

# Regeneron Corporate Presentation

A u g u s t 2 0 2 3

***REGENERON***<sup>®</sup>

This non-promotional presentation contains investigational data as well as forward-looking statements; actual results may vary materially.

# 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 forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of 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") and research and clinical programs now underway or planned, including without limitation EYLEA® (afibercept) Injection, Dupixent® (dupilumab) Injection, Libtayo® (cemiplimab) Injection, Praluent® (alirocucumab) Injection, Kevzara® (sarilumab) Injection, Evkeeza® (evinacumab), afibercept 8 mg, pozelimab, odronextamab, itepekimab, fianlimab, garetosmab, linvoseltamab, REGN5713-5714-5715, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), 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 our anticipated milestones referenced in this presentation; safety issues resulting from the administration 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 Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for Regeneron's Products, such as those listed above (including the timing of any action by the U.S. Food and Drug Administration on the Biologics License Application for afibercept 8 mg); the extent to which the results from the research and development programs conducted by us and/or our 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 our ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; 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 on the commercial success of Regeneron's Products and Regeneron's Product Candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; the ability of our 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; our ability to meet any of our 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 our 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 our business; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors" of Regeneron's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events, or otherwise.

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# REGENERON

## Executing on our core competencies



**#1 prescribed** FDA approved anti-VEGF treatment for retinal disease



~\$2.8B net product sales in 2Q23<sup>†</sup>

**Now approved** for 5 Type 2 allergic diseases

**Breakthrough therapy** designation for COPD<sup>‡</sup>



Emerging portfolio of immuno-oncology antibodies

## Investing in Regeneron

Investing ~\$4.4B into R&D in 2023<sup>\*</sup>

Announced new \$3B share repurchase program in Feb 2023

(Over \$11B shares repurchased since Nov 2019<sup>§</sup>)

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

## Looking ahead to the future

**Over 35** therapeutic candidates in various stages of clinical development

**Acquired full global rights to Libtayo** from Sanofi, strengthening commitment to oncology

**Expanding partnerships** with leading companies in new technologies



Regeneron Genetics Center

driving new breakthroughs and target discovery



# Delivering results across the organization



2Q 2023 Total Revenues  
**+11% YoY**

2Q 2023 Non-GAAP EPS\*  
**\$10.24**

## Notable R&D Pipeline Advancements

### Aflibercept 8mg

- Reported positive 2-year data (96 weeks) from Phase 3 PHOTON study in DME
- Anticipate mid-August data submission to FDA to address observations from a pre-approval inspection of Catalent facility; potential FDA approval anticipated before end of 3Q



### Itepekimab

- Phase 3 BOREAS data in COPD presented at ATS and published in the *New England Journal of Medicine*
- Granted Breakthrough Therapy designation for COPD by FDA
- Itepekimab Phase 3 AERIFY program in COPD passed an interim futility analysis



- Updated Phase 1 data for fianlimab in combination with Libtayo in melanoma presented at ASCO showing consistent ORR, including in patients treated with adjuvant PD-1
- Updated Phase 2 data for linvoseltamab in MM presented at ASCO showing deep, durable responses in heavily pre-treated patients
- First patient dosed in Phase 1 study for REGN5837 (CD22xCD28) costimulatory bispecific in combination with odronextamab (CD20xCD3) in aggressive B-NHL

# Meaningful advances across therapeutic areas in 1H 2023

## Ophthalmology

### EYLEA (VEGF Trap)

- FDA approval in **Retinopathy of Prematurity**

### Aflibercept 8mg (VEGF Trap)

- CRL received in June 2023 due to unresolved FDA inspection observations at a third-party contract manufacturing organization, Catalent\*
- Anticipate mid-August data submission to FDA to address observations from a pre-approval inspection of Catalent facility; potential FDA approval anticipated before end of 3Q
- Announced positive 2-year data from Phase 3 PHOTON study in **Diabetic Macular Edema**
- Regulatory applications submitted in EU and Japan

## Immunology

### DUPIXENT (anti-IL-4R $\alpha$ )

- EC approval as **first and only treatment** indicated for **Eosinophilic Esophagitis**
- EC approval as **first biologic** for pediatric (6mos – 5yrs) **Atopic Dermatitis**
- Reported positive data Phase 3 data and received Breakthrough Therapy Designation for **COPD** with eosinophilic phenotype
- sBLA accepted for **Chronic Spontaneous Urticaria** (PDUFA October 22, 2023)
- Phase 2/3 study initiated in **Eosinophilic Gastroenteritis** and Phase 2 study initiated in **Ulcerative Colitis**

### Itepekimab (anti-IL-33)

- Phase 3 program in **COPD** passed an interim futility analysis

## Oncology

### LIBTAYO (anti-PD-1)

- EC approval in combination with chemotherapy in **1L advanced NSCLC** for patients with  $\geq 1\%$  PD-L1 expression
- Phase 2 study initiated in combination with BioNTech's BNT116 in patients with **1L NSCLC**

### OTHER ONCOLOGY

- Phase 2/3 study initiated for fianlimab + Libtayo in **1L advanced NSCLC**
- Phase 1 study initiated for CD22xCD28 in combination with odronextamab in **B-NHL**
- Reported updated Phase 2 data for livoseltamab in **Multiple Myeloma**
- Reported updated Phase 1 data for fianlimab + Libtayo in **Melanoma**

## Broader Pipeline

- Kevzara approved by FDA as first and only biologic for **Polymyalgia Rheumatica**
- Evkeeza approved by FDA in **pediatric HoFH**
- BLA for pozelimab in **CHAPLE** accepted by FDA (PDUFA August 20, 2023)
- Reported interim Phase 1 results for ALN-APP<sup>†</sup> in **early onset Alzheimer's** and presented updated data at AAIC
- Initiated Phase 2 study for HSD17B13 siRNA in **Nonalcoholic Steatohepatitis**

\* CRL did not identify any issues with clinical efficacy or safety, trial design, labeling or drug substance manufacturing. No additional clinical data or trials have been requested

<sup>†</sup> in collaboration with Alnylam.

# Aflibercept 8 mg has potential to shift treatment paradigm; positions Regeneron for continued leadership in retinal disease



**Aflibercept 8 mg** has the potential to become the next-generation standard-of-care anti-VEGF treatment



**Reducing treatment burden** for patients with wAMD and DME remains a **high unmet need**

If approved, patients eligible for aflibercept 8 mg could benefit from **extended dosing intervals**

**CRL received in June 2023**

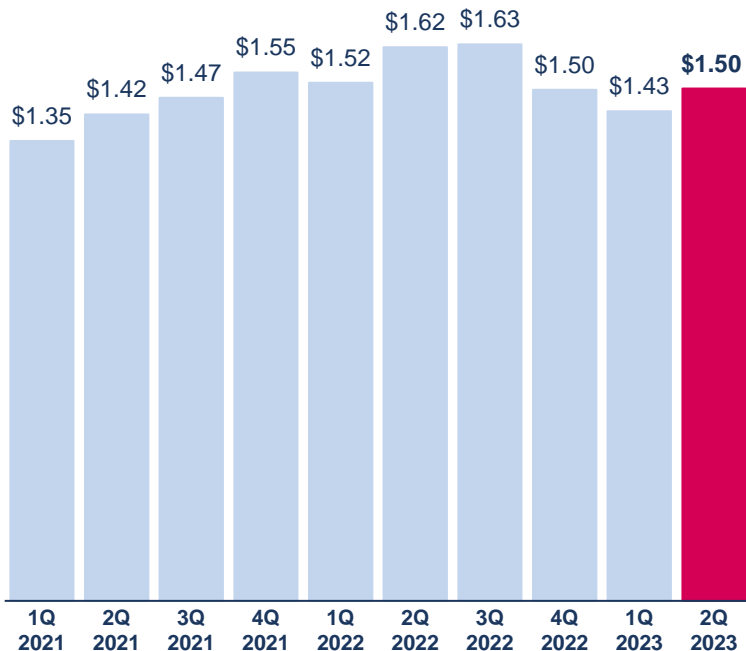
**No issues with clinical efficacy or safety, trial design, labeling or drug substance manufacturing were identified in CRL**

**Working with Catalent and FDA to reach resolution as soon as possible; potential FDA approval in Q3 2023**

**Teams are launch-ready pending FDA approval**

# Maintaining U.S. VEGF category leadership in 2023

Standard-of-care based on 11+ years of safety and efficacy experience, breadth of indications, and flexible dosing regimens



U.S. Net Product Sales, in \$ Billions

## #1 anti-VEGF treatment for retinal diseases

- Q2 2023 U.S. net product sales of \$1.50B (-7% YoY, +5% QoQ)
- Inventory remained within normal range (5-10 days on hand) with minimal change versus Q1 2023

**Maintaining category leadership** with stable 46% total category share and ~70% branded share in Q2 2023\*

**Prepared to launch** aflibercept 8mg upon approval

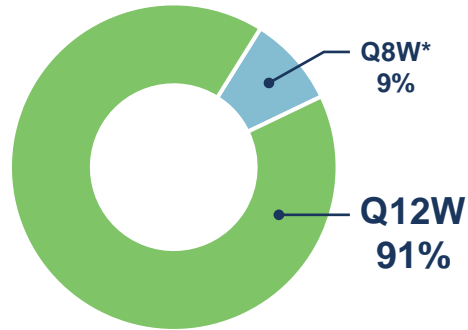
Demographic trends expected to drive future category growth



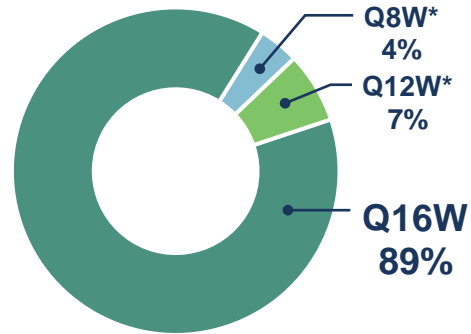
# 93% of aflibercept 8 mg DME patients maintained dosing intervals $\geq 12$ weeks through week 48

Aflibercept 8 mg 12- and 16-week dosing regimens achieved non-inferior vision gains compared to aflibercept 2 mg 8-week dosing regimen

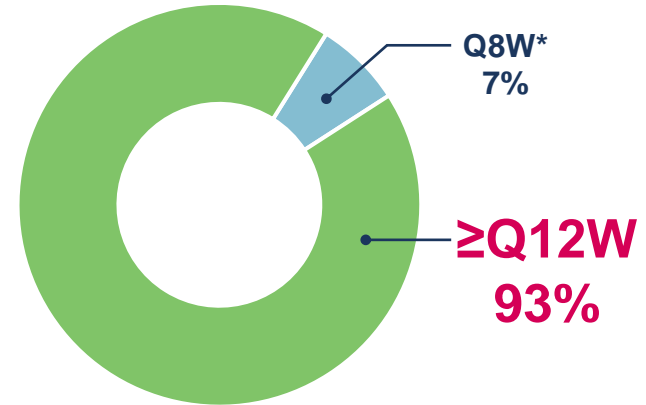
Aflibercept 8 mg Q12W  
(N=300<sup>‡</sup>)



Aflibercept 8 mg Q16W  
(N=156<sup>‡</sup>)



Pooled Aflibercept 8 mg  
(N=456<sup>‡</sup>)



**Safety of aflibercept 8 mg comparable to that of aflibercept 2 mg**

### Mean # of injections through week 48<sup>†</sup>

Aflibercept 2 mg (Q8W)	7.7
Aflibercept 8 mg (Q12W)	5.7
Aflibercept 8 mg (Q16W)	4.9

\*Patients shortened based on dose-regimen modification assessments at some point through week 48.

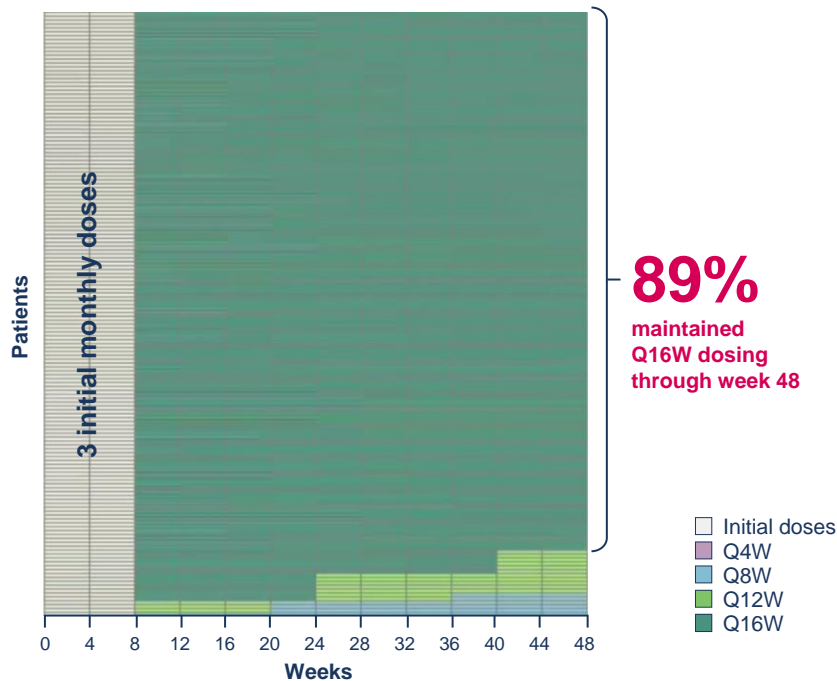
<sup>†</sup>Aflibercept 2 mg Q8W n=167, aflibercept 8 mg Q12W n=328, aflibercept 8 mg Q16W n=163. <sup>‡</sup>Patients completing week 48.

All dosing regimens after 3 initial monthly doses

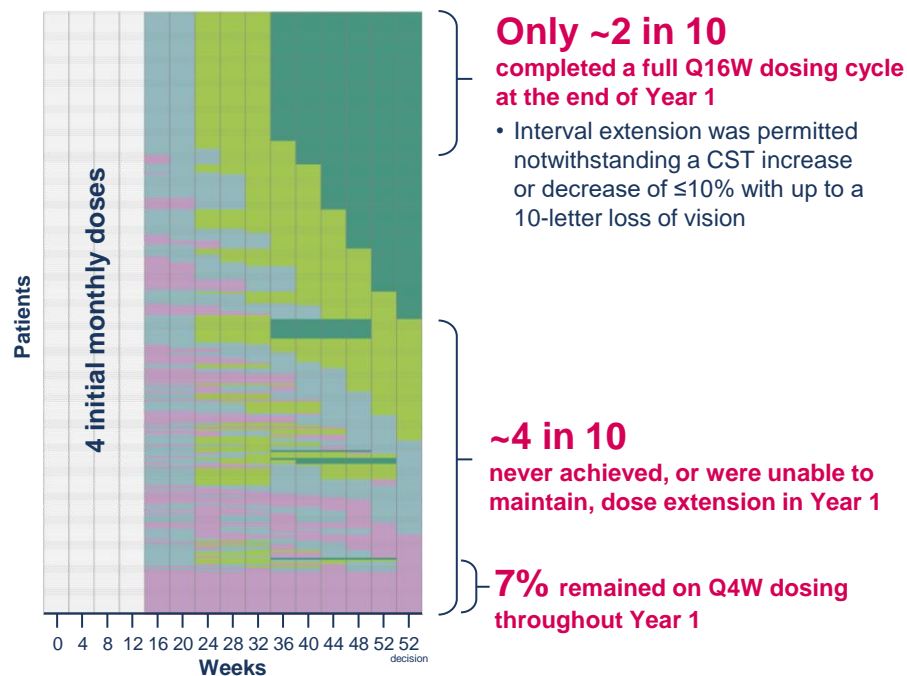


# Aflibercept 8 mg and faricimab trial data in DME patients

Dosing intervals of DME patients randomized to aflibercept 8 mg Q16W arm (N=156) in PHOTON study, through 48 weeks



Dosing intervals of DME patients randomized to faricimab 6 mg PTI arm (N=308) in RHINE study, through 52 weeks\*



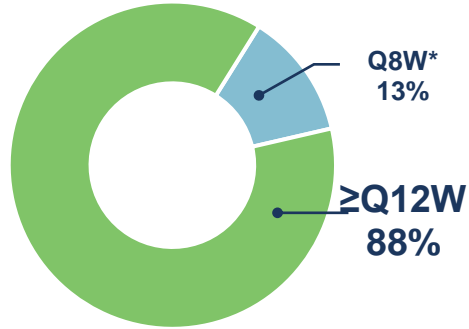
\*Wycoff C et al. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomized, double-masked, phase 3 trials. *Lancet* 2022; 399: 741–55. Colors modified for consistency.



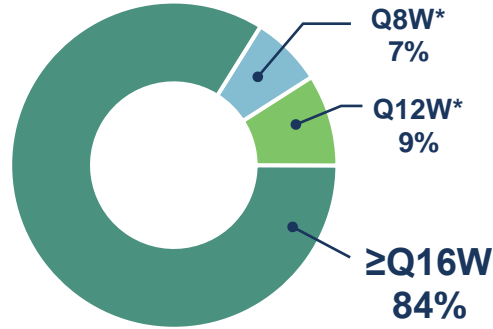
# 89% of aflibercept 8 mg DME patients maintained dosing intervals $\geq 12$ weeks through week 96

Aflibercept 8 mg Q12W and Q16W groups had non-inferior vision gains compared to aflibercept 2 mg Q8W, with up to 6 fewer injections

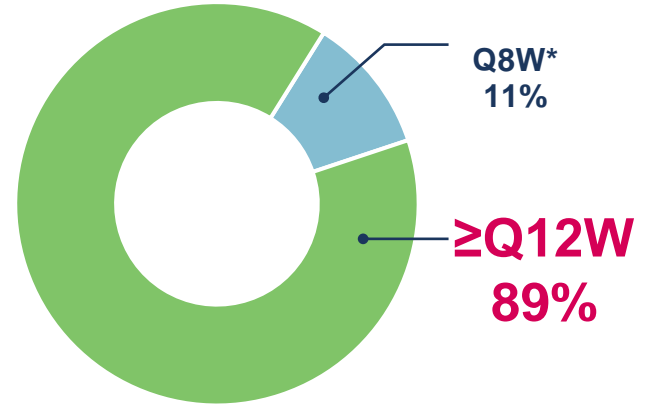
**Aflibercept 8 mg Q12W**  
(N=256<sup>‡</sup>)



**Aflibercept 8 mg Q16W**  
(N=139<sup>‡</sup>)



**Pooled Aflibercept 8 mg**  
(N=395<sup>‡</sup>)



**Safety of aflibercept 8 mg comparable to that of aflibercept 2 mg over 96 weeks**

Mean # of injections through week 96 <sup>†</sup>		
Aflibercept 2 mg (Q8W)	13.8	(Out of 14)
Aflibercept 8 mg (Q12W)	9.5	(Out of 10)
Aflibercept 8 mg (Q16W)	7.8	(Out of 8)

<sup>‡</sup>Patients shortened based on dose-regimen modification assessments at some point through week 96.

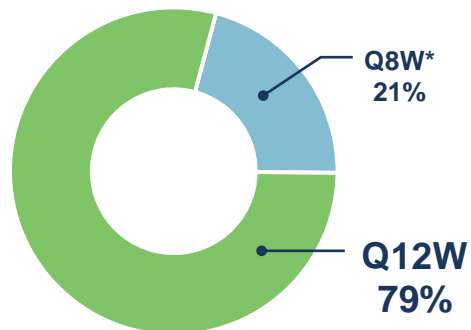
<sup>†</sup>Patients completing week 96: aflibercept 2 mg Q8W n=139, aflibercept 8 mg Q12W n=256, aflibercept 8 mg Q16W n=139. <sup>‡</sup>Patients completing week 96  
All dosing regimens after 3 initial monthly doses.

# 83% of aflibercept 8 mg wAMD patients maintained dosing intervals $\geq 12$ weeks through week 48

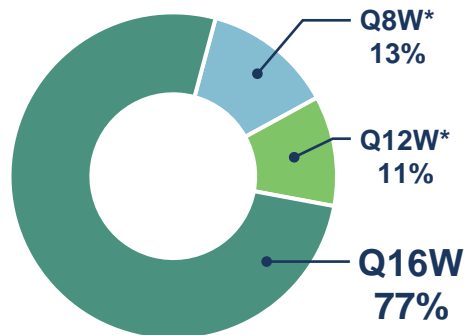


Aflibercept 8 mg 12- and 16-week dosing regimens achieved non-inferior vision gains compared to aflibercept 2 mg 8-week dosing regimen

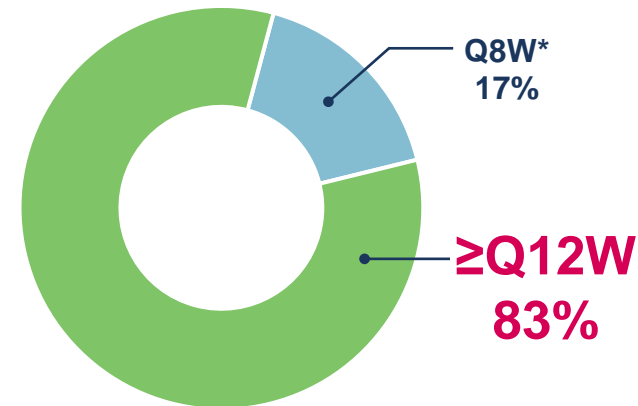
**Aflibercept 8 mg Q12W**  
(N=316<sup>‡</sup>)



**Aflibercept 8 mg Q16W**  
(N=312<sup>‡</sup>)



**Pooled Aflibercept 8 mg**  
(N=628<sup>‡</sup>)



**Safety of aflibercept 8 mg comparable to that of aflibercept 2 mg**

**2-year (96 week) data expected in 3Q 2023**

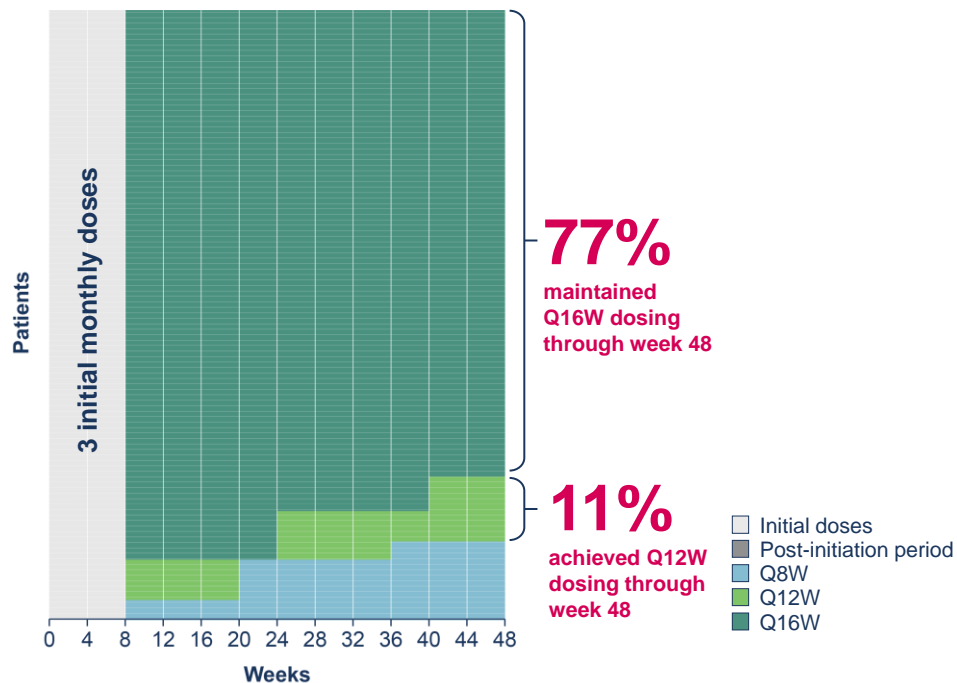
**Mean # of injections in first 48 weeks<sup>†</sup>**

Aflibercept 2 mg (Q8W)	6.9
Aflibercept 8 mg (Q12W)	6.1
Aflibercept 8 mg (Q16W)	5.2

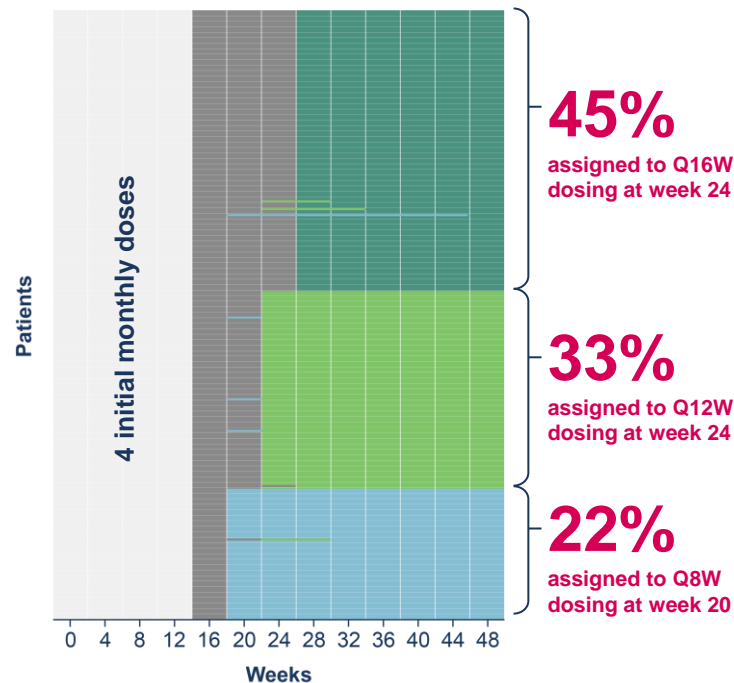
\*Patients shortened based on DRM assessments at some point through week 48.  
<sup>†</sup>Patients completing 48 week; 2 mg Q8W n=309, 8 mg Q12W n=316, 8 mg Q16W n=312. <sup>‡</sup>Patients completing week 48.  
 Note: Percentages may not add to 100% due to rounding. Bayer AG is the lead sponsor of the PULSAR study.  
 All dosing regimens after 3 initial monthly doses

# Aflibercept 8 mg and faricimab trial data in wAMD patients

Dosing intervals of wAMD patients randomized to aflibercept 8 mg Q16W arm (N=312) in PULSAR study



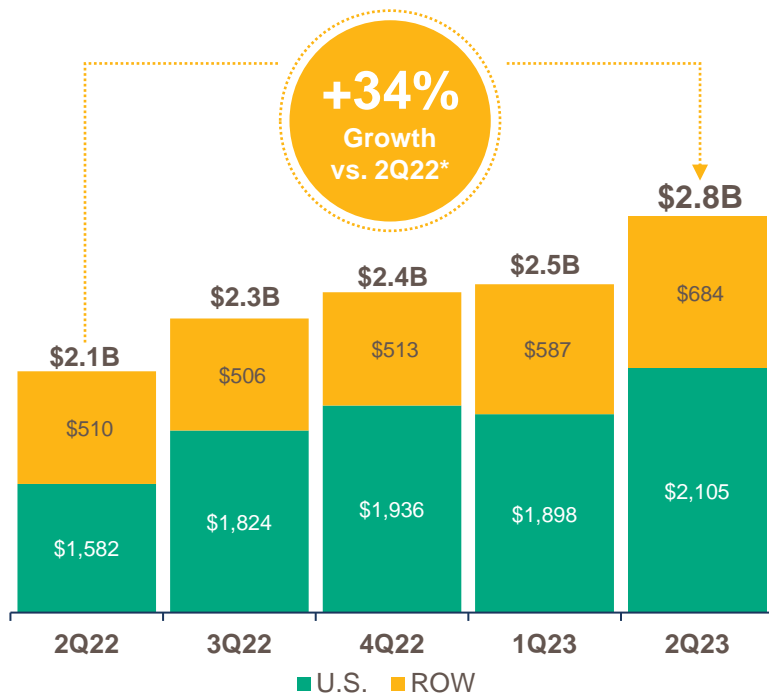
Dosing intervals of wAMD patients randomized to faricimab 6 mg in TENAYA and LUCERNE studies (n=665)\*  
(Dose interval shortening was not permitted in Year 1 per studies' protocols)



# Q2 2023 Dupixent global net product sales grew 34%\* YoY, now annualizing at ~\$11B



Continued market penetration, new indications, and younger populations represent significant opportunity for continued growth



Sanofi records global net product sales of Dupixent, \$ Millions

## Regulatory and clinical progress continuing in 2023:

### Atopic Dermatitis

- ✓ Approved by EC as **first biologic** medicine for AD patients aged 6 months to 5 years

### Eosinophilic Esophagitis

- ✓ Approved by EC as **first and only** treatment for EoE ages 12+

### Chronic Spontaneous Urticaria

- ✓ sBLA for CSU **accepted** by FDA (PDUFA October 22, 2023)

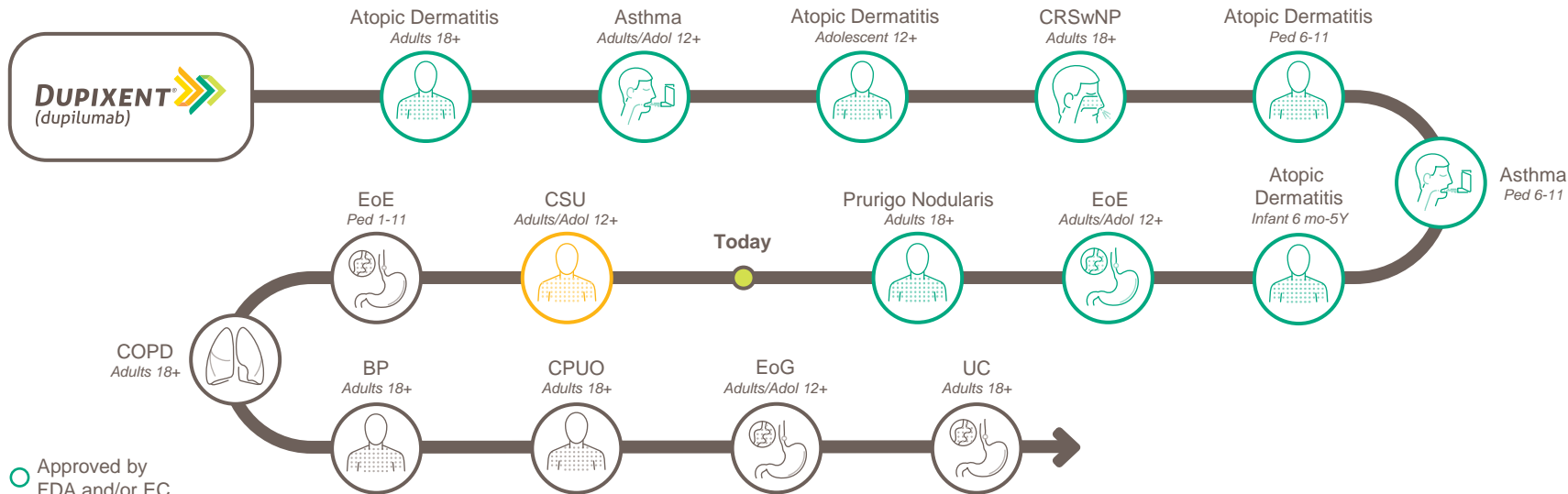
### Chronic Obstructive Pulmonary Disease (COPD)

- ✓ **First and only biologic** to show clinically meaningful and statistically significant reduction in exacerbations and improvement in lung function
- ✓ Granted FDA **Breakthrough Therapy** designation

Approved in **five indications** with positive pivotal results in **seven Type 2 allergic diseases**

# 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



- Approved by FDA and/or EC
- Under regulatory review
- Investigational indications

**Dupixent’s differentiated mechanism of action can benefit patients suffering from multiple Type 2 allergic diseases**

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

## DUPIXENT® (dupilumab)

- Potential to address COPD with an eosinophilic phenotype (Eos  $\geq 300/\mu\text{l}$ ) in both **current and former smokers**
- Granted **Breakthrough Therapy** designation
- **First and only** biologic to achieve **clinically meaningful** and **statistically significant** results vs. placebo\*:
  - ✓ 30% reduction in exacerbations (p=0.0005)
  - ✓ Significant improvement in lung function (83 mL FEV<sub>1</sub> benefit, p=0.0003)
  - ✓ Significant QoL improvements
- Results from replicate Phase 3 NOTUS study expected in mid-2024; study fully enrolled in May 2023

	Type 2	Non-Type 2
Former Smokers (70% of COPD patients)	Dupixent or itepekimab >350K patients	Itepekimab only ~600K patients
Current Smokers (30% of COPD patients)	Dupixent only ~150K patients	—

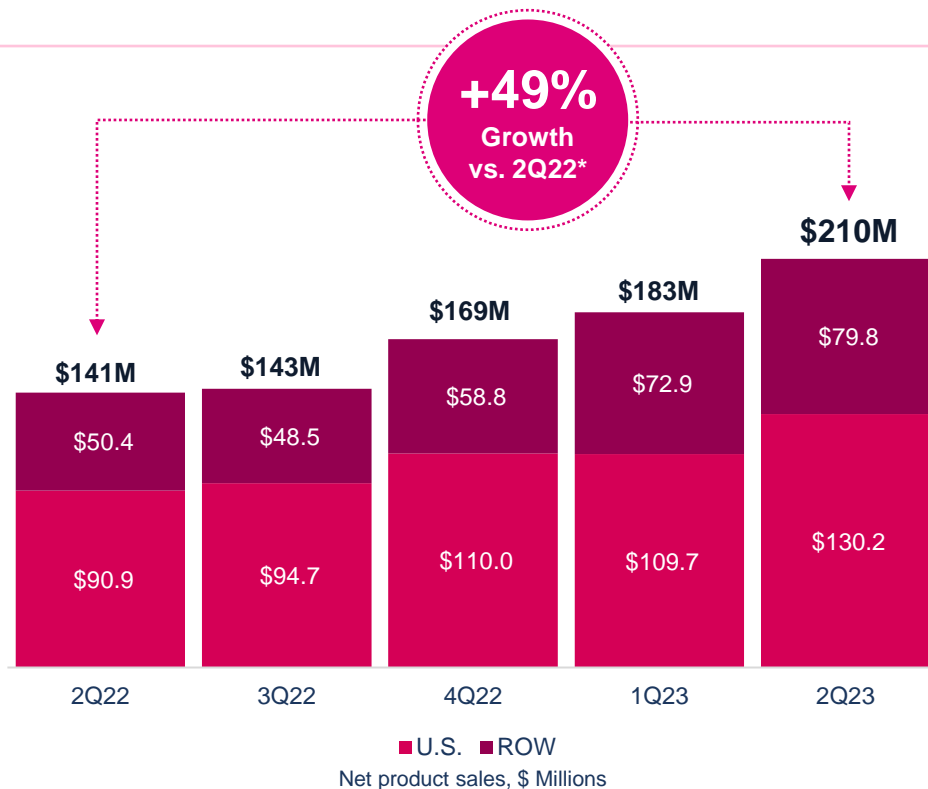
Current U.S., EU and Japan addressable patient estimates

## Itepekimab (anti IL-33)

- Potential to address COPD in **former smokers**
- Demonstrated **42% reduction in exacerbations** in former smokers vs. placebo in Phase 2 study
- Two Phase 3 studies ongoing:
  - ✓ AERIFY-1 enrolling
  - ✓ AERIFY-2 enrolling
- Phase 3 program **passed interim futility analysis**
- Pivotal data from both AERIFY studies expected in 2025
- Includes patients with both high and low eosinophil counts

# 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

- Q2 2023 U.S. net product sales of \$130M (+43% YoY) and rest of world sales of \$80M (+58% YoY)
- FY 2022 U.S. net product sales of \$375M (+22% YoY) and rest of world sales of \$204M (+34% 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 ≥1% PD-L1 expression

## Dermato-Oncology

- Leading anti-PD-1/L1 therapy in approved non-melanoma skin cancers
- Approved in both advanced CSCC and BCC
- Foundational therapy for future combination approach in melanoma



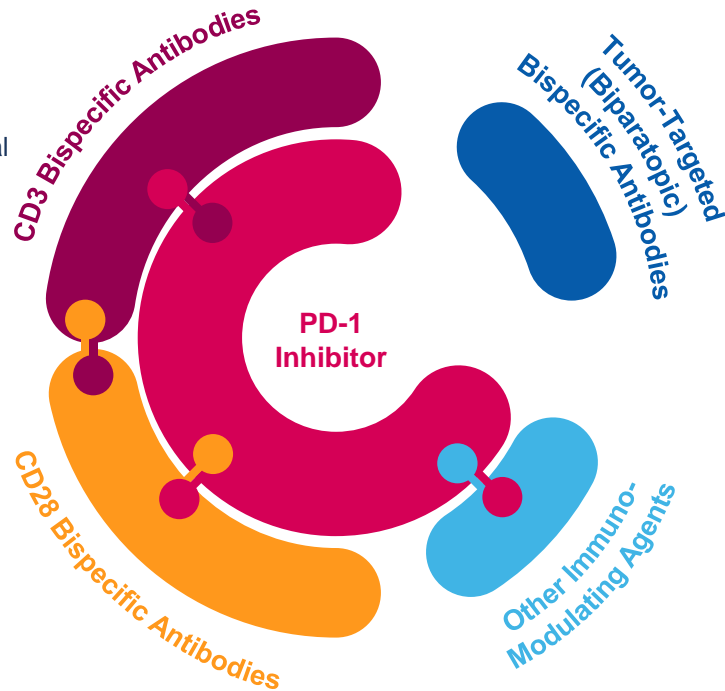
# Unique flexibility of internally developed pipeline drives potential for novel and differentiated combinations

## CD3 Bispecifics: “Signal 1”

Designed to bridge tumor-associated antigens on cancer cells with CD3-expressing T cells, resulting in potential local T-cell activation and cytotoxicity

## CD28 Bispecifics: “Signal 2”

Designed to increase the activity of T cells that recognize tumor antigens by augmenting costimulatory signals



## Tumor-Targeted Biparatopics

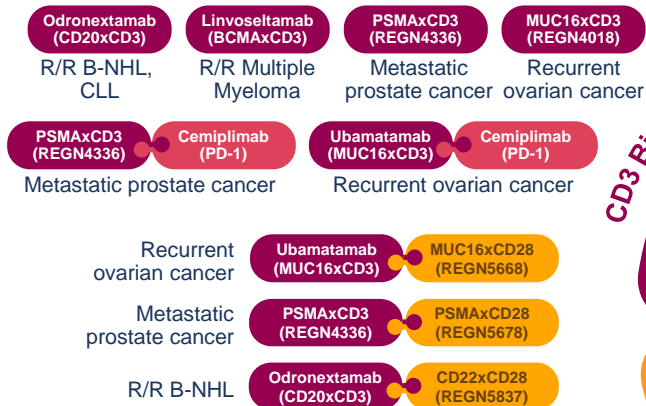
Designed to disrupt cellular signaling and/or deliver a cytotoxic drug to tumor cells

## Modulating immune response

Designed to overcome the tumor suppressive microenvironment (e.g., by inhibition of checkpoints, or targeted delivery of immuno-modulators)

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

## CD3 Bispecifics: "Signal 1"



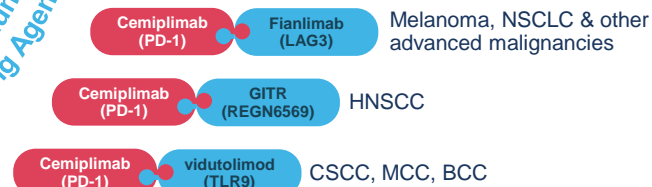
## CD28 Bispecifics: "Signal 2"



## Tumor-Targeted Biparatopics



## Modulating immune response



# Continued progress & developments across oncology pipeline

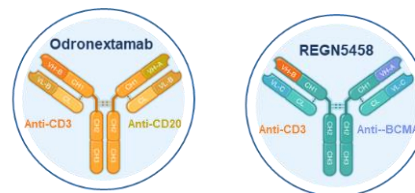
Regeneron positioned to enhance and extend treatment options and benefit across many cancer settings

## Solid tumors



- **Fianlimab (LAG-3)** – Presented Phase 1 data in advanced melanoma at ASCO 2023; Phase 3 study in 1L advanced and adjuvant melanoma with Libtayo ongoing, initiated Phase 2/3 studies in 1L advanced NSCLC; initiating Phase 2 study in perioperative melanoma, and Phase 2 study in perioperative NSCLC
- **REGN5678 (PSMAxCD28)** – Plan to enroll monotherapy cohort; discontinued enrollment in cohorts in combinations with Libtayo due to reported adverse events
- **Ubatamab (MUC16xCD3)** – Reported initial monotherapy ovarian cancer data; Libtayo combo data expected 2H23
- **REGN5668 (MUC16xCD28)** – Dose escalation in Libtayo and ubamatamab combinations for ovarian cancer ongoing
- **REGN4336 (PSMAxCD3)** – Dose escalation in mCRPC ongoing
- **REGN7075 (EGFRxCD28)** – Dose escalation with Libtayo in advanced cancers ongoing
- **REGN5093 (METxMET)** – Reported initial data in MET-altered advanced NSCLC
- **REGN5093-M114 (METxMET ADC)** – Dose escalation in MET-overexpressing NSCLC ongoing

## Hematology-Oncology



- **Odronextamab (CD20xCD3)** – Pivotal Phase 2 presented at ASH 2022; Phase 3 program to initiate in 2H 2023; BLA acceptance on track for 2H23
- First patient dosed in Phase 1 study of CD22xCD28 in combination with odronextamab in aggressive B-NHL
- **Linvoseltamab (BCMAxCD3)** – Updated pivotal Phase 2 data presented at ASCO 2023; Phase 3 study to initiate in 3Q23; received Fast-Track designation from FDA; BLA planned in 4Q23

# Continuing momentum in oncology pipeline in 2023 and beyond

Tumor type	Initial indication	Upcoming expected data disclosure			
		2023	2024	2025+	
Hematology	Lymphoma	Odronextamab *		Odronextamab, CD22xCD28	
	Multiple myeloma	Linvoseltamab *			
Dermato-oncology	Adjuvant CSCC			Cemiplimab *	
	Advanced CSCC (PD-1 resistant)			Vidutolimod, Cemiplimab	
	Perioperative melanoma			Fianlimab, Cemiplimab *	
	Adjuvant melanoma			Fianlimab, Cemiplimab *	
	Advanced melanoma (1L)	Fianlimab, Cemiplimab ✓		Fianlimab, Cemiplimab *	
Other solid tumors	MET-altered advanced NSCLC		METxMET ADC		
	Perioperative NSCLC			Fianlimab, Cemiplimab	
	Advanced NSCLC (1L)			Fianlimab, Cemiplimab	
	Ovarian cancer (2L+)		Ubamatamab, Cemiplimab		MUC16xCD28, Cemiplimab
					Ubamatamab, MUC16xCD28
	Metastatic castration-resistant prostate cancer				PSMAxCD28, Cemiplimab
					PSMAxCD3, Cemiplimab
	SCCHN			PSMAxCD3, PSMAxCD28	
	EGFR+ solid tumors			GITR, Cemiplimab	
			EGFRxCD28, Cemiplimab		

# Costimulatory bispecifics platform: Status and next steps

Costimulatory bispecifics will be studied in combination with both Libtayo and a growing list of CD3 bispecifics



## PSMAxCD28 (REGN5678) + Libtayo

- ✓ Share initial Phase 1 data
- Present additional data at medical meeting in 2024
- Select go-forward dose(s) in 2023

## PSMAxCD28 (REGN5678) + PSMAxCD3 (REGN4336)

- Phase 1 study planned
- Initial data in 2025+



## MUC16xCD28 (REGN5668) + Ubamatamab (MUC16xCD3)

- ✓ Initiate Phase 1 (dose escalation)
- Initial data in 2024

## MUC16xCD28 (REGN5668) + Libtayo

- ✓ Initiate Phase 1 (dose escalation)
- Initial data in 2024



## EGFRxCD28 (REGN7075) + Libtayo

- ✓ Phase 1 early dose escalation data presented at SITC 2022
- Present updated data in 2024



## CD22xCD28 (REGN5837) + Odronextamab (CD20xCD3)

- ✓ Supportive preclinical data presented at SITC 2022\*
- ✓ Initiated phase 1/2 study in B-NHL

## TAAxCD28 + Linvoseltamab (BCMAxCD3)

- Phase 1 study in 3L+ multiple myeloma to initiate in 2024

# REGN17092 binds outside variable RBD and has demonstrated high neutralization activity against all key lineages

## Differentiated vs. prior antibody approaches

- Binding site outside of immunodominant, highly variable RBD and NTD regions, which may lower risk of losing activity against future variants
- Targeted epitope highly conserved, with over 99.9% conservation since beginning of the pandemic
- Demonstrated high neutralization potency against all key SARS-CoV-2 lineages to date

## Targeting treatment and prophylactic setting

- In the U.S. alone, millions of immuno-compromised people will not adequately respond to vaccination
- Antibodies can be dosed prophylactically to prevent infection and severe COVID-19 disease

Variant	Lineage	REGEN-COV*	Xevudy†	Evusheld‡	Bebtelovimab§	REGN17092
Omicron	D614G	✓✓✓	✓✓	✓✓✓	✓✓✓	✓✓✓
	BA.2	✓	✓	—	✓✓✓	✓✓✓
	BA.4/5	✓	✓	✓✓	✓✓✓	✓✓✓
	BA.4.6	✗	✗	✗	✓✓✓	✓✓✓
	BA.2.75	✗	✓	—	✓✓✓	✓✓✓
	BQ.1	✗	✓	✗	✗	✓✓✓
	BQ.1.1	✗	✗	✗	✗	✓✓✓
	XBB	✗	✓	✗	✗	✓✓✓
	XBB.1.5	✗	✓	✗	✗	✓✓✓
	XBB.1.16	✗	✓	✗	✗	✓✓✓

NOTE: Neutralizing activity from published studies or measured by Regeneron using publicly available sequences.

✓✓✓ High neutralizing activity ( $IC_{50} < 10^{-10}$  M)

✓✓ Limited neutralizing activity ( $10^{-10}$  M  $< IC_{50} < 10^{-9}$  M)

✓ Low neutralizing activity ( $10^{-9}$  M  $< IC_{50} < 10^{-8}$  M)

✗ No neutralizing activity ( $IC_{50} > 10^{-8}$  M)

— Not evaluated for neutralizing activity

**Anticipate initiating clinical trial in 2H 2023**

\*REGEN-COV (casirivimab (REGN10933) and imdevimab (REGN10987)) is an unapproved investigational therapy and was developed by Regeneron Pharmaceuticals, Inc. REGEN-COV is currently not authorized for use.

†Xevudy (sotrovimab, also known as VIR-7831 and GSK4182136) was developed by GlaxoSmithKline plc and Vir Biotechnology, Inc.

‡Evusheld (AZD7442, combination of tixagevimab (AZD8895) and cilgavimab (AZD1061)) was discovered by Vanderbilt University Medical Center and licensed to AstraZeneca.

§Bebtelovimab (LY-CoV1404; LY3853113) was discovered by AbCellera and the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center and was licensed to Eli Lilly and Company.

# Evolution of Regeneron's turn-key technologies powering our science and pipeline

COMMITMENT TO  
MOUSE GENETICS



1988

MOUSE GENETICS »»» VELOCIMMUNE MOUSE with humanized immune system »»» Multiple approved & clinical-stage antibodies & bispecifics

Regeneron  
is founded

UNLOCKING POWER  
OF HUMAN GENETICS



2014

Regeneron Genetics Center »»» >2M Humans Sequenced »»» Targets and Genetic Medicine Pipeline

**BIOLOGICS  
TO TARGET  
GENETIC  
MEDICINES**

**Biologics:  
Turn-Key Therapeutic Platforms**



Traps



Antibodies



CD3 bispecifics  
Costimulatory bispecifics

VELOCIGENE® | VELOCIMOUSE® | VELOCIMMUNE® | VELOCIMAB®  
VELOCIT® | VELOCIHUM® | VELOCI-BI®

**Genetic Medicines:  
Turn-Key Therapeutic Platforms**



siRNA



Genome editing  
(insertion/knockout)



Gene Therapy

CRISPR/Cas9 Tech | RNAi | Next-Gen Editing  
Viral Vector Tech | AAV

# Regeneron genetic medicines

Powerful resource linking human genetic variation to disease; empowering strategic partnerships to drive the future of medicine



Regeneron Genetics Center

## World leading human sequencing

- Over 2M human exomes sequenced
- Linked to Electronic Health Records
- 200+ collaborations globally



## Novel genetics-based drug target discovery

- RGC discovered ~30 novel drug targets



## Genetics-based drug development enabling precision medicine

- RGC data and analyses identifies targets in diseases of interest, enhancing the probability of success
- RGC creates analytical models that identify that may be most successful within a REGN clinical trial of interest



## Leveraging new turnkey therapeutic approaches

- siRNA gene silencing
- Genome editing – Knockout/ Insertion
- Targeted viral-based gene delivery and expression



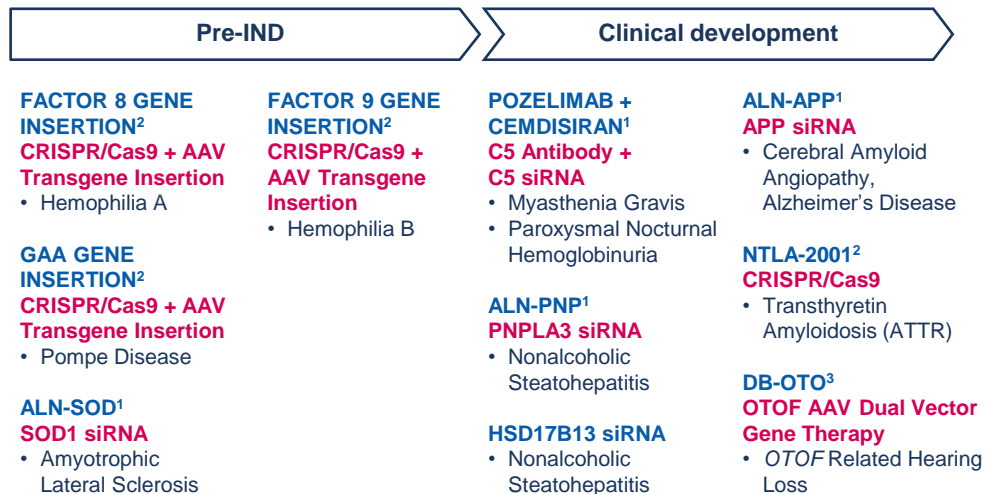
## Regeneron is investing in and delivering technologies well beyond antibodies

- 6 genetics medicines programs in the clinic
- 3-5 additional potential targets to advance to IND-enabling studies in next 12 months
- 30+ additional programs in research and candidate selection phase
- 10+ novel genetic targets discovered

## Several opportunities emerging from Regeneron genetics medicines:

- NTLA-2001: initiate a global pivotal trial for ATTR-CM by YE23, subject to regulatory feedback
- C5 combo program Phase 3 studies in Myasthenia Gravis and PNH ongoing
- HSD17B13 siRNA Phase 2 initiated in NASH
- PNPLA3 siRNA Phase 1 for NASH initiated
- ALN-APP: presented interim Phase 1 results at AAIC
- DB-OTO gene therapy Phase 1/2 for hearing loss initiated in 2Q 2023

# Regeneron genetics medicines



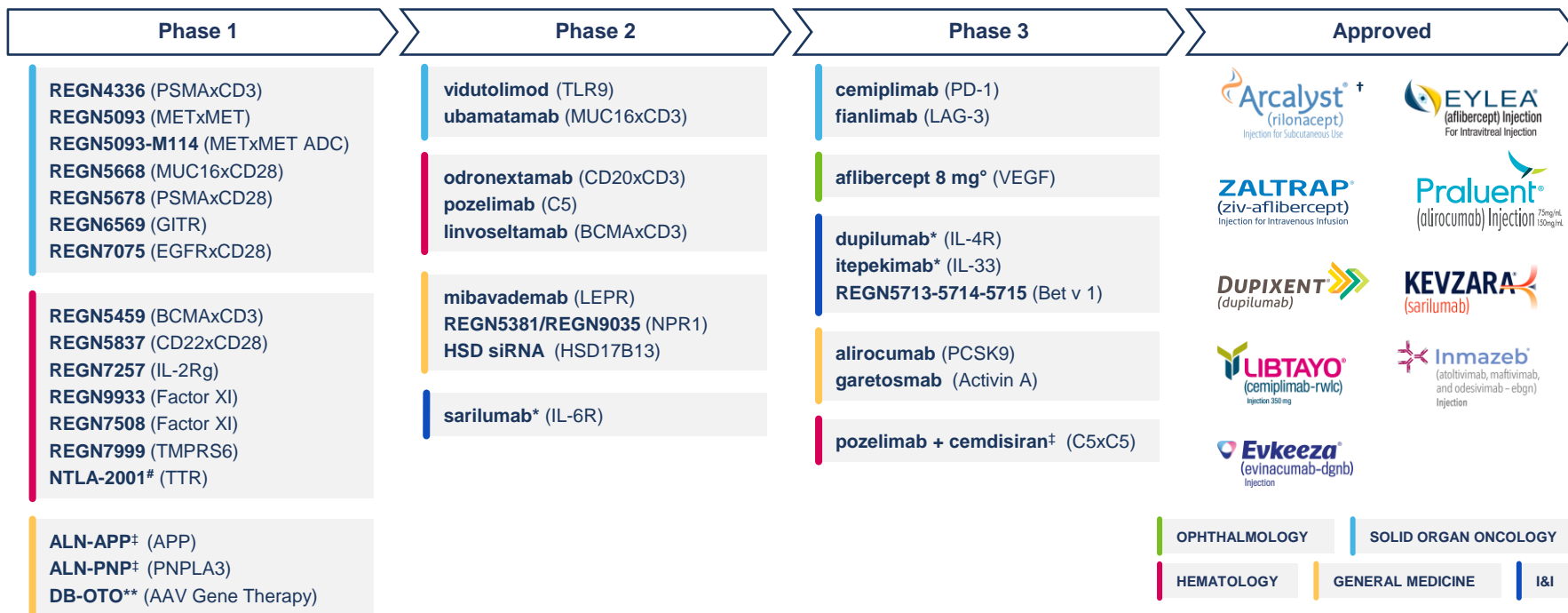
### Additional programs

30+ programs in research and candidate selection

Collaborations with:  
1. Alnylam Pharmaceuticals  
2. Intellia Therapeutics  
3. Decibel Therapeutics

*This graphic displays pipeline drug candidates currently undergoing clinical testing in a variety of diseases. The safety and efficacy of these drug candidates have not been fully evaluated by any regulatory authorities for the indications described in this section.*


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



Collaboration with: \*Sanofi; †Alnylam; #Intellia; °Bayer, \*\*Decibel  
<sup>‡</sup>Kiniksa is solely responsible for development and commercialization of ARCALYST

Over 30 product candidates

# Multiple potential FDA filings: 2023-2025+

2023	2024	2025+
<b>DUPIXENT*</b> Pediatric EoE (mid)	<b>DUPIXENT*</b> Type 2 COPD	<b>LIBTAYO</b> Adjuvant CSCC
<b>PRALUENT</b> Pediatric HeFH (mid) 		<b>DUPIXENT*</b> CPUO
<b>Odronextamab</b> B-Cell NHL (2H)		<b>DUPIXENT*</b> Bullous Pemphigoid
<b>Linvoseltamab</b> R/R Multiple Myeloma (2H)		<b>Aflibercept 8 mg</b> RVO
		<b>Fianlimab + LIBTAYO</b> Advanced Melanoma
		<b>Pozelimab ± cemdisiran*</b> C5-mediated diseases
		<b>Garetosmab</b> FOP
		<b>Itepekimab*</b> COPD

BLA

sBLA

# 2023 key milestones

## Ophthalmology

- FDA approval for EYLEA in ROP (Q1) ✓
- BLA acceptance for aflibercept 8 mg in DME and wAMD (Q1) ✓
- FDA approval\* and U.S. launch of aflibercept 8 mg
- Two-year data for PHOTON (DME) ✓ and PULSAR (wAMD) studies (Q3)

## Dupixent

- sBLA acceptance for CSU (Q1) ✓
- EC decision on pediatric AD (6mo – 5yr) (1H) ✓
- Report data for Phase 3 study in Type 2 COPD (1H) ✓
- sBLA acceptance for pediatric EoE (Q3)
- FDA decision on CSU (PDUFA October 22, 2023)

## Pozelimab (anti-C5 antibody)

- FDA acceptance of CHAPLE BLA (1H) ✓
- FDA decision on CHAPLE (PDUFA August 20, 2023)

## Solid Organ Oncology

- Fianlimab + Libtayo:
  - Initiate Phase 2 study in perioperative melanoma (2H)
  - Initiate Phase 2/3 studies in 1L advanced NSCLC (1H) ✓
  - Initiate Phase 2 study in perioperative NSCLC (2H)
- Report additional data for PSMAxCD28+Libtayo (2H) – now anticipated in 2024
- Report initial data across solid organ oncology, including for CD3 bispecifics and CD28 costimulatory bispecifics
- EC decision for Libtayo in combination with chemotherapy in 1L advanced NSCLC (1H) ✓

## Odrone tamab (CD20xCD3)

- Initiate confirmatory studies in FL & DLBCL, including earlier lines (2H)
- Initiate Phase 1 study in combination with REGN5837 (CD22xCD28) in aggressive B-NHL (1H) ✓
- BLA and MAA acceptance in B-NHL (2H)

## Linvoseltamab (BCMAxCD3)

- Report updated pivotal Phase 2 data in R/R Multiple Myeloma (4Q)
- Initiate confirmatory study in MM (3Q), including in earlier lines
- Initiate Phase 1 study in combination with TAAxCD28 in MM (2H) – now anticipated in 2024
- BLA acceptance in 3L+ MM (4Q)

\* On June 27, 2023, the FDA issued a CRL for the BLA for aflibercept 8 mg for the treatment of patients with wAMD, DME and DR, solely due to an ongoing review of inspection findings at a third-party contract manufacturer that Regeneron engaged to fill vials with aflibercept 8 mg, Catalent. The CRL did not identify any issues with the aflibercept 8 mg clinical efficacy or safety, trial design, labeling or drug substance manufacturing, and no additional clinical data or trials have been requested. Regeneron is committed to working closely with the FDA and Catalent to bring aflibercept 8 mg to patients with wAMD, DME and DR as quickly as possible, with potential FDA approval in Q3 2023.

This slide contains investigational drug candidates that have not been approved by any regulatory authority.

# 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*



- **\$1.8 billion** investment in Tarrytown 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*



- **Libtayo acquisition** provides flexibility on existing and future oncology collaborations involving Libtayo combinations
- Collaborations with Sonoma Biotherapeutics and CytomX add **novel, innovative pipeline opportunities**

## Repurchase Shares



- Deploy excess cash to opportunistically repurchase shares
- **\$3 billion** authorization for share repurchases announced in February 2023
- Over **\$11 billion** in share repurchases since November 2019, including **\$723 million** in 2Q23

# 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



## Foster a culture of integrity and excellence

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



## 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



**Our mission:**  
Use the power of science to repeatedly bring new medicines to people with serious diseases

# GAAP to non-GAAP reconciliation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP R&D	\$ 1,085.3	\$ 794.3	\$ 2,186.5	\$ 1,638.1
Stock-based compensation expense	109.1	89.7	248.6	182.1
Acquisition-related integration costs	2.6	14.6	4.2	14.6
Non-GAAP R&D	\$ 973.6	\$ 690.0	\$ 1,933.7	\$ 1,441.4
GAAP SG&A	\$ 652.0	\$ 476.3	\$ 1,253.1	\$ 926.3
Stock-based compensation expense	73.3	57.5	150.1	118.2
Acquisition-related integration costs	16.5	1.1	26.1	1.1
Non-GAAP SG&A	\$ 562.2	\$ 417.7	\$ 1,076.9	\$ 807.0
GAAP COGS	\$ 192.4	\$ 149.2	\$ 400.8	\$ 356.5
Stock-based compensation expense	19.6	12.6	42.0	26.4
Acquisition-related integration costs	0.5	—	0.5	—
Intangible asset amortization expense	19.8	—	38.3	—
Charges related to REGEN-COV	(10.0)	—	(10.0)	58.0
Non-GAAP COGS	\$ 162.5	\$ 136.6	\$ 330.0	\$ 272.1
GAAP other income (expense), net	\$ 66.4	\$ (146.7)	\$ (22.3)	\$ (344.1)
Other income/expense: Losses (gains) on investments, net	30.9	166.3	197.5	370.8
Non-GAAP other income (expense), net	\$ 97.3	\$ 19.6	\$ 175.2	\$ 26.7
GAAP net income	\$ 968.4	\$ 852.1	\$ 1,786.2	\$ 1,825.6
Total of GAAP to non-GAAP reconciling items above	262.3	341.8	697.3	771.2
Income tax effect of GAAP to non-GAAP reconciling items	(49.1)	(67.0)	(134.4)	(152.3)
Non-GAAP net income	\$ 1,181.6	\$ 1,126.9	\$ 2,349.1	\$ 2,444.5
Non-GAAP net income per share - basic	\$ 11.04	\$ 10.44	\$ 21.95	\$ 22.78
Non-GAAP net income per share - diluted	\$ 10.24	\$ 9.77	\$ 20.32	\$ 21.26
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	107.0	107.9	107.0	107.3
Non-GAAP net income per share - diluted	115.4	115.4	115.6	115.0

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<i>Revenue reconciliation:</i>				
Total revenues	\$ 3,158.1	\$ 2,857.2	\$ 6,320.2	\$ 5,822.3
Global gross profit payment from Roche in connection with sales of Ronapreve	—	8.2	222.2	224.5
Other	(3.8)	—	(3.8)	—
Total revenues excluding Ronapreve	\$ 3,161.9	\$ 2,849.0	\$ 6,101.8	\$ 5,597.8
<i>Effective tax rate reconciliation:</i>				
GAAP ETR	10.6%	11.5%	8.0%	9.8%
Income tax effect of GAAP to non-GAAP reconciling items	1.6%	2.1%	3.0%	2.8%
Non-GAAP ETR	12.2%	13.6%	11.0%	12.6%

## Q2 2023 vs Q2 2022

Total Dupixent Net Product Sales - Global	
% growth as reported	33%
% growth at constant currency	34%
Total Libtayo Net Product Sales - Outside the U.S.	
% growth as reported	58%
% growth at constant currency	58%
Total Libtayo Net Product Sales - Global	
% growth as reported	49%
% growth at constant currency	49%
Total EYLEA Net Product Sales - Outside the U.S.	
% growth as reported	2%
% growth at constant currency	4%

## Q2 2023 vs Q1 2023

Total Dupixent Net Product Sales - Global	
% growth as reported	12%
% growth at constant currency	12%

# Abbreviations & definitions

Abbreviation	Definition
1L	Front line
2L+	Second line and beyond
3L+	Third line and beyond
AAIC	Alzheimer's Association International Conference
AAV	Adeno-associated virus
ATS	American Thoracic Society
AD	Atopic dermatitis
ASCO	American Society of Clinical Oncology
BCC	Basal cell carcinoma
BCMA	B-cell maturation antigen
BLA	Biologics license application
B-NHL	B-cell non-Hodgkin's lymphoma
BP	Bullous pemphigoid
CHAPLE	CD55-deficient protein-losing enteropathy
CLL	Chronic lymphocytic leukemia
COPD	Chronic obstructive pulmonary disease
CPUO	Chronic pruritis of unknown origin
CRL	Complete response letter
CRSwNP	Chronic sinusitis with nasal polyposis
CST	Central Subfield Thickness
CSCC	Cutaneous squamous cell carcinoma
CSU	Chronic spontaneous urticaria

Abbreviation	Definition
DLBCL	Diffuse large B-cell lymphoma
DME	Diabetic macular edema
DR	Diabetic retinopathy
EC	European Commission
EGFR	Epidermal growth factor receptor
EoE	Eosinophilic esophagitis
EoG	Eosinophilic Gastroenteritis
FL	Follicular lymphoma
FEV1	Forced expiratory volume (1 second)
FOP	Fibrodysplasia ossificans progressive
GITR	Glucocorticoid-induced TNFR-related protein
HeFH	Heterozygous familial hypercholesterolemia
HNSCC	Head and neck squamous cell carcinoma
HoFH	Homozygous familial hypercholesterolemia
IC50	Half maximal inhibitory concentration
LAG-3	Lymphocyte-activation gene 3
LDL	Low-density lipoprotein
M	Molar
mCRPC	Metastatic castration-resistant prostate cancer
MCC	Merkel cell carcinoma
MM	Multiple myeloma
MUC16	Mucin 16

Abbreviation	Definition
NASH	Non-alcoholic steatohepatitis
NSCLC	Non-small cell lung cancer
NTD	N-terminal domain
ORR	Overall Response Rate
PD-1/PD-(L)1	Programmed cell death protein/(ligand) 1
PDUFA	Prescription Drug User Fee Act
PSMA	Prostate-specific membrane antigen
PTI	Personalized treatment interval
QoL	Quality of Life
RBD	Receptor binding domain
RNAi	RNA interference
ROP	Retinopathy of prematurity
ROW	Rest of world
RVO	Retinal vein occlusion
sBLA	Supplemental biologics license application
SCCHN	Squamous cell carcinoma of the head and neck
SITC	Society for Immunotherapy of Cancer
siRNA	Small interfering RNA
TAA	Tumor-associated antigen
UC	Ulcerative Colitis
VEGF	Vascular endothelial growth factor
wAMD	Wet age-related macular degeneration