current standards of care
Obesity	trevogrumab ± garetosmab	2028	Obesity, T2DM	Potential to improve quality of weight loss when combined with GLP-1 therapy
Food allergy treatment	Dupixent + linvoseltamab	TBD	lgE-mediated food allergies	Groundbreaking approach to potentially reverse severe food allergy

### 2025 key upcoming milestones

#### **FYI FA HD**

- RVO sBLA acceptance √; FDA decision (PDUFA Aug 19)
- Pre-filled syringe FDA decision and launch CRL received
- Addition of 2-year data in wAMD and DME to FDA label CRL received
- Addition of Q4W dosing to FDA label for all indications (PDUFA Aug 19)

#### **Dupixent / I&I**

- Report pivotal data for itepekimab in COPD (mid); submit BLA (2H)
- Dupixent CSU FDA decision ✓
- Initiate additional Phase 3 studies for itepekimab ✓
- · Report additional data for Dupixent + BCMA in severe food allergies

#### Internal Medicine

- Report proof-of-concept data of combination of semaglutide and trevogrumab with and without garetosmab in obesity (2H)
- Report Phase 3 data for garetosmab in FOP (2H)

#### **Solid Organ Oncology**

- Submit sBLA for Libtayo in adjuvant CSCC√
- Report results from Phase 3 study of fianlimab + cemiplimab vs. pembrolizumab monotherapy in 1L metastatic melanoma (2H); submit BLA pending results (2H)
- Report initial Phase 2 data for fianlimab + cemiplimab in 1L advanced NSCLC studies continuing until next analysis in 1Q 2026
- Report additional data for ubamatamab (MUC16xCD3) in ovarian cancer (2H)
- · Report additional data across solid tumor costimulatory bispecific programs:
  - Nezastomig (PSMAxCD28) + cemiplimab in mCRPC √
  - EGFRxCD28 + cemiplimab -- dose expansion cohorts (2H)
  - MUC16xCD28 + ubamatamab in ovarian cancer

#### Hematology

- Initiate Phase 3 program for Factor XI antibodies across multiple indications

#### **Genetic Medicines**

- Report additional data for DB-OTO (mid)
- Report pivotal Phase 3 data for pozelimab+cemdisiran in gMG (2H)

## Continuing to deliver on capital allocation priorities to drive long-term growth



## Internal Investment

in our world-class R&D capabilities and capital expenditures to support sustainable growth

- Investing >\$5 billion into R&D in 2025<sup>†</sup>
- Continued investments in R&D and manufacturing capacity in the U.S.
  - Ongoing and planned investments in New York and North Carolina infrastructure and manufacturing expected to total more than \$7B



## **Business Development**

to expand pipeline and maximize commercial opportunities

- Strong financial position provides significant optionality to pursue business development opportunities that complement our internal capabilities
- Collaboration agreements provide innovative pipeline opportunities



#### Return Capital to Shareholders

with share repurchases and dividends

- Over \$1B in share repurchases in Q1 2025
- Additional \$3B program authorized in February 2025; ~\$3.9B remaining in aggregate authorizations\*
- First quarterly cash dividend paid; second dividend of \$0.88/share to be paid June 6, 2025 to shareholders of record as of May 20, 2025



#### **OUR MISSION**

Use the power of science to repeatedly bring new medicines to people with serious diseases

Three responsibility focus areas reflect our "doing well by doing good" ethos



#### Improve the lives of people with serious diseases

- · Pipeline innovation
- Access and affordability
- · Patient advocacy







#### Foster a culture of integrity and excellence

- · Product quality and safety
- · Healthy and engaged workforce
- · Ethics and integrity
- Responsible supply chain







#### **Build sustainable communities**

- STEM education sponsorship of top science competitions:
- Regeneron Science Talent Search
- Regeneron International Science and Engineering Fair
- Environmental sustainability







**REGENERON<sup>®</sup>** 

### **GAAP to Non-GAAP Reconciliations**

REGENERON PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION (Unaudited)
(In millions, except per share data)

(in millions, except per snare data)				
	Т	hree Mon Marc		
		2025		2024
GAAP R&D	\$	1,327.4	\$	1,248.4
Stock-based compensation expense		141.0		123.0
Acquisition and integration costs		_		3.8
Non-GAAP R&D	\$	1,186.4	\$	1,121.6
GAAP SG&A	S	633.0	S	689.0
Stock-based compensation expense	Ф	95.2	Þ	86.2
Acquisition and integration costs		0.8		18.8
Non-GAAP SG&A	\$	537.0	•	584.0
NOII-GAAF SG&A	Φ	537.0	\$	364.0
GAAP COGS	\$	265.5	\$	240.4
Stock-based compensation expense		19.5		20.9
Acquisition and integration costs		_		0.4
Intangible asset amortization expense		28.7		23.2
Non-GAAP COGS	\$	217.3	\$	195.9
GAAP other operating expense (income), net	S		S	15.3
Change in fair value of contingent consideration	φ	_	φ	15.3
Non-GAAP other operating expense (income), net	\$		\$	10.0
Non-GAAP other operating expense (income), her	Ψ		9	
GAAP other income (expense), net	\$	313.3	\$	(50.7)
(Gains) losses on investments, net		(139.9)		196.1
Non-GAAP other income (expense), net	\$	173.4	\$	145.4
GAAP net income	s	808.7	s	722.0
Total of GAAP to non-GAAP reconciling items above	Φ	145.3	Φ	487.7
Income tax effect of GAAP to non-GAAP reconciling items		(25.6)		(93.8)
Non-GAAP net income	-	928.4	_	1,115.9
NOT-GAAF TEL IIICOTTE	\$	920.4	\$	1,115.8
Non-GAAP net income per share - basic	\$	8.70	\$	10.35
Non-GAAP net income per share - diluted	\$	8.22	\$	9.55
Shares used in calculating:				
Non-GAAP net income per share - basic		106.7		107.8
Non-GAAP net income per share - diluted		113.0		116.8

	Q1 2025 vs Q1 2024
Total Dupixent Net Product Sales - Global	
% growth as reported	19%
% growth at constant currency	20%
Total Libtayo Net Product Sales - Global	
% growth as reported	8%
% growth at constant currency	8%
Total EYLEA & EYLEA 8mg Net Product Sales - Outside the U.S.	
% growth as reported	1%
% growth at constant currency	5%

### **Abbreviations and Definitions**

Abbreviation	Definition
1L	First line
AACR	American Association for Cancer Research
AAV	Adeno-associated virus
ALS	Amyotrophic lateral sclerosis
aPTT	Activated Partial Thromboplastin Time
BCC	Basal cell carcinoma
BCMA	B-cell maturation antigen
BP	Bullous pemphigoid
CAR-T	Chimeric antigen receptor T-cell
CI	Confidence Interval
CNS	Central nervous system
COPD	Chronic obstructive pulmonary disease
CPUO	Chronic pruritus of unkown origin
CR	Complete response
CRC	Colorectal Cancer
CRS	Cytokine release syndrome
CRSsNP	Chronic sinusitis without nasal polyposis
CRSwNP	Chronic sinusitis with nasal polyposis
CSCC	Cutaneous squamous cell carcinoma
CSU	Chronic spontaneous urticaria
dB HL	Decibel hearing loss

Abbreviation	Definition
DFS	Disease-Free Survival
DOAC	Direct oral anticoagulants
DR	Diabetic retinopathy
DXA	Dual-energy X-ray absorptiometry
EC	European Commission
ECOG	Eastern Cooperative Oncology Group
EGFR	Epidermal growth factor receptor
EoE	Eosinophilic Esophagisits
FIH	First in human
FL	Follicular lymphoma
FLIPI	Follicular Lymphoma
	International Prognostic Index
FOP	Fibrodysplasia Ossificans
	Progressiva
GA	Geographic atrophy
GAA	Alpha glucosidase
GELF	Groupe d'Etude des
	Lymphomes Folliculaires
GI	Gastrointestinal
GIP	Gastric inhibitory polypeptide
GLP-1	Glucagon-like peptide 1
gMG	Generalized myasthenia gravis
HCC	Hepatocellular carcinoma
HCP	Healthcare Provider
HNSCC	Head and neck squamous
	· · · · · · · · · · · · · · · · · · ·

Abbreviation	Definition
HR	Hazard Ratio
HTT	Huntingtin
ICANS	Immune effector cell-
ICANS	associated neurotoxicity syndrome
IgE	Immunoglobulin-E
IND	Initial new drug application
KM	Kaplan-Meier curve
LAG-3	Lymphocyte-activation gene 3
LEPR	Leptin receptor
LMWH	Low molecular weight heparin
LOF/GOF	Loss of function/ Gain of function
MAPT	Microtubule-associated protein tau
MASH	Metabolic Dysfunction-Associated Steatohepatitis
mCRPC	Metastatic castration-resistant prostate cancer
MGUS	Monoclonal gammopathy of unknown significance
MM	Multiple myeloma
m0S	Median overall survival
mPFS	Median progression-free survival
MUC16	Mucin 16
NAFLD	Non-alcoholic fatty liver disease
NHP	Non-human primate
NR	Not Reached
NSCLC	Non-small cell lung cancer
ORR	Overall Response Rate

Abbreviation	Definition
PD-1/PD-(L)1	Programmed cell death protein/(ligand) 1
PDUFA	Prescription Drug User Fee Act
PK	Pharmacokinetic
PNH	Paroxysmal nocturnal hemoglobinuria
POC	Proof-of-concept
PR	Partial response
PSMA	Prostate-specific
	membrane antigen
R/R	Relapsed/Refractory
RCC	Renal cell carcinoma
RGC	Regeneron Genetics Center
RVO	Retinal vein occlusion
(s)BLA	(Supplemental) biologics license application
SC	Subcutaneous
sCR	Stringent complete response
SD	Stable disease
siRNA	Small interfering RNA
SOC	Standard of care
SPAF	Stroke Prevention in Atrial Fibrillation
T2DM	Type 2 diabetes mellitus
TEAE	Treatment-emergent adverse events
TRAE	Treatment-related adverse events
VEGF	Vascular endothelial growth factor
VTE	Venous thromboembolism