## Regeneron Corporate Presentation

MAY 2024

**REGENERON®** 

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

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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 on the commercial success of Regeneron's Product and Regeneron's Product Candidates; Regeneron's ability to manufacture and manage supply chains for multiple products and product candidates; 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 and Regeneron's Product Candidates; the availability and extent of reimbursement of Regeneron's Products from third-party payors, 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 new policies and procedures adopted by such payors; unanticipated expenses; the costs of developing, producing, and selling products; Regeneron's ability to meet any of its financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; 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 (such as the COVID-19 pandemic) on Regeneron's business; and 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), other 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), 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. 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## REGENERON

### **Executing on our** core competencies



#### #1 prescribed

FDA approved anti-VEGF treatment for retinal disease



~\$3.1B net product sales in 1024<sup>†</sup>



#### Now FDA approved

Aspire to become new standardof-care



Emerging portfolio of immuno-oncology antibodies

### **Investing in** Regeneron

- Investing ~\$5B into R&D in 2024\*
- New \$3B share repurchase program authorized in April 2024
- Repurchased over \$12B of shares since Nov 2019§

### Looking ahead to the future

- Over 35 therapeutic candidates in various stages of clinical development
- **Pioneering** novel therapeutic approaches including in genetic medicines
- **Expanding partnerships** with leading companies in new technologies











Advancing a best-in-class. diversified pipeline based on innovation and strategic partnerships



driving new breakthroughs and target discovery

## Continued execution driving strong results





1Q 2024 Total Revenues\*†

+7% YoY

10 2024 Non-GAAP EPS<sup>†</sup>

\$9.55

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



 EYLEA HD (known as EYLEA 8 mg outside of U.S.) approved in EU and Japan for wAMD and DME

### DUPIXENT

- sBLA accepted for priority review for COPD with evidence of Type 2 inflammation (PDUFA June 27, 2024)
- Approved in Japan for CSU in patients age 12+; regulatory application submitted in EU
- Approved for pediatric (1 -11 years) EoE in US; under review in EU
- BLA for linvoseltamab for MM accepted by FDA for Priority Review (PDUFA Aug 22, 2024); Phase 3 confirmatory study currently enrolling
- Positive pivotal data for linvoseltamab presented at American Association for Cancer Research (AACR)
- Praluent approved by FDA for pediatric (8+ year) HeFH
- · Acquired clinical and preclinical programs from 2seventy bio
- · Initiated Phase 2 study of ALN-APP in cerebral amyloid angiopathy
- Initiated Phase 2 study of itepekimab in non-cystic fibrosis bronchiectasis

## EYLEA HD approved in U.S. for wAMD, DME, and DR



has the potential to become the **next-generation standard-of-care** anti-VEGF treatment

10 2024 U.S. Net Product Sales:

\$200 million

achieved in second full quarter following launch



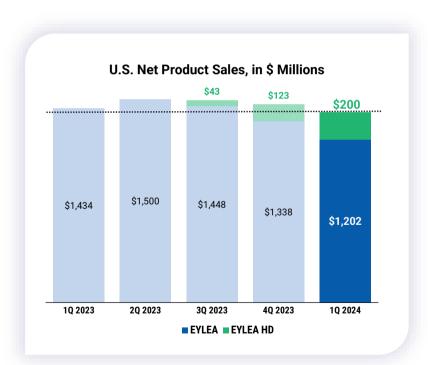


1Q 2024 combined EYLEA HD + EYLEA U.S. net product sales of **\$1.4 billion** 

- FDA approval for wAMD, DME and DR received in August 2023
- Early indicators suggest broad initial uptake across treatment landscape
- Strong 2-year data from pivotal PULSAR and PHOTON studies presented in 2023, supporting best-in-class efficacy, safety, and durability profile
- >80% of eligible lives have coverage; vast majority of covered lives have first-line or single-step-edit access to Eylea HD
- CMS-assigned permanent J-Code took effect on April 1, 2024

## Maintaining U.S. anti-VEGF category leadership with Eylea HD launch

Building on 12+ years of safety and efficacy experience, breadth of indications, and flexible dosing regimens







### 01 2024 combined revenues of \$1.4 billion

#### **Eylea HD launched in late August 2023**

- 1Q 2024 U.S. net product sales of \$200M
- U.S. net product sales of \$366M since launch

#### **Eylea remains #1 anti-VEGF treatment for retinal diseases**

- 1Q 2024 U.S. net product sales of \$1.2B
  - Negatively impacted by changing market dynamics, resulting in a lower net selling price and lower volumes

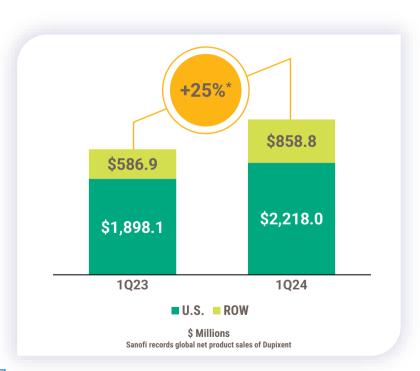
Net product sales of EYLEA and EYLEA HD in 1Q 2024 were negatively impacted by ~\$40 million due to sequential net reduction in wholesaler inventory

**45%** category share for Eylea HD and Eylea in 1Q 2024\*



## Dupixent global net product sales grew 25%\*

In the first quarter of 2024, Dupixent global net sales grew **25**%\* **to ~\$3.1 billion**Incremental market penetration, new indications, and younger populations represent significant opportunity for continued growth



## >850,000 patients on therapy globally

## Approved in <u>FIVE</u> indications in the U.S., positive pivotal results in <u>SEVEN</u> Type 2 allergic diseases

- **▼ TRx** #1 prescribed biologic in 4 of 5 approved indications

### **Pediatric Eosinophilic Esophagitis**

▼ FDA-approved in Jan 2024 in patients as young as 1 year old (≥15 kg)

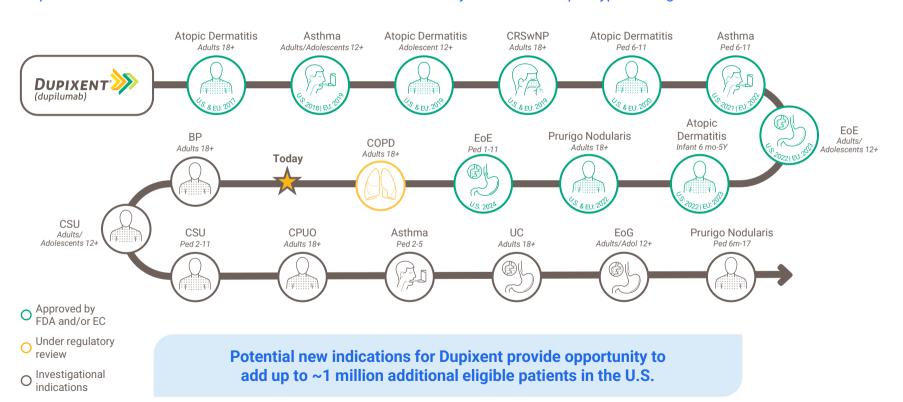
### **Chronic Obstructive Pulmonary Disease**

- Reported positive results for pivotal BOREAS and NOTUS studies
- Granted priority review by FDA (PDUFA June 27, 2024); EC decision expected 2H24



## Delivering on "pipeline in a product" potential

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



## Potential to change the COPD treatment paradigm with Dupixent and itepekimab



(anti-IL4/13)

Positive results in Phase 3 BOREAS and NOTUS studies in eosinophilic COPD reported during 2023

sBLA accepted for Priority Review (PDUFA June 27, 2024)

	BOREAS	NOTUS
Primary endpoint: Significant reduction in moderate or severe COPD exacerbations over 52 weeks compared to placebo	<b>30%</b> (p=0.0005)	<b>34%</b> (p=0.0002)
Key secondary endpoint: Significant improvement in lung function at week 12 compared to placebo*	<b>+83 mL</b> (p<0.0001)	<b>+82 mL</b> (p=0.0001)

Lung function benefit vs. placebo observed at Week 12 sustained at Week 52 Safety findings generally consistent with known safety profile of Dupixent

### **Itepekimab**

(anti-IL-33)

Positive data in former smokers in Phase 2 COPD study informed Phase 3 trial design

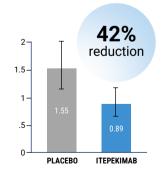
Phase 3 AERIFY studies passed interim futility analysis in 2023; studies nearing complete enrollment

#### Demonstrated 42% reduction in exacerbations in former smokers vs. placebo in Phase 2 study

- RGC-generated human genetics data support rationale for IL-33 blockade to treat COPD
- Pivotal results from both AERIFY studies expected in 2025

#### Phase 2 COPD Trial

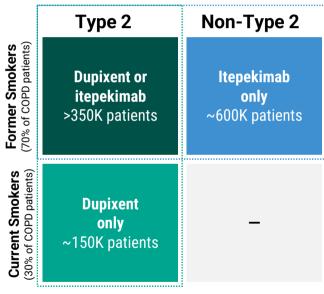
Itepekimab led to 42% reduction in exacerbations in former smokers



## Dupixent & itepekimab: Two opportunities to address high unmet need in COPD



- Potential to address COPD with a Type 2 inflammatory 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\*
- sBLA accepted for Priority Review (PDUFA June 27, 2024)
  - Granted Breakthrough Therapy Designation by FDA
  - **✔** EC decision expected 2H24



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

## Itepekimab

(anti IL-33)

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

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

400

300

200

Baseline

Day

85-99

(avg)

Control

bispecific

(single dose)

Day

169

SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

#### ALLERGY

A therapeutic strategy to target distinct sources of IgE and durably reverse allergy

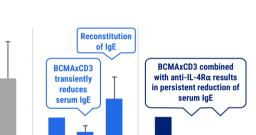
Andre Limnander, Navneet Kaur, Seblewongel Asrat, Carley Tasker, Anita Boyapati, Li-Hong Ben. John Janczy, Paulina Pedraza, Pablo Abreu, Wen-Chi Chen, Stephen Godin, Benjamin J. Daniel, Harvey Chin, Michelle DeVeaux, Karen Rodriguez Lorenc, Andres Sirulnik, Olivier Harari, Neil Stahl, Matthew A. Sleeman, Andrew J. Murphy, George D. Yancopoulos, Jamie M. Orengo\*

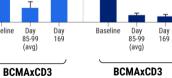
#### **Linvoseltamab and Dupixent regimen could** eliminate IgE: potential groundbreaking approach for controlling severe allergy

- Immunoalobulin E (IaE) is the key driver of allergic reactions, such as food allergies; long-lived plasma cells consistently produce IaE2
- In atopic patients, transient linvoseltamab treatment with **Dupixent maintenance** has the potential to permanently eliminate IgE and durably reverse severe allergies, while allowing the restoration of other immunoglobulins



Transient plasma cell depletion with BCMAxCD3 plus sustained IL-4Ra blockade durably eliminates IgE production in cynomolaus monkeys1



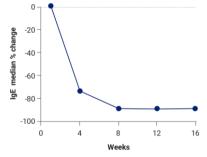


bispecific (single dose) + IL-4Ra antibody (OW)



#### Myeloma patients treated with linvoseltamab rapidly reduce IgE levels<sup>1</sup>

Median concentrations of serum IgE over time in MM patients (n=12) receiving OW linvoseltamab\*



- Linvoseltamab effectively eliminates BCMA-expressing cells, including long-lived plasma cells
- IaE reduction seen in myeloma patients supports the two-drug regimen for severe food allergies

Clinical trial with the two-drug regimen in patients with severe food allergies now underway

Baseline

bispecific

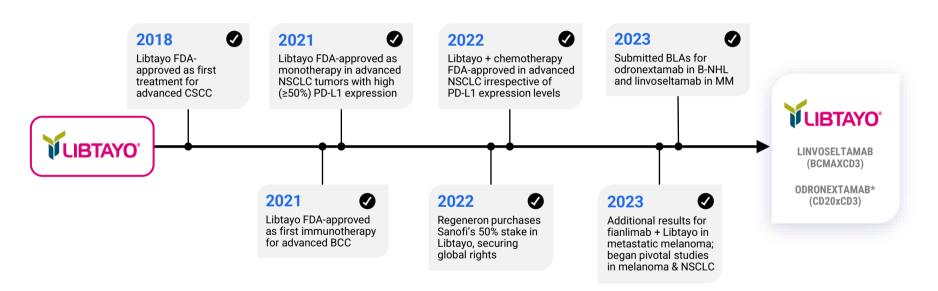
(single dose)

<sup>&</sup>lt;sup>1</sup>Adapted from Limnander et al, Sci. Transl. Med. 2023. Asrat et al, Sci. Immunol. 2020.

<sup>\*</sup> Pooled data from n=12 multiple myeloma patients from the LINKER-MM1 Phase 1 study, treated with six different dose levels of linvoseltamab

## Striving for global leadership in oncology

Potential for multiple FDA-approved products by end of 2024, spanning solid and hematological malignancies



Libtayo poised to exceed \$1 billion in global net product sales in 2024; Robust oncology pipeline driven primarily by Libtayo combinations

## Harnessing the immune system to fight cancer

Regeneron has validated 3 independent classes of internally-developed immuno-oncology agents in clinical trials

Checkpoint Inhibitors (anti-PD-1 & anti-LAG-3)



(anti-PD-1) CSCC, BCC, NSCLC

#### **Fianlimab**

(anti-LAG-3) Melanoma, NSCLC, HCC CD3 Bispecifics ("Signal 1")

Odronextamab

Linvoseltamab

(CD20xCD3) B-NHL

REGN4336

**Ubamatamab** 

(MUC16xCD3)

Ovarian Cancer

(BCMAxCD3) (PSMAxCD3) MM Prostate Cancer CD28 Costimulatory Bispecifics ("Signal 2")

Nezastomig

(PSMAxCD28)
Prostate Cancer

REGN5668 (MUC16xCD28)

Ovarian Cancer

**REGN7075** 

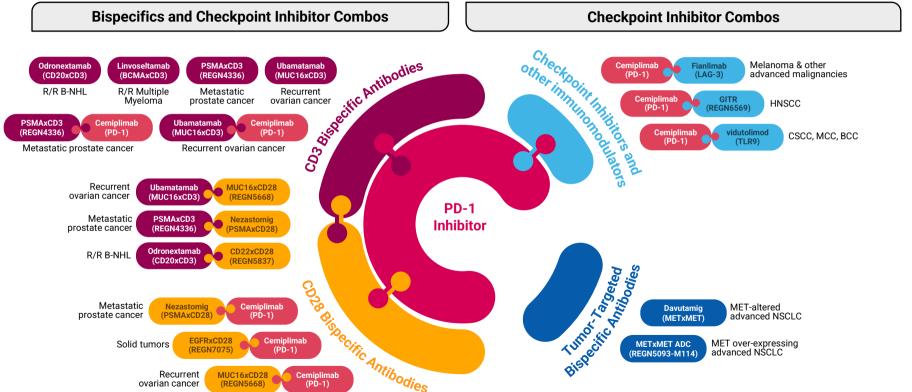
(EGFRxCD28)
Solid Tumors

**REGN5837** 

(CD22xCD28)

Broad pipeline of clinical-stage assets supports novel immuno-oncology combinations

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





## Libtayo: Key growth driver and oncology portfolio foundation

Market leader in advanced cutaneous squamous cell carcinoma and advanced basal cell carcinoma



### **Strong and Consistent Growth**

 Q1 2024 U.S. net product sales of \$159M (+45% YoY) and rest of world sales of \$105M (+43%\* YoY)

#### **Non-Small Cell Lung Cancer**

- One of two PD-1 antibodies FDA-approved for use in combination with chemotherapy irrespective of histology or PD-L1 expression levels in 1L NSCLC
- Approved by EC in 1L NSCLC in combination with platinum-based chemotherapy for patients with PD-L1 expression ≥ 1%

#### **Dermato-Oncology**

- Leading anti-PD-1/L1 therapy in approved non-melanoma skin cancers
- Plan to conduct interim analysis from Phase 3 study in adjuvant CSCC (2H24)
- Foundational therapy for future combination approaches in melanoma

## Fianlimab (anti-LAG-3) + cemiplimab (anti-PD-1): Combining two checkpoint inhibitors

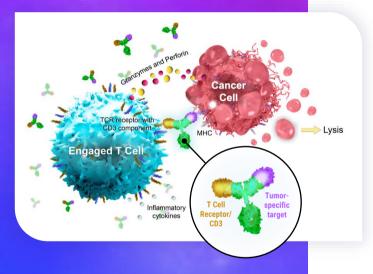
Results from three independent 1L metastatic melanoma cohorts from the FIH study demonstrated strong efficacy signal, including in patients treated with adjuvant anti-PD-1 therapy

		Phase 1	Phase 2	Phase 3	_	Results in 1L Metastatic Melano	ma			
	1L Metastatic Melanoma	Enrolling - Data	expected 2025			<b>fianlimab + cemiplimab</b> FIH POC study <sup>1</sup>	ORR	DCR	mPFS (KM-estimate)	
Melanoma	Adjuvant Melanoma	Enrolling				Cohort MM1 (n=40) Initial	63%	80%	24 mo	
	Perioperative Melanoma	Initiating 1H24		•		Cohort MM2 (n=40) Confirmatory	63%	80%	15 mo	
Lung	Advanced NSCLC	Enrolling - Initia	al data 2H24		•	Cohort MM3 (n=18) PD-1 in adjuvant setting	56%	67%	12 mo	
(NSCLC)	Perioperative NSCLC	Initiating 1H24		_ '	RELATIVITY-047 Phase 3 <sup>2</sup>					
					_	nivolumab (n=359)	33%	51%	4.6 mo	
	Perioperative HCC	Enrolling				nivolumab + relatlimab (n=355)	43%	63%	10.2 mo	
Other solid tumors	Perioperative CSCC	e CSCC Initiating 2024				Safety profile of fiant				
tuiii010	Perioperative HNSCC	Initiating 2025				combination similar to anti-PD-1 monotherap				

<sup>&</sup>lt;sup>1</sup>Hamid, O. Significant durable response with fianlimab (anti-LAG-3) and cemiplimab (anti-PD-1) in advanced melanoma: post adjuvant PD-1 analysis, ASCO 2023.

<sup>&</sup>lt;sup>2</sup>Long, G. Relatlimab and nivolumab versus nivolumab in previously untreated metastatic or unresectable melanoma: Overall survival and response rates from RELATIVITY-047, ASCO Plenary Series, March 2022.

# Regeneron's leading CD3 bispecifics



Our blood cancer research is focused on bispecific antibodies that are being investigated both as monotherapies and in various combinations

#### Linvoseltamab (BCMAxCD3) - MM

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

Confirmatory Phase 3 study underway; expanding into early stages of disease

BLA accepted for Priority Review in R/R MM (PDUFA August 22, 2024)

EU submission accepted, currently under review

#### Odronextamab (CD20xCD3) - NHL

Odronextamab has the potential to treat both indolent and aggressive lymphomas with potential best-in-class efficacy in FL and a competitive profile in DLBCL, including patients previously treated with CAR-T therapy

Phase 3 OLYMPIA program underway and enrolling patients in earlier lines of therapy

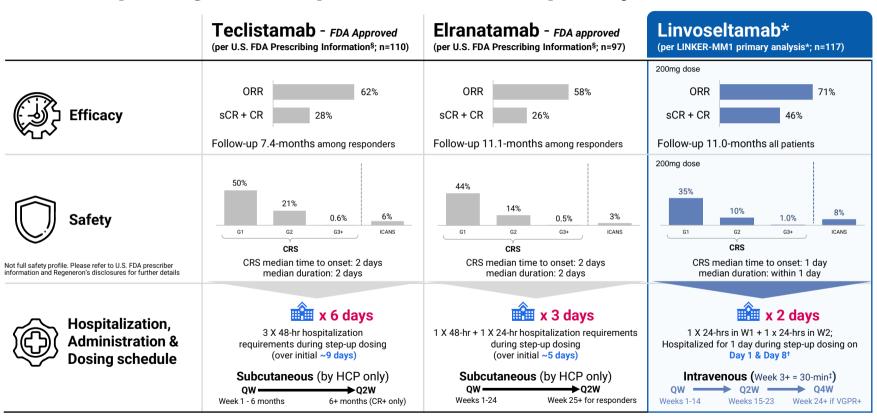
CRLs received for DLBCL and FL solely due to enrollment status of confirmatory trials

Update to be shared on enrollment and FDA timelines later this year

EU submission completed; decision expected 2H 2024

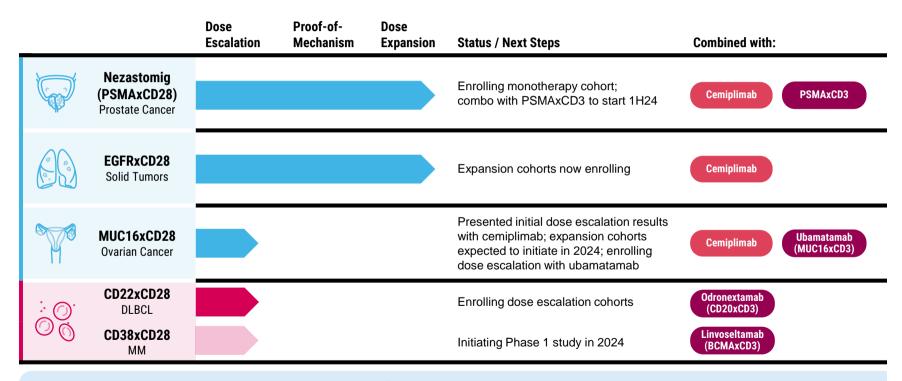
17 REGENERONS

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



<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.

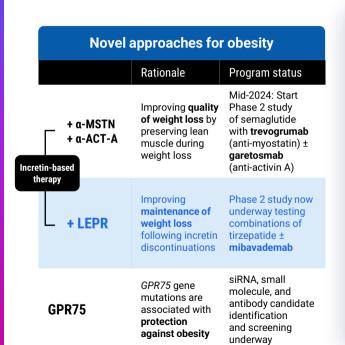
## **Progressing CD28 costimulatory bispecifics**

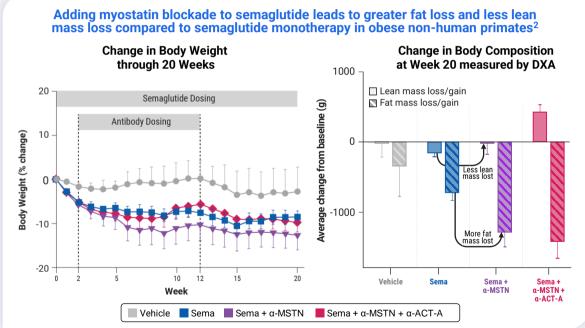


Additional costimulatory bispecifics expected to enter the clinic in 2024 and beyond

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

Incretin-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 lean muscle mass<sup>1</sup>

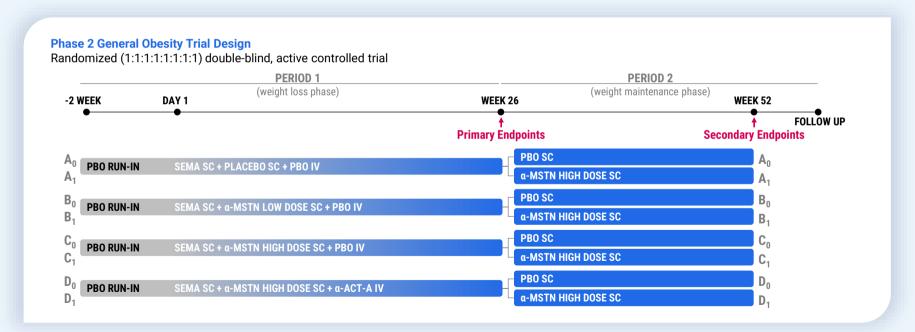




## Obesity clinical program to start in mid-2024

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

Enrollment of obese patients expected to begin in mid-2024; safety and tolerability trial of high-dose trevogrumab
in healthy volunteers is fully enrolled



## Next-generation approach to anticoagulation via Factor XI inhibition offers potential for blood clot prevention with minimal bleeding

REGN9933 and REGN7508: Both Factor XI antibodies rapidly advancing to pivotal trials starting in late 2024/early 2025

### Current standard of care: targeting Factor Xa

- \$20Bn atrial fibrillation market is dominated by Direct Oral Anticoagulants (DOACs), which target Factor Xa
  - Effective at reducing thrombotic events, but carry elevated risk of bleeding
  - Utilization rate is only ~50%, mainly due to bleeding risk

#### **Future vision: inhibiting Factor XI**

- More specific inhibition of the intrinsic coagulation pathway
- Our FXI antibodies could address unmet need in thrombosis prevention
  - higher specificity and efficacy vs. small molecule inhibitors
  - more complete inhibition of FXI vs. competitor FXI antibodies<sup>1</sup>

#### 

#### **Emerging evidence supports targeting FXI for anticoagulation:**



#### Human FXI deficiency: protection against thrombosis, low bleeding risk

 Genetic data from patients with FXI deficiency suggest reduced risk of myocardial infarction, stroke and venous thromboembolism (VTE), with only mild bleeding phenotype (data from RGC<sup>2</sup>, others)



Preclinical FXI data: antithrombotic efficacy without bleeding



External clinical FXI validation: antithrombotic efficacy, reduced bleeding compared to SOC

#### **REGN9933 and REGN7508:**

#### Rapid path to pivotal trials in 2024/2025

- Based on preclinical, NHP, unpublished healthy volunteer data, and Phase 2 POC data (expected in 2H24)
- · Phase 3 indications to be announced



## Regeneron Genetic Medicines: multiple investigational approaches for treatment of genetic diseases

Established clinical proof-of-principle across several diseases with novel genetic medicine technologies



### siRNA Gene Silencing

(alone and antibody combos)

- First clinical results demonstrating silencing of a pathological gene in human brain (APP)\*
- Pioneers in siRNA + antibody combo (C5)



#### **CRISPR**

## Knockout and Insertion Genome Editing

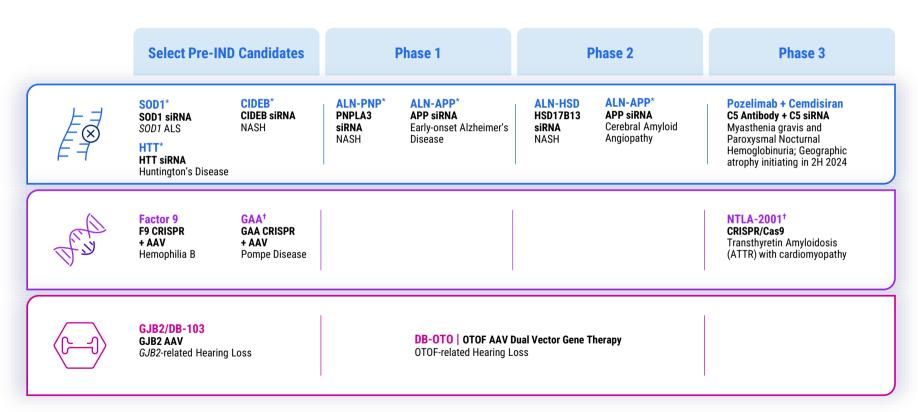
- Gene knockout: first clinical results demonstrating genome editing in humans; Phase 3 started (TTR)<sup>†</sup>
- Gene insertion: interventional trial portion of the clinical program to start in 2024 (*Factor 9*)



### AAV Gene Therapy

- Local delivery: restored hearing in first treated patient (OTOF)
- Antibody-targeted delivery: proofof-concept in non-human primates; clinical approach in development (muscle disorders)

## Regeneron Genetic Medicines pipeline



## Geographic atrophy (in dry AMD): Extending our C5 siRNA + antibody approach to ophthalmology

Current Goographic

Pivotal Phase 3 program to initiate in 2H 2024

### **Program Overview**

(Initiating in 2H 2024)

Two Phase 3 pivotal trials (multi-center, randomized, double-masked) in geographic atrophy secondary to age-related macular degeneration

		Atrophy Landscape	(Pozelimab + Cemdisiran Combo)
ዅ፟፟ቝ፟ ቝ፟ዅ፟ቝ፟ ቝ፟ዅ፞ቝ፟	Market Opportunity	<ul> <li>~1M diagnosed in U.S.</li> <li>Increasing diagnosis and drug-treatment rates</li> <li>2 approved agents, many more in development</li> </ul>	<ul><li>Leadership in ophthalmology</li><li>Differentiated MOA</li></ul>
p Chil	Route of Administration	<ul> <li>Q4W/Q8W intravitreal injections</li> <li>Bilateral disease requires injections in each eye</li> </ul>	<ul> <li>Less invasive treatment option</li> <li>Systemic administration enables treatment of bilateral disease</li> <li>Q4W systemic treatment</li> </ul>
	Ocular Safety	<ul> <li>Reported cases of occlusive retinal vasculitis along with other ocular safety events</li> </ul>	<ul> <li>Systemic administration potentially reduces risk of ocular safety events</li> </ul>
Ø	Efficacy	<ul> <li>Approved agents lack evidence of maintenance of visual function</li> </ul>	<ul> <li>Opportunity to demonstrate greater reduction in lesion growth rate along with preservation of visual function</li> </ul>
Ų	Office Visits	<ul> <li>Administered in office by retinal specialist</li> </ul>	<ul> <li>Potential for self-administration (subcutaneous coformulation)</li> </ul>

Paganaran Opportunity

## Regeneron restores hearing in a profoundly deaf child

DB-OTO AAV-based dual-vector gene therapy delivered to the inner ear to rescue hearing in infants

### **Gene therapy for genetic hearing loss**

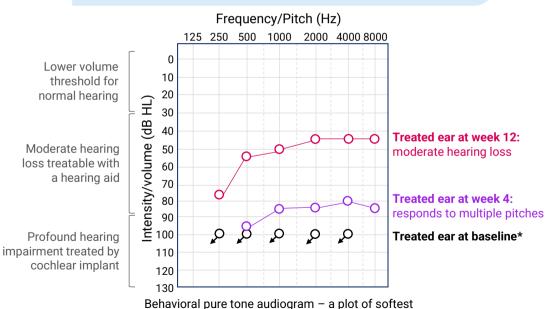
Potentially first-in-class, one-time treatment to rescue hearing in infants born with profound deafness due to biallelic OTOF mutations

- DB-OTO is a surgically delivered AAV-based dual-vector gene therapy that selectively expresses functional OTOF in the inner ear hair cells of patients, enabling the ear to transmit sound to the brain
- Preliminary, positive safety and efficacy results from the first patient (<2 years old) continue to show improvements in auditory responses, now through week 12, compared to baseline
- Paves the way for next gene therapy for genetic hearing loss – GJB2
  - Currently in IND-enabling studies

#### **Preliminary results for first patient dosed:**

Profoundly deaf child at baseline, demonstrates markedly improved hearing at 12 weeks post-treatment

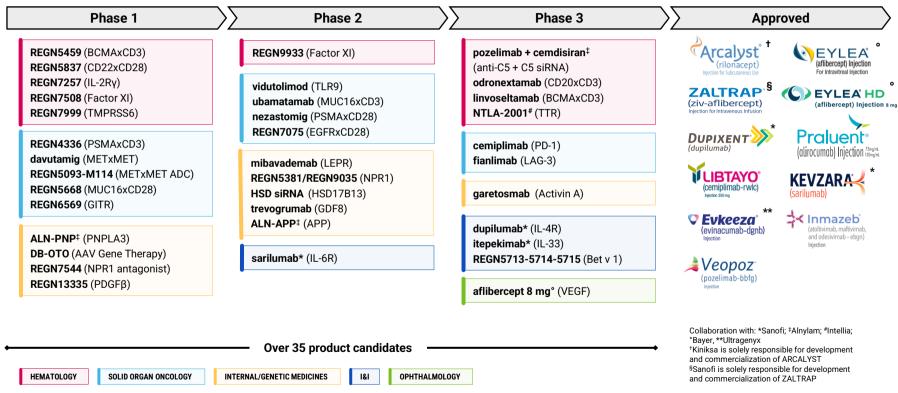
Updated data to be presented at ASGCT in May



sounds a patient can hear in an individual ear

\*Arrows indicate no response at maximum level tested

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





## 2024 key upcoming milestones

#### **Ophthalmology**

- EU decision for aflibercept 8 mg in wAMD and DME √
- Japan decision for aflibercept 8 mg in wAMD and DME √
- · Initiate pivotal RVO study of Eylea HD to enable FDA filing (mid)
- Obtain permanent J-code for EYLEA HD ✓
- Initiate pivotal studies of pozelimab + cemdisiran combination in geographic atrophy (2H)

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

- Regulatory decisions for pediatric (1-11 yrs) eosinophilic esophagitis in U.S. 
   ✓ and EU (2H)
- sBLA acceptance for COPD with a Type 2 inflammatory phenotype √; potential FDA approval (PDUFA June 27, 2024); EC decision (2H)
- Report results from ongoing Phase 3 study in CSU (4Q)
- Initiate Phase 1 study in severe food allergy following transient linvoseltamab treatment
- · Complete enrollment of Phase 3 studies of itepekimab in COPD (2H)

#### Obesity

 Initiate Phase 2 proof-of-concept study of combination of semaglutide and trevogrumab (anti-myostatin) with and without garetosmab (anti-Activin A) (mid-2024)

#### **Solid Organ Oncology**

- Report potentially pivotal interim analysis of Libtayo in Adjuvant CSCC (2H)
- Report results from Phase 3 study of fianlimab + cemiplimab in 1L metastatic melanoma (now 2025); initial data in 1L advanced NSCLC (2H)
- Initiate potentially pivotal Phase 2 studies for fianlimab + cemiplimab in perioperative melanoma (1H) and perioperative NSCLC (1H)
- Initiate dose-expansion cohorts of EGFRxCD28+cemiplimab in EGFR-high tumors √
- Initiate cohorts combining PSMAxCD28 + PSMAxCD3 in mCRPC as well as PSMAxCD28 monotherapy in RCC (1H)

#### Hematology

- FDA decision on odronextamab in R/R FL and R/R DLBCL CRLs received; EU decision (2H)
- BLA acceptance for linvoseltamab in R/R multiple myeloma √, potential FDA approval (PDUFA August 22, 2024); EU submission √
- Initiate Phase 1 study of linvoseltamab in combination with CD38xCD28 costimulatory bispecific in multiple myeloma
- Report Phase 2 proof-of-concept results for Factor XI antibody (2H)

#### **Genetic Medicines**

- Initiate Phase 1 study of Factor 9 gene insertion in hemophilia (mid)
- · Report additional proof-of-concept data for DB-OTO
- Initiate proof-of-concept study of SOD1 siRNA in ALS

## 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 ~\$5B into R&D in 2024<sup>†</sup>
- Expansion of Tarrytown HQ R&D facilities announced in July 2021
- Continued investments in research and development and manufacturing capacity



## **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
- Newly initiated collaborations and acquisition of Decibel Therapeutics add novel, innovative pipeline opportunities



### Repurchase Shares

- Deploy excess cash to opportunistically repurchase shares
- >\$12 billion in share repurchases since November 2019, including ~\$300 million in 1Q24 and ~\$2.2 billion in FY 2023
- New \$3 billion program authorized in April 2024; ~\$1.2 billion remaining\* on February 2023 authorization

### **Our mission:**

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

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

## Improve the lives of people with serious diseases

- Pipeline innovation
- Access to medicine and fair pricing
- Patient advocacy



## **Build sustainable** communities

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

Member of
Dow Jones
Sustainability Indices
Powered by the S&P Global CSA









## Foster a culture of integrity and excellence

- Product quality and safety
- Diverse, healthy and engaged workforce
- Ethics and integrity





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

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

	Three Months Ended March 31,			
		2024		2023
GAAP R&D	\$	1,248.4	\$	1,101.2
Stock-based compensation expense		123.0		139.5
Acquisition and integration costs		3.8		1.6
Non-GAAP R&D	\$	1,121.6	\$	960.1
GAAP SG&A	\$	689.0	\$	601.1
Stock-based compensation expense		86.2		76.8
Acquisition and integration costs		18.8		9.6
Non-GAAP SG&A	\$	584.0	\$	514.7
GAAP COGS	\$	240.4	\$	208.4
Stock-based compensation expense		20.9		22.4
Acquisition and integration costs		0.4		_
Intangible asset amortization expense		23.2		18.5
Non-GAAP COGS	\$	195.9	\$	167.5
GAAP other operating expense (income), net	\$	15.3	\$	(0.5)
Change in fair value of contingent consideration		15.3		
Non-GAAP other operating expense (income), net	\$	_	\$	(0.5)
GAAP other income (expense), net	\$	(50.7)	\$	(88.7)
Losses on investments, net		196.1		166.6
Non-GAAP other income (expense), net	\$	145.4	\$	77.9
GAAP net income	\$	722.0	\$	817.8
Total of GAAP to non-GAAP reconciling items above		487.7		435.0
Income tax effect of GAAP to non-GAAP reconciling items		(93.8)	_	(85.3)
Non-GAAP net income	\$	1,115.9	\$	1,167.5
Non-GAAP net income per share - basic	\$	10.35	\$	10.90
Non-GAAP net income per share - diluted	\$	9.55	\$	10.09
Shares used in calculating:				
Non-GAAP net income per share - basic		107.8		107.1
Non-GAAP net income per share - diluted		116.8		115.7

	Three Months Ended March 31,			
		2024		2023
Revenue reconciliation:				
Total revenues	\$	3,145.0	\$	3,162.1
Global gross profit payment from Roche in connection with sales of Ronapreve		0.5		222.2
Total revenues excluding Ronapreve	\$	3,144.5	\$	2,939.9
Effective tax rate reconciliation:				
GAAP ETR		(3.0%)		4.7%
Income tax effect of GAAP to non-GAAP reconciling items		9.1%		5.0%
Non-GAAP ETR		6.1%		9.7%

Q1 2024 vs Q1 2023
24%
25%
44%
43%
45%
44%
(1%)
2%

## **Abbreviations and Definitions**

Abbreviation	Definition	Abbreviation	Definition
1L	First line	FIH	First in human
AAV	Adeno-associated virus	FL	Follicular lymphoma
ALS	Amyotrophic lateral sclerosis	GA	Geographic atrophy
APP	Amyloid precursor protein	GAA	Alpha glucosidase
ATTR-CM	Transthyretin amyloidosis with cardiomyopathy	GITR	Glucocorticoid-induced TNFR-related protein
BCC	Basal cell carcinoma	GLP-1	Glucagon-like peptide 1
BCMA	B-cell maturation antigen	HCC	Hepatocellular carcinoma
BLA	Biologics license application	HCP	Healthcare Provider
B-NHL	B-cell non-Hodgkin's lymphoma	HeFH	Heterozygous familial hypercholesterolemia
BP	Bullous pemphigoid	HNSCC	Head and neck squamous cell carcinoma
CAR-T	Chimeric antigen receptor T-cell	Hz	Hertz
CMS	Center for Medicare & Medicaid Services	ICANS	Immune effector cell-associated neurotoxicity syndrome
COPD	Chronic obstructive pulmonary disease	IND	Initial new drug application
CPU0	Chronic pruritis of unknown origin	IV	Intravenous
CR	Complete response	KM	Kaplan-Meier curve
CRS	Cytokine release syndrome	LAG-3	Lymphocyte-activation gene 3
CRSwNP	Chronic sinusitis with nasal polyposis	LEPR	Leptin receptor
CSCC	Cutaneous squamous cell carcinoma	MCC	Merkel cell carcinoma
CSU	Chronic spontaneous urticaria	mCRPC	Metastatic castration-resistant prostate cancer
dB HL	Decibel hearing loss	MM	Multiple myeloma
DCR	Duration of complete response	MOA	Mechanism of action
DLBCL	Diffuse large B-cell lymphoma	mPFS	Median progression-free survival
DME	Diabetic macular edema	MUC16	Mucin 16
DR	Diabetic retinopathy	NASH	Non-alcoholic steatohepatitis
DXA	Dual-energy X-ray absorptiometry	NBRx	New to Brand Prescriptions
EC	European Commission	NHP	Non-human primate
EGFR	Epidermal growth factor receptor	NSCLC	Non-small cell lung cancer
EoE	Eosinophilic esophagitis	ORR	Overall Response Rate
EoG	Eosinophilic gastroenteritis	OTOF .	Otoferlin

Abbreviation	Definition
PB0	Placebo
PD-1/PD-(L)1	Programmed cell death protein/(ligand) 1
PDUFA	Prescription Drug User Fee Act
POC	Proof-of-concept
PSMA	Prostate-specific membrane antigen
R/R	Relapsed/Refractory
RCC	Renal cell carcinoma
RGC	Regeneron Genetics Center
ROW	Rest of world
RVO	Retinal vein occlusion
sBLA	Supplemental biologics license application
SC	Subcutaneous
sCR	Stringent complete response
siRNA	Small interfering RNA
SOC	Standard of Care
TLR9	Toll-like receptor 9
TRx	Total prescriptions
TTR	Transthyretin protein
UC	Ulcerative colitis
VEGF	Vascular endothelial growth factor
VGPR	Very good partial response
wAMD	Wet age-related macular degeneration