

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of  
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 8, 2024 (January 8, 2024)

REGENERON PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

New York  
(State or other jurisdiction of incorporation)

000-19034  
(Commission  
File Number)

13-344607  
(I.R.S. Employer  
Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York  
(Address of principal executive offices)

10591-6707  
(Zip Code)

Registrant's telephone number, including area code: (914) 847-7000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock – par value \$0.001 per share	REGN	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02. Results of Operations and Financial Condition.**

On January 8, 2024, at the 42nd Annual J.P. Morgan Healthcare Conference, Leonard S. Schleifer, M.D., Ph.D., Board Co-Chair, President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”), and George D. Yancopoulos, M.D., Ph.D., Board Co-Chair, President and Chief Scientific Officer of Regeneron, are providing a corporate update.

The presentation includes information regarding the Company’s preliminary (unaudited) fourth quarter 2023 U.S. net product sales of EYLEA® HD (afibercept) Injection 8 mg of approximately \$123 million and the Company’s preliminary (unaudited) fourth quarter 2023 U.S. net product sales of EYLEA® (afibercept) Injection of approximately \$1.34 billion.

Additionally, the Company currently expects that its financial results calculated in accordance with U.S. generally accepted accounting principles (“GAAP”) and its non-GAAP financial results for the fourth quarter 2023 will include an acquired in-process research and development (“IPR&D”) charge of \$30 million on a pre-tax basis. This charge relates to a payment to extend the Company’s collaboration with Intellia Therapeutics, Inc. This acquired IPR&D charge is expected to negatively impact each of GAAP and non-GAAP net income per diluted share for the fourth quarter 2023 by approximately \$0.21.

Acquired IPR&D charges may include IPR&D acquired in connection with asset acquisitions as well as up-front, opt-in, and certain development milestone payments related to collaboration and licensing agreements. Regeneron does not forecast such acquired IPR&D charges due to the uncertainty of the future occurrence, magnitude, and timing of these transactions in any given period.

Regeneron’s results for the fourth quarter 2023 have not been finalized and are subject to Regeneron’s financial statement closing procedures. There can be no assurance that actual results will not differ from the preliminary (unaudited) estimates described herein.

**Item 7.01. Regulation FD Disclosure.**

The information set forth under Item 2.02 of this Current Report on Form 8-K is incorporated by reference herein. A copy of the presentation referenced in Item 2.02 is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 7.01.

The information included in Item 2.02 and the information included or incorporated in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

99.1 [Presentation by Leonard S. Schleifer, M.D., Ph.D., Board Co-Chair, President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., and George D. Yancopoulos, M.D., Ph.D., Board Co-Chair, President and Chief Scientific Officer of Regeneron Pharmaceuticals, Inc., at the 42nd Annual J.P. Morgan Healthcare Conference.](#)

104 Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

---

**Note Regarding Forward-Looking Statements**

*This Current Report on Form 8-K (this "Report") 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, Regeneron's expectations with respect to commercialization of its marketed products (including EYLEA<sup>®</sup> HD (aflibercept) Injection 8 mg and EYLEA<sup>®</sup> (aflibercept) Injection), competitive and other relevant developments affecting the market share of Regeneron's marketed products, and other relevant factors (whether within or without Regeneron's control) impacting the degree to which commercialization of Regeneron's marketed products is successful, as well as the impact of any of the foregoing on Regeneron's results of operations; Regeneron's expected acquired in-process research and development charge for the quarterly period ended December 31, 2023 and its expected impact on GAAP and non-GAAP net income per diluted share for this period as discussed in this Report; and the potential for any license, collaboration, or supply agreement, including Regeneron's agreement with Intellia Therapeutics, Inc. referenced in this Report, to be cancelled or terminated. A more complete description of these and other material risks can be found in Regeneron's filings 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.*

**Note Regarding Non-GAAP Financial Measures**

*This Report references non-GAAP net income per diluted share, which is a financial measure that is not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). This non-GAAP financial measure is computed by excluding certain non-cash and/or other items from the related GAAP financial measure. The Company also includes a non-GAAP adjustment for the estimated income tax effect of reconciling items. The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. Management uses this and other non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of such non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP.*

---

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

/s/ Joseph J. LaRosa

Joseph J. LaRosa

Executive Vice President, General Counsel and Secretary

Date: January 8, 2024

---

# J.P.Morgan Healthcare Conference

JANUARY 8, 2024

**REGENERON**<sup>®</sup>

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

J.P.Morgan Healthcare Conference 2024

## Strategy & Business Update



**Leonard S. Schleifer, MD, PhD**

Co-Founder, Board Co-Chair,  
President & Chief Executive Officer

## Note regarding forward-looking statements

This presentation includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "intend," "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements include, among others, the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron 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® (aflibercept) Injection, EYLEA HD (aflibercept) Injection 8 mg, Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, Evkeeza® (evinacumab) Injection, Veopoz™ (pozelimab) Injection, onconectamab, itepekimab, lincoseltamab, REGN5713-5714-5715, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), Regeneron's and its collaborators' earlier-stage research and clinical programs; the likelihood and timing of achieving any of the anticipated milestones discussed or referenced in this presentation; safety 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 Regeneron's late-stage product candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impact research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or prevent the completion of development or commercialization of Regeneron's Products and Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or otherwise competitive with, 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; impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and regulatory agencies on Regeneron's Products and Regeneron's Product Candidates; Regeneron's ability to manufacture and manage supply chains for multiple products and product candidates and other steps related to the manufacture, 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 inpatient maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determination 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 obligations, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement 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 (including 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 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 without limitation litigation initiated by 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 these proceedings and investigations 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 filings with the 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 statement that may be updated, amended, or replaced by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or forecast, as a result of new information, future events, or otherwise.



2023 achievements  
across key strategic  
priorities position  
Regeneron to  
deliver long-term  
shareholder value

**REGENERON**  
SCIENCE TO MEDICINE®

FDA approval and successful launch of  
positions retinal franchise for prolonged

Exceptional **Dupixent clinical and comm**  
**execution**; unprecedented data in eosinophilic  
COPD to enable potential 2024 launch

Significant **immuno-oncology** pipeline p  
across checkpoint inhibitor, CD3 bispeci  
CD28 costimulatory bispecific platforms  
**BLA submissions for odronextamab and**  
**linvoseltamab**

Emerging data from **hematology, geneti**  
and **obesity** pipelines support advancing  
potential first- and best-in-class opportu

4

Note: Definitions for all acronyms and abbreviations  
in this presentation can be found on slide 33.

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



# Delivered on key goals presented at J.P.Morgan 2023

## Ophthalmology

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

## Dupixent

- sBLA acceptance for CSU ✓
- EC decision on pediatric AD (6mo – 5yr) ✓
- Report data for Phase 3 study in Type 2 COPD ✓
- sBLA acceptance for pediatric EoE ✓
- FDA decision on CSU – received CRL

## Veopoz (anti-C5 antibody)

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

## Solid Organ Oncology

- Fianlimab + Libtayo:
  - Initiate Phase 2/3 studies in 1L advanced NSCLC ✓
  - Initiate Phase 2 study in perioperative melanoma –
  - Initiate Phase 2 study in perioperative NSCLC – 20;
- Report additional data for PSMAXCD28+Libtayo – 20
- Report initial data across solid organ oncology, including bispecifics and CD28 costimulatory bispecifics ✓
- EC decision for Libtayo in combination with chemotherapy in 1L advanced NSCLC ✓

## Odronextamab (CD20xCD3)

- Initiate confirmatory studies in FL & DLBCL, including
- Initiate Phase 1 study in combination with REGN5837 in aggressive DLBCL ✓
- BLA and MAA acceptance in B-NHL ✓

## Linvoseltamab (BCMAXCD3)

- Report updated pivotal Phase 2 data in R/R Multiple Myeloma
- Initiate confirmatory study in MM, including in earlier
- Initiate Phase 1 study in combination with TAAxCD28
- BLA submission in 3L+ MM ✓

# EYLEA HD approved by FDA for wAMD, DME, and DR



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

4Q 2023 U.S. Net Product Sales\*:

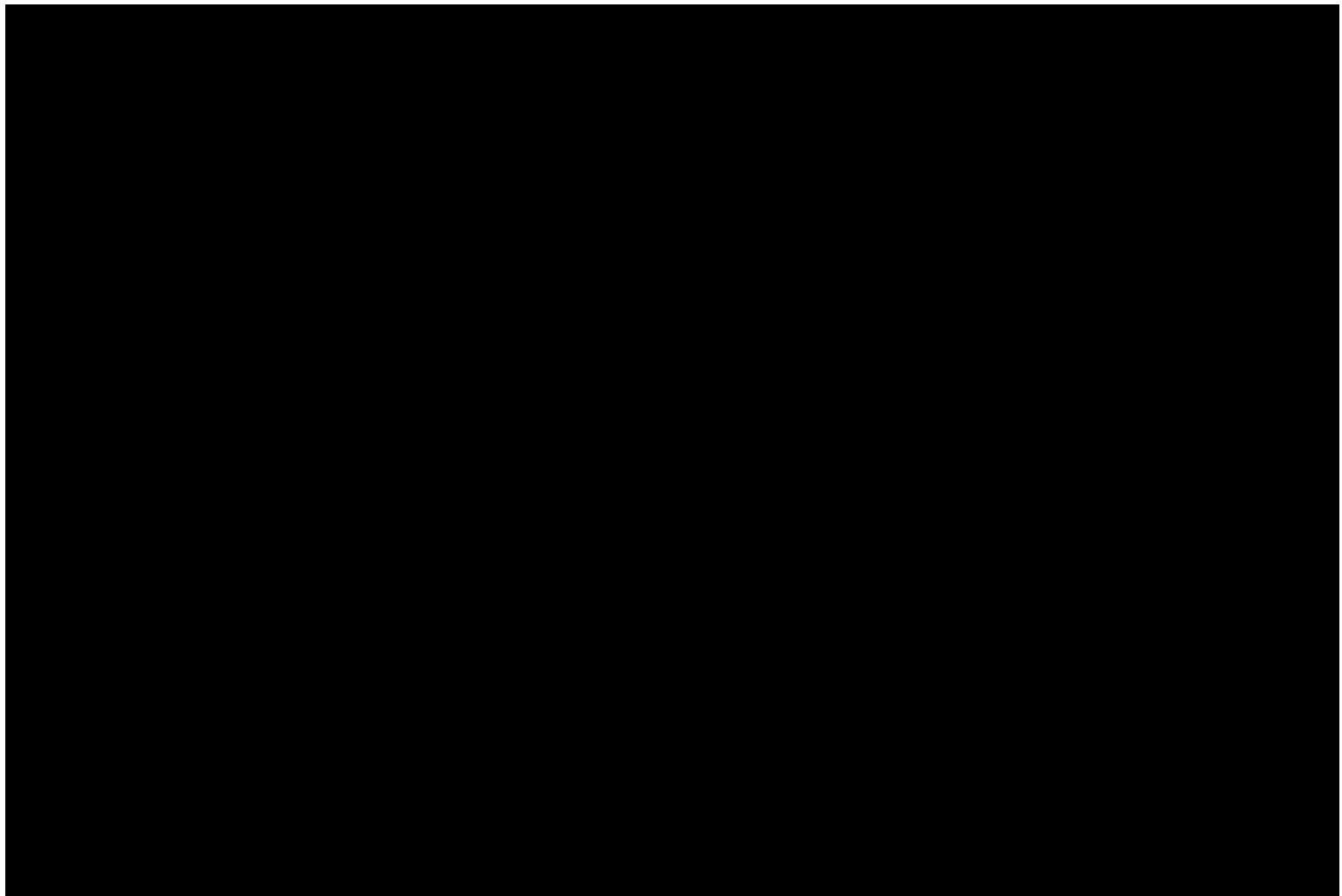
# \$123 million

achieved in first full quarter following launch



4Q 2023 combined EYLEA  
U.S. net product sales of :

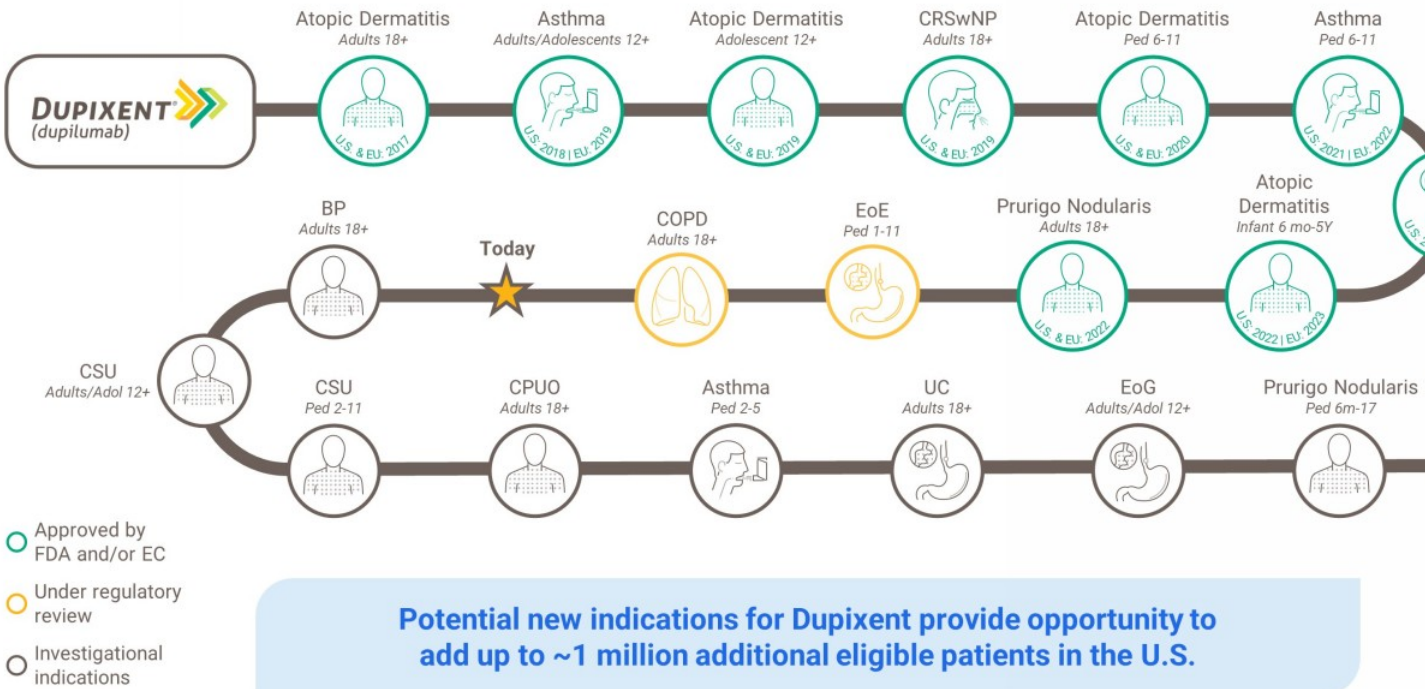
- ✓ **FDA approval** for wAMD, DM received in August 2023
- ✓ Early indicators suggest **bro uptake** across treatment lan
- ✓ **Strong 2-year data** from pivo and PHOTON studies preser 2023, supporting **best-in-cla** safety, and durability profile
- ✓ **~2/3 of eligible lives have c** majority of covered lives hav **single-step-edit access** to E
- ✓ **100% of Medicare jurisdic** confirmed paid claims
- ✓ Remain on track for **perman** on April 1, 2024



---

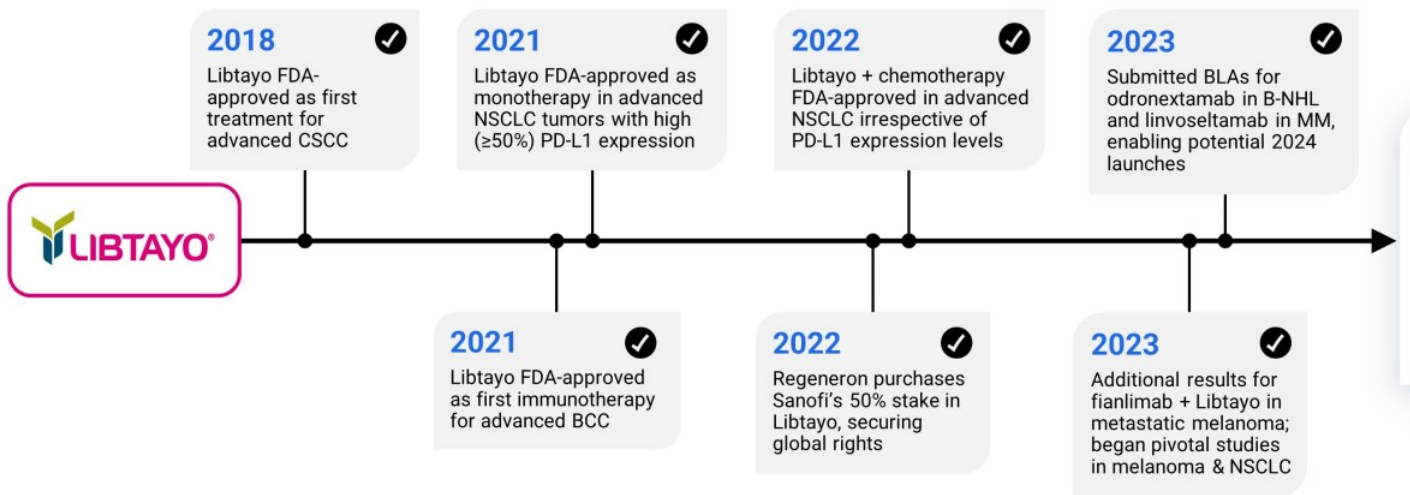
# Delivering on “pipeline in a product” potential

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



# Striving for global leadership in oncology

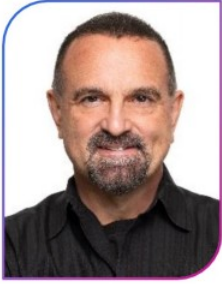
Potential for up to three FDA-approved products by end of 2024, spanning solid and hematological malignancies



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

J.P.Morgan Healthcare Conference 2024

## Research & Pipeline Update



**George D. Yancopoulos, MD, PhD**

Co-Founder, Board Co-Chair,  
President & Chief Scientific Officer



# Relentless Innovation

After 35 years, Regeneron is still pushing the boundaries of science and technology

2023 was another year of scientific “firsts”

## Dupixent in COPD\*

First biologic to achieve clinically meaningful reduction in COPD exacerbations and improvement in lung function

## CRISPR gene editing†

First to initiate a pivotal *in vivo* CRISPR gene editing study by U.S. FDA

## CD28 costimulatory bispecifics

First to dose patients with costimulatory bispecific in combination with a CD3 bispecific for both solid and heme tumors

## siRNA in CNS†

First clinical results demonstrating silencing of a pathologic human brain

## Antibody + siRNA targeting C5

Generated first data combining antibody and siRNA therapeutic classes (for targeting C5 in PNH)

## Gene therapy for hearing‡

Restored hearing in profound child with otoferlin gene 1

## Reversing severe allergy

Published preclinical results on potential groundbreaking approach for reversing severe allergy

Collaboration with:  
\* Sanofi; † Alnylam; ‡ Intellia




# Harnessing the immune system to fight cancer

## Regeneron has validated 3 independent classes of internally-developed immuno-oncology

- One approved medicine, two under regulatory review
- Robust pipeline of immuno-oncology combinations

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

 **LIBTAYO**<sup>®</sup>  
(cemiplimab-rwlc)  
Injection 350 mg  
(anti-PD-1)  
CSCC, BCC, NSCLC

**Fianlimab**  
(anti-LAG-3)  
Melanoma, NSCLC

### CD3 Bispecifics ("Signal 1")

**Odronextamab**  
(CD20xCD3)  
B-NHL

**Ubamatamab**  
(MUC16xCD3)  
Ovarian Cancer

**Linvoseltamab**  
(BCMAxCD3)  
MM

**REGN4336**  
(PSMAxCD3)  
Prostate Cancer

### CD28 Costimulatory ("Signal 2")

**REGN5678**  
(PSMAxCD28) (M  
Prostate Cancer O

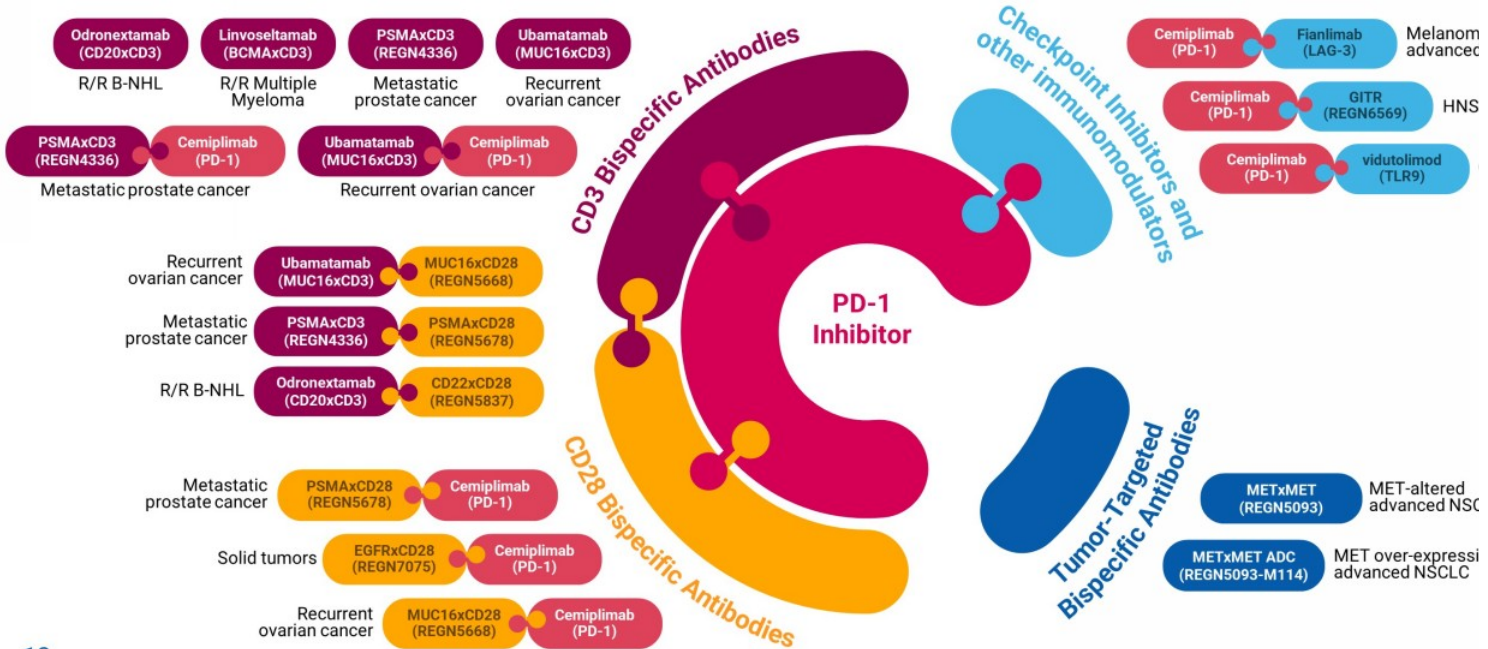
**REGN7075**  
(EGFRxCD28) (I  
Solid Tumors

Broad pipeline of clinical-stage assets and numerous preclinical assets planned to advance to clinical studies

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

## Bispecifics and Checkpoint Inhibitor Combos

## Checkpoint Inhibitor Combos



# 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 Melanoma					
Melanoma	1L Metastatic Melanoma	Potentially pivotal data expected 2H24			<b>fianlimab + cemiplimab</b> FIH POC study <sup>1</sup>	ORR	D			
	Adjuvant Melanoma	Enrolling						<b>Cohort MM1</b> (n=40) <i>Initial</i>	63%	8
	Perioperative Melanoma	Initiating 1H24						<b>Cohort MM2</b> (n=40) <i>Confirmatory</i>	63%	8
Lung (NSCLC)	Advanced NSCLC	Enrolling	Initial data expected 2H24		<b>Cohort MM3</b> (n=18) <i>PD-1 in adjuvant setting</i>	56%	6			
	Perioperative NSCLC	Initiating 1H24			<b>Combined</b> (n=98)	<b>61%</b>	<b>7</b>			
Other solid tumors	Perioperative HCC	Enrolling			<b>RELATIVITY-047 Phase 3<sup>2</sup></b>					
	Perioperative CSCC	Initiating 2024			nivolumab (n=359)	33%	5			
	Perioperative HNSCC	Initiating 2024			nivolumab + relatlimab (n=355)	43%	6			

**Safety profile of fianlimab + ce  
combination similar to anti-PD-1**

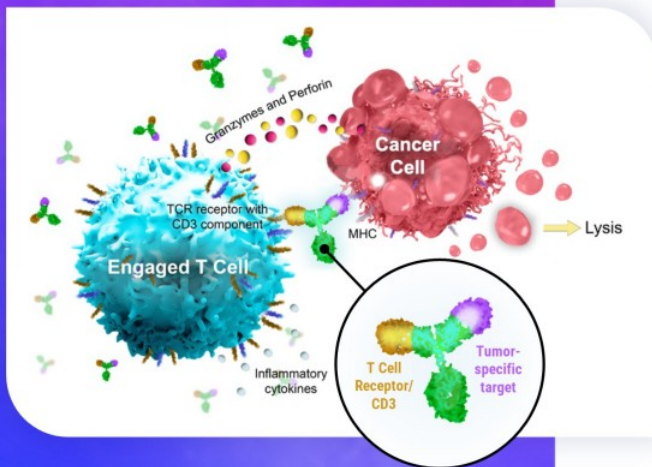
<sup>1</sup>Hamid, O. Significant durable response with fianlimab (anti-LAG-3) and cemiplimab (anti-PD-1) in advanced melanoma: post adjuvant PD-1 analysis, ASCO 2023.

<sup>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.

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

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

# Regeneron's leading CD3 bispecifics



Our blood cancer research is focused on bispecific antibodies that are being investigated both as monotherapies and in combination with each other and emerging therapeutic modalities

## 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 submitted  
December 2023  
multiple m  
pending FI

EU submission  
planned for

## Odronextamab (CD20xCD3) – NHL

Odronextamab can 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









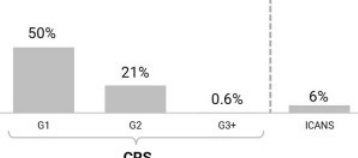
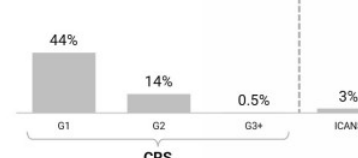
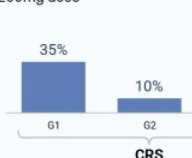








Confirmatory Phase 3 OLYMPIA program underway and enrolling patients in earlier lines of therapy

BLA accepted  
for R/R FL  
(PDUFA M

EU submission  
decision ex












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

	<b>Teclistamab - FDA Approved</b> (per U.S. FDA Prescribing Information*)	<b>Elranatamab - FDA approved</b> (per U.S. FDA Prescribing Information*)	<b>Linvoseltamab</b> (per LINKER-MM1 primary endpoint)
 <b>Efficacy</b>	ORR  62% sCR + CR  28% Follow-up 7.4-months among responders	ORR  58% sCR + CR  26% Follow-up 11.1-months among responders	200mg dose ORR  58% sCR + CR  26% Follow-up 11.0-months
 <b>Safety</b>  <small>Not full safety profile. Please refer to U.S. FDA prescriber information and Regeneron's disclosures for further details</small>	 <p>CRS                      CRS median time to onset: 2 days                      median duration: 2 days</p>	 <p>CRS                      CRS median time to onset: 2 days                      median duration: 2 days</p>	200mg dose  <p>CRS                      CRS median time to onset: 2 days                      median duration: 2 days</p>
 <b>Hospitalization, Administration &amp; Dosing schedule</b>	<p> <b>x 6 days</b>                      3 X 48-hr hospitalization requirements during step-up dosing (over initial ~9 days)</p> <p><b>Subcutaneous (by HCP only)</b>                      QW </p>	<p> <b>x 3 days</b>                      1 X 48-hr + 1 X 24-hr hospitalization requirements during step-up dosing (over initial ~5 days)</p> <p><b>Subcutaneous (by HCP only)</b>                      QW  → Q2W                      Weeks 1-24      Week 25+ for responders</p>	<p> <b>x 3 days</b>                      1 X 24-hrs in W1 + Hospitalized for 1 day during Day 1 &amp; 2</p> <p><b>Intravenous (by HCP only)</b>                      QW  → Q2W                       Weeks 1-14      Weeks 15-23</p>

\* Data source: Regeneron press release from Dec 7, 2023. † Per Protocol. ‡ 30-min as long as patient tolerability allows; discretion at Day 8.

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

# Progressing CD28 costimulatory bispecifics

		Dose Escalation	Proof-of-Mechanism	Dose Expansion	Status / Next Steps	Combined with:
	<b>PSMAxCD28</b> Prostate Cancer				Enrolling monotherapy cohort; combo with PSMAxCD3 to start 1H24	<b>Cemiplimab</b>
	<b>EGFRxCD28</b> Solid Tumors				Expansion cohorts with cemiplimab to initiate in 1H24 in multiple tumors	<b>Cemiplimab</b>
	<b>MUC16xCD28</b> Ovarian Cancer				Presented initial dose escalation results with cemiplimab; expansion cohorts expected to initiate in 2024; enrolling dose escalation with ubamatamab	<b>Cemiplimab</b>
	<b>CD22xCD28</b> DLBCL				Enrolling dose escalation cohorts	<b>Odronextamab (CD20xCD3)</b>
	<b>CD38xCD28</b> MM				Initiating Phase 1 study in 2024	<b>Linvoseltamab (BCMAxCD3)</b>

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

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

**DUPIXENT**  (anti-IL4/13)  
(dupilumab)

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

sBLA submission completed in December 2023

	BOREAS	NOTUS
<b>Primary endpoint:</b> 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)
<b>Key secondary endpoint:</b> 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

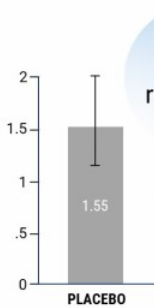
**Itepekimab**  
(anti-IL-33)

Positive data in former smokers in Phase 2 C informed Phase 3 trial design

Phase 3 AERIFY studies passed interim futility in 2023

- 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 CC**  
Itepekimab led to 4 exacerbations in f





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

SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

## ALLERGY

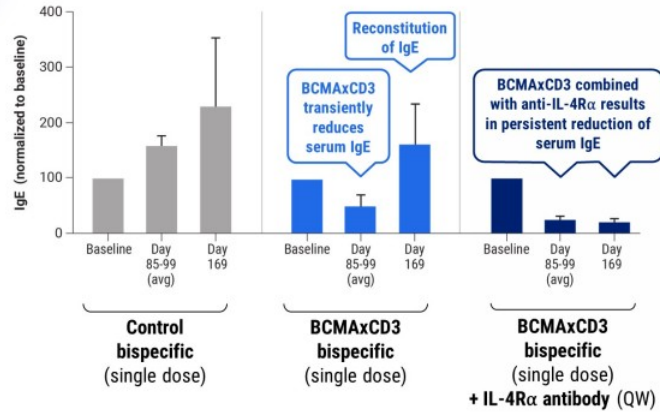
A therapeutic strategy to target distinct sources of IgE and durably reverse allergy

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. Steeman, Andrew J. Murphy, George D. Yancopoulos, Jamie M. Orengo\*

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

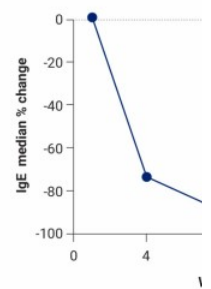
- **Immunoglobulin E (IgE)** is the key driver of allergic reactions, such as food allergies; long-lived plasma cells consistently produce IgE<sup>2</sup>
- In atopic patients, **transient linvoseltamab treatment with Dupixent maintenance** has the potential of permanently eliminating IgE and durably reversing severe allergies, while allowing the restoration of other immunoglobulins

**Transient plasma cell depletion with BCMAxCD3 plus sustained IL-4Rα blockade durably eliminates IgE production in cynomolgus monkeys<sup>1</sup>**



**Myeloma patients linvoseltamab rapid**

Median concentrations MM patients (n=12) rec



- Linvoseltamab + BCMA-expressing long-lived plasma cells
- IgE reduction seen in patients supported by Dupixent regimen for severe allergies

**Clinical trial with the two-drug regimen in patients with severe food allergies to begin in 2023**

<sup>1</sup>Adapted from Limnander et al, Sci. Transl. Med. 2023.<sup>2</sup>Asrat et al, Sci. Immunol. 2020.

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

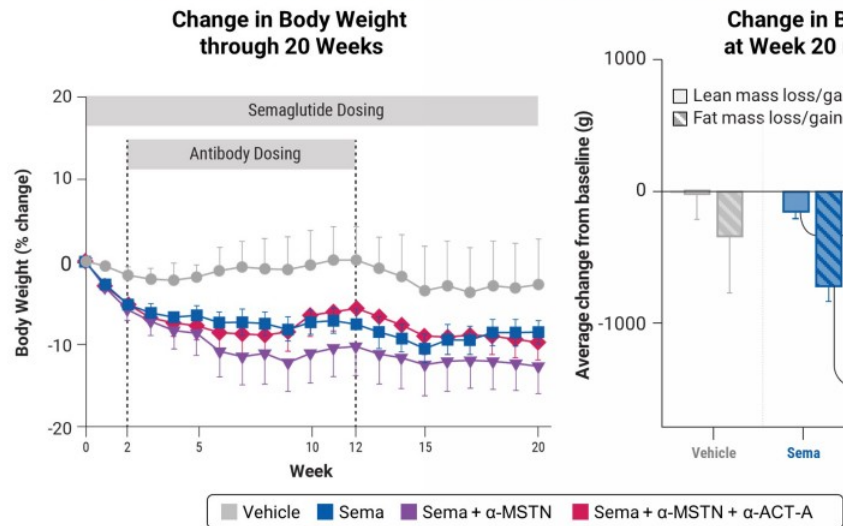
This slide contains investigational drug candidates that have not been approved by any regulatory authority.

# 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 this weight loss is due to decreases in lean muscle mass<sup>1</sup>

Novel approaches for obesity		
	Rationale	Program status
Incretin-based therapy	Improving upon once weekly standard of care in obesity/T2DM	NHP studies underway for our <b>antibody-tethered GLP-1 ligand</b>
+ $\alpha$ -MSTN + $\alpha$ -ACT-A	Improving <b>quality of weight loss</b> by preserving lean muscle during weight loss	Mid-2024: Start Phase 2 study of semaglutide with <b>trevogrumab</b> (anti-myostatin) $\pm$ <b>garetosmab</b> (anti-activin A)
GPR75	GPR75 gene mutations are associated with <b>protection against obesity</b>	siRNA, small molecule, and antibody candidate identification and screening underway

## Adding myostatin blockade to semaglutide leads to greater fat loss and less lean mass loss compared to semaglutide monotherapy in obese non-human primates



20 <sup>1</sup>Wilding, Diabetes Obes Metab, 2022; PMID: 35441470, <sup>2</sup>from Mastaitis J, et al. Manuscript in preparation and ADA 2023 presentation, n=10 per arm; DXA: dual-energy X-ray absorptiometry measurement

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

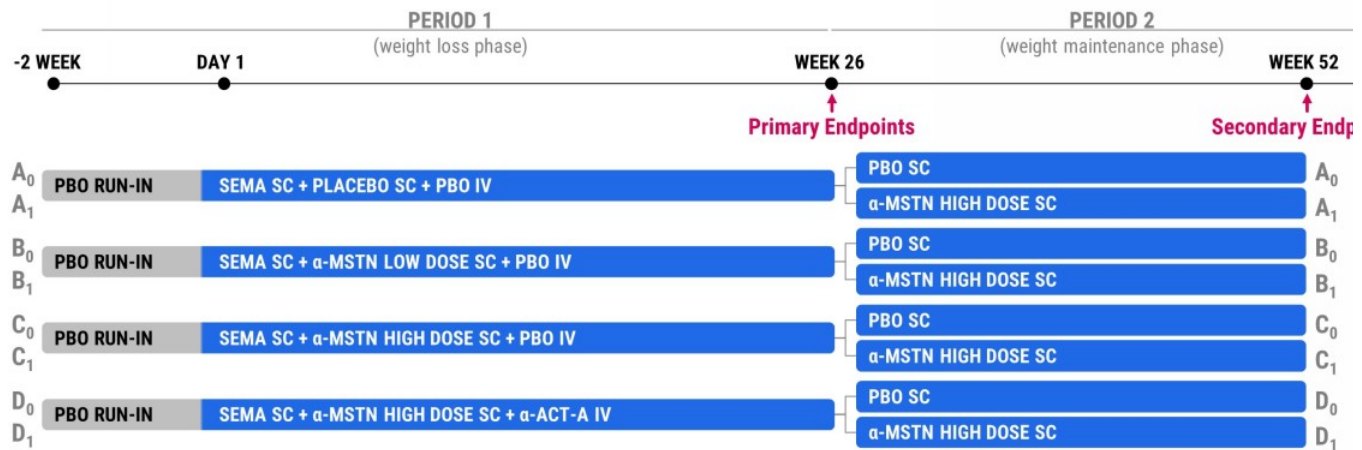
# Obesity clinical program to start in mid-2024

Phase 2 study to investigate if addition of trevogrumab (anti-myostatin) to semaglutide with and without glucagon-like peptide-1 receptor agonist (GLP-1 RA) improves the quality of weight loss and/or improves maintenance of weight loss post semaglutide treatment

- Obese patient enrollment starting mid-2024, pending safety and tolerability trial of high dose trevogrumab in healthy volunteers

## Phase 2 General Obesity Trial Design

Randomized (1:1:1:1:1) double-blind, active controlled trial

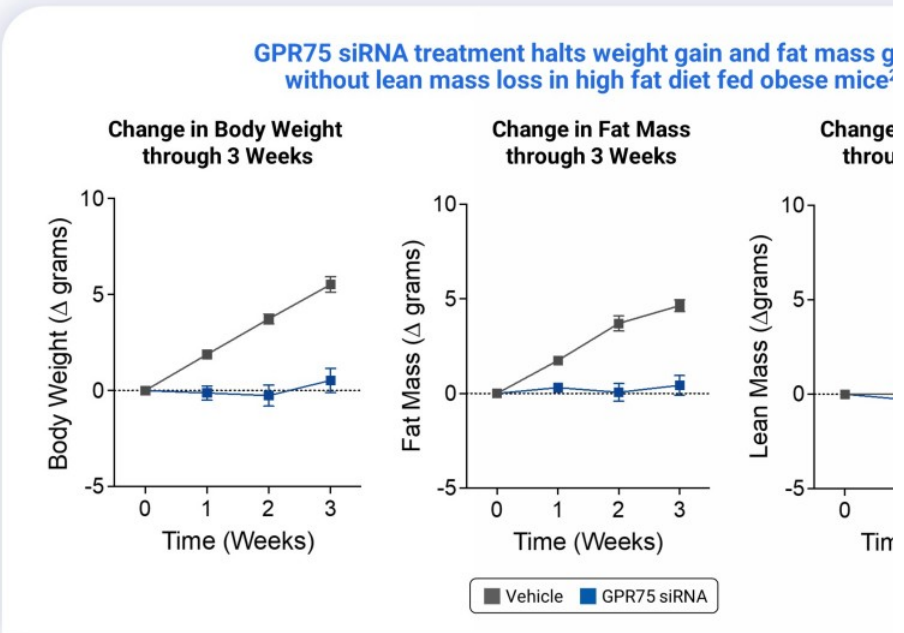
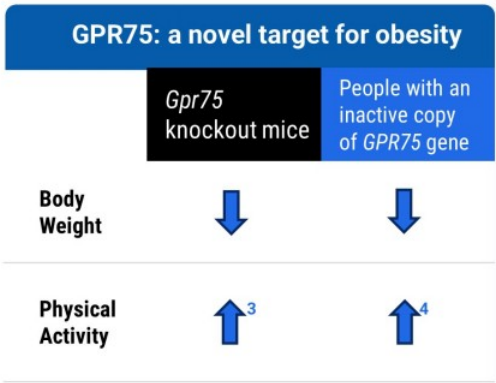


# Leveraging Regeneron's novel genetics discovery – GPR75 as a target for obesity

Exome sequencing of ~640,000 individuals revealed that gene variants in *GPR75* are associated with reduced risk of obesity. Individuals with at least one inactive copy of the *GPR75* gene had lower BMI and, on average, tended to weigh about 10% less.

**Regeneron is pursuing three modalities to target GPR75:**

- siRNA collaboration with Alnylam
- Small molecule collaboration with AstraZeneca
- Antibody approach



22 <sup>1</sup>Akbari, Science, 2021; PMID: 34210852, <sup>2</sup>unpublished data for humanized GPR75 mice, n=20-21 per arm, <sup>3</sup>unpublished data for *Gpr75* knockout mice versus wild-type mice, <sup>4</sup>unpublished self-reported data (via the International Physical Activity Questionnaire [IPAQ]) for a small number of heterozygous *GPR75* pLOF carriers versus non-carriers; pLOF – predicted Loss Of Function

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



# 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

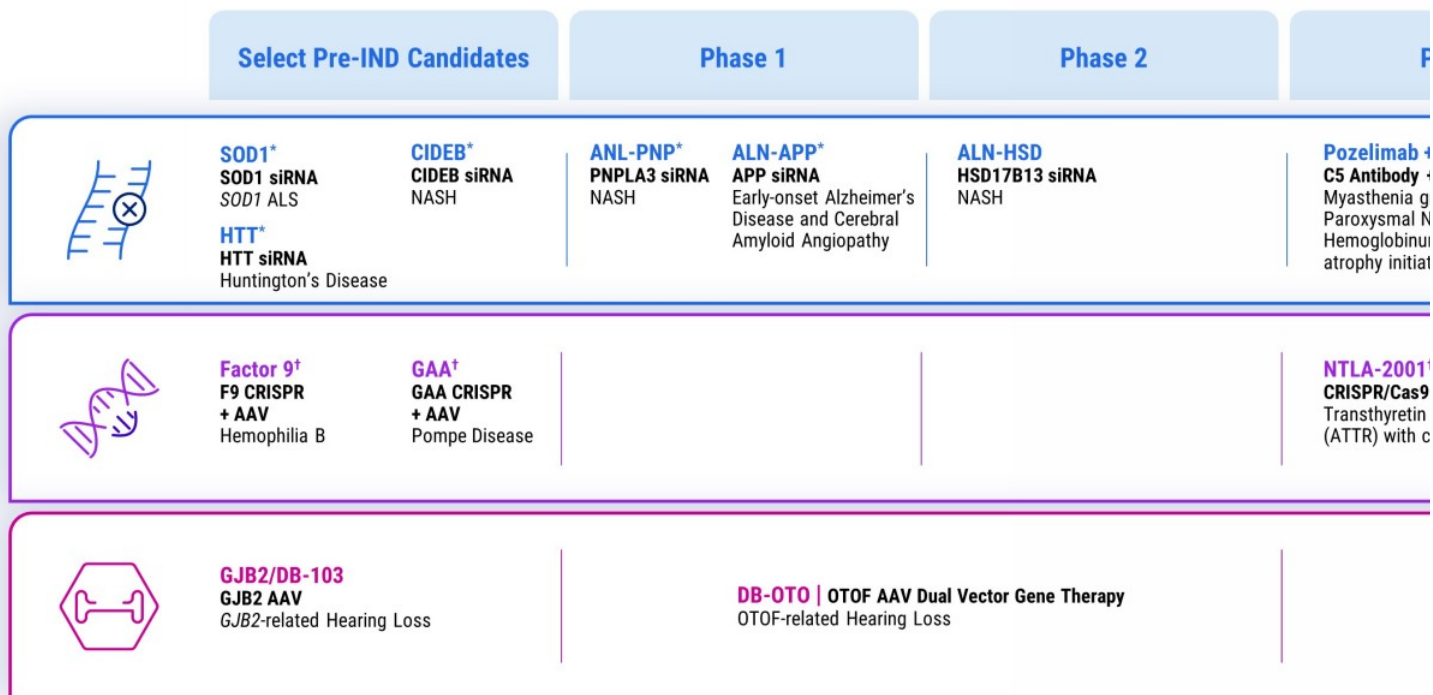
- Gene knockout: first clinical results demonstrating genome editing in humans; Phase 3 started (**TTR**)<sup>†</sup>
- Gene insertion: clinical program to start in 2024, pending regulatory approval (**Factor 9**)<sup>†</sup>



## AAV Gene Ther

- Local delivery: restore first treated patient (**C**)
- Antibody-targeted del of-concept in non-hur clinical approach in d (**muscle disorders**)

# Regeneron Genetic Medicines pipeline



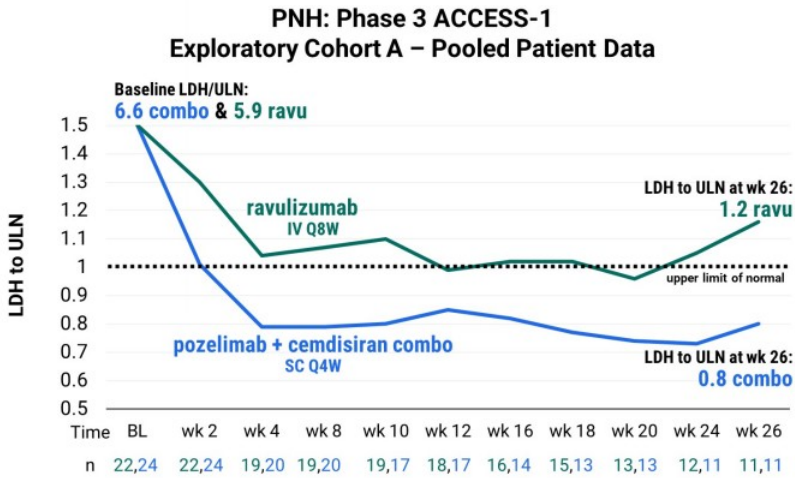
24 Collaboration with: \*Alnylam; †Intellia.

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

# Regeneron pioneers first combination of siRNA + antibody therapeutic

siRNA reduces target load so that antibody can completely block target for extended period

Prior to this combination, no treatment has reduced and sustained average LDH to normal levels in PNH patients



**Pozelimab + cemdisiran – reduces LDH levels in almost all patients**

**Prior to this combination, no treatment has reduced and sustained average LDH to normal levels in PNH patients**

**Primary Endpoint:** the percent change in lactate dehydrogenase (LDH) from baseline to week 26. LDH is a well-accepted biomarker of hemolysis – with adequate control and normalization defined as  $\leq 1.5$  and  $\leq 1.0$  times the upper limit of normal (ULN), respectively. Only patients that completed 26 weeks of the study were evaluated for efficacy at the time of the data cut.

	Overview	Status
<b>PNH</b>	<b>Phase 3 ACCESS-1</b> Complement inhibitor-naïve patients	<ul style="list-style-type: none"> <li>Cohort A recently</li> <li>Cohort E expected</li> </ul>
<b>gMG</b>	<b>Phase 3 NIMBLE</b> Patients with symptomatic generalized myasthenia gravis	<ul style="list-style-type: none"> <li>Study er</li> <li>Data exp</li> </ul>
<b>GA</b>	Patients with geographic atrophy secondary to age-related macular degeneration  Systemic administration - <i>Single subcutaneous injection to treat bilateral disease</i>	<ul style="list-style-type: none"> <li>Phase 3 initiating</li> </ul>

**Our antibody + siRNA combination has the potential on current standards of care across many disease complement mediated disorders:**

- Complete and sustained C5 inhibition at a lower dose
- Reduced dosing frequency
- Convenient subcutaneous formulation








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

Pivotal Phase 3 program to initiate in 2H 2024

## Program Overview

*(Trials to initiate in 2H 2024)*

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

	Current Geographic Atrophy Landscape	Regeneron Opportunity (Pozelimab + Cemd)
 <b>Market Opportunity</b>	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <li>Leadership in o</li> <li>Differentiated N</li> </ul>
 <b>Route of Administration</b>	<ul style="list-style-type: none"> <li>Q4W/Q8W intravitreal injections</li> <li>Bilateral disease requires injections in each eye</li> </ul>	<ul style="list-style-type: none"> <li>Less invasive tr</li> <li>Systemic admin treatment of bil</li> <li>Q4W systemic 1</li> </ul>
 <b>Ocular Safety</b>	<ul style="list-style-type: none"> <li>Reported cases of occlusive retinal vasculitis along with other ocular safety events</li> </ul>	<ul style="list-style-type: none"> <li>Systemic admin potentially redu of ocular safety</li> </ul>
 <b>Efficacy</b>	<ul style="list-style-type: none"> <li>Approved agents lack evidence of maintenance of visual function</li> </ul>	<ul style="list-style-type: none"> <li>Opportunity to c greater reductio growth rate alo preservation of</li> </ul>
 <b>Office Visits</b>	<ul style="list-style-type: none"> <li>Administered in office by retinal specialist</li> </ul>	<ul style="list-style-type: none"> <li>Potential for se (subcutaneous</li> </ul>

# Regeneron restores hearing in a profoundly deaf child

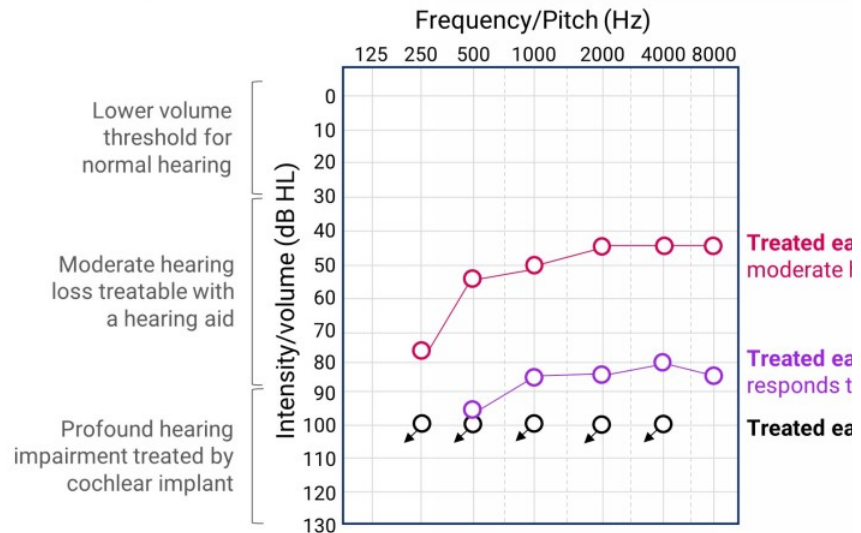
DB-OTO AAV-based dual-vector gene therapy delivered to the inner ear to rescue hearing in infants

## 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



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

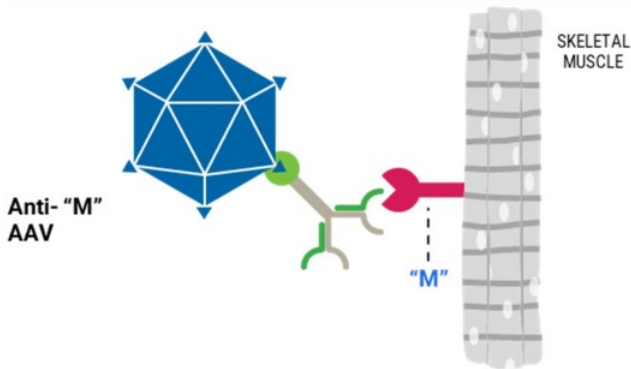
\*Arrows indicate no response at maximum level tested

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

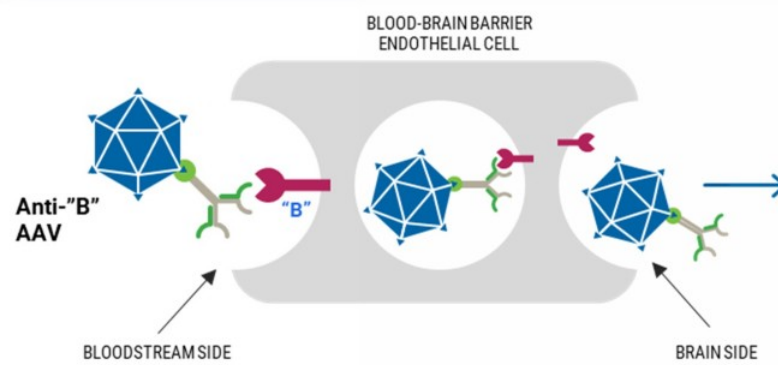
# Optimizing genetic medicines with antibody-targeted deli

Targeting of vector delivery with the skeletal muscle cell-specific protein ("M") and blood-brain barrier endothelial cell-specific protein ("B")

## Skeletal Muscle Targeting Platform



## Blood-Brain Barrier Crossing Platform



"M"- and "B"-mediated AAV9 delivery results in enhanced targeting to skeletal muscles and the central nervous system, respectively, as well as de-targeting other organs like the liver and heart.

# 2024 key upcoming milestones

## Ophthalmology

- EU decision for aflibercept 8 mg in wAMD and DME – **Now Approved** ✓
- Japan decision for aflibercept 8 mg in wAMD and DME (1H)
- Initiate pivotal RVO study of Eylea HD to enable FDA filing (mid)
- Obtain permanent J-code for EYLEA HD (2Q)
- Initiate pivotal studies of pozelimab + cemdisiran combination in geographic atrophy (2H)

## Dupixent / I&I

- Regulatory decisions for pediatric (1-11 yrs) eosinophilic esophagitis (U.S. Q1, EU 2H)
- sBLA acceptance for COPD with a Type 2 inflammatory phenotype (Q1); potential FDA approval (mid/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)

## Solid Organ Oncology

- Report potentially pivotal interim analysis of Libtayo in Adju
- Report potentially pivotal results from Phase 2/3 study of fi in 1L metastatic melanoma (2H); initial data in 1L advanced
- Initiate potentially pivotal Phase 2 studies for fianlimab + ce perioperative melanoma (1H) and perioperative NSCLC (1H)
- Initiate dose-expansion cohorts of EGFRxCD28 + cemiplima tumors (1H)
- Initiate cohorts combining PSMAxCD28 + PSMAxCD3 in mC PSMAxCD28 monotherapy in RCC (1H)

## Hematology

- FDA decision on odronextamab in R/R FL and R/R DLBCL (1
- BLA acceptance for linvoseltamab in R/R multiple myeloma approval (2H); EU submission (1Q)
- Initiate Phase 1 study of linvoseltamab in combination with costimulatory bispecific in multiple myeloma
- Report Phase 2 proof-of-concept results for Factor XI antibc

## Genetic Medicines

- Initiate Phase 1 study of *Factor 9* gene insertion in hemophi
- Report additional proof-of-concept data for DB-OTO
- Initiate proof-of-concept study of SOD1 siRNA in ALS



# Our mission:

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

## Three responsibility focus areas all 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 CSI



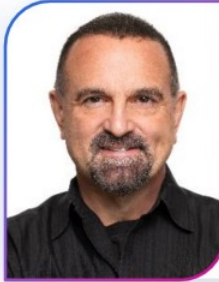
Fo of ex

# Q&A



**Leonard  
S. Schleifer,  
MD, PhD**

Co-Founder, Board  
Co-Chair, President &  
Chief Executive Officer



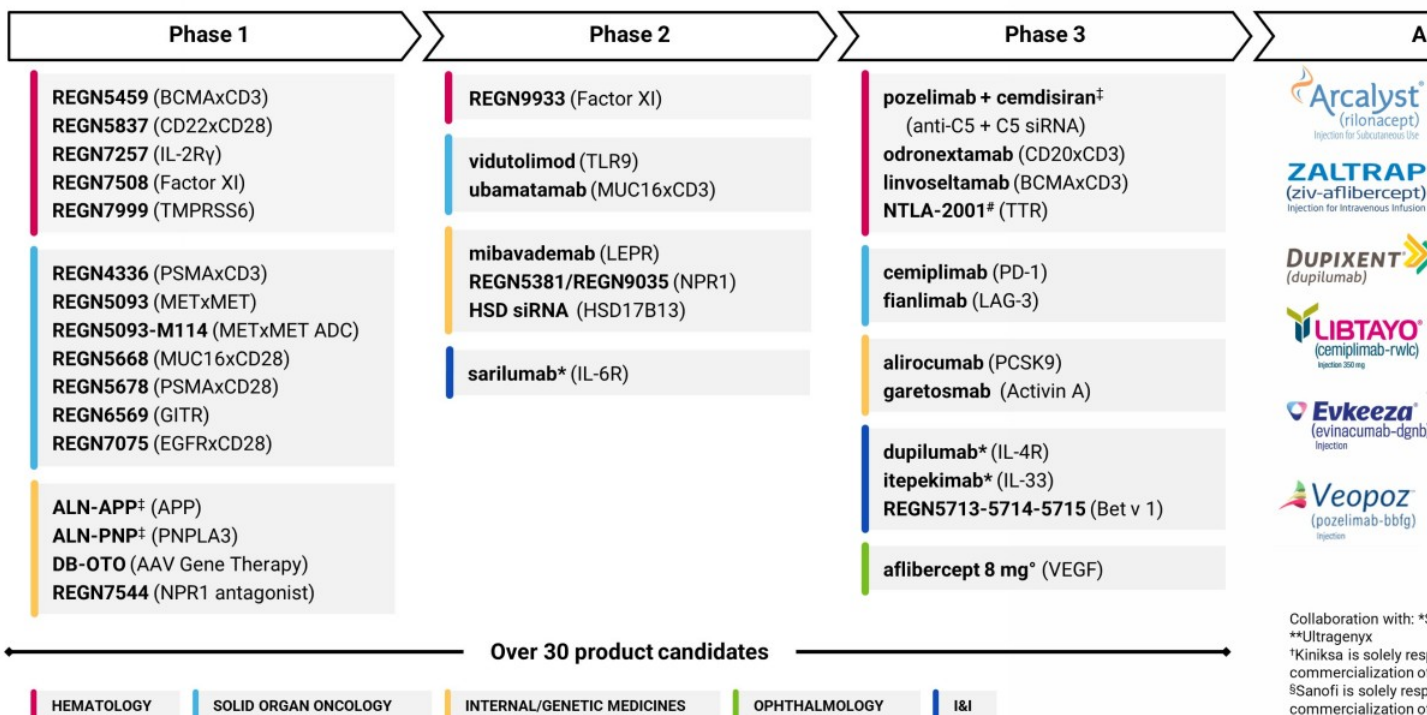
**George D.  
Yancopoulos,  
MD, PhD**

Co-Founder, Board  
Co-Chair, President &  
Chief Scientific Officer



**Mari  
McC**  
EVP, He

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



Collaboration with: \*  
 \*\*Ultragenyx  
 †Kiniksa is solely responsible for commercialization of  
 ‡Sanofi is solely responsible for commercialization of



# Abbreviations and Definitions

Abbreviation	Definition	Abbreviation	Definition	Abbreviation	Definition
1L	First line	FIH	First in human	NSCLC	Non-small cell l
AAV	Adeno-associated virus	FL	Follicular lymphoma	ORR	Overall Respons
ALS	Amyotrophic lateral sclerosis	GA	Geographic atrophy	OTOF	Otoferlin
APP	Amyloid precursor protein	GAA	Alpha glucosidase	PBO	Placebo
BCC	Basal cell carcinoma	GITR	Glucocorticoid-induced TNFR-related protein	PD-1/PD-(L)1	Programmed ce
BCMA	B-cell maturation antigen	GLP-1	Glucagon-like peptide 1	PDUFA	Prescription Dru
BLA	Biologics license application	GLP-1R	Glucagon-like peptide 1 receptor	PNH	Paroxysmal noc
B-NHL	B-cell non-Hodgkin's lymphoma	gMG	Generalized myasthenia gravis	POC	Proof-of-concep
BP	Bullous pemphigoid	HCC	Hepatocellular carcinoma	PSMA	Prostate-specifi
CAR-T	Chimeric antigen receptor T-cell	HCP	Healthcare Provider	R/R	Relapsed/Refra
CIndU-COLD	Chronic inducible urticaria – cold	HNSCC	Head and neck squamous cell carcinoma	RCC	Renal cell carcin
CNS	Central nervous system	Hz	Hertz	RGC	Regeneron Gene
COPD	Chronic obstructive pulmonary disease	ICANS	Immune effector cell-associated neurotoxicity syndrome	ROW	Rest of world
CPUO	Chronic pruritis of unknown origin	IND	Initial new drug application	RVO	Retinal vein occ
CR	Complete response	IV	Intravenous	sBLA	Supplemental bi
CRS	Cytokine release syndrome	KM	Kaplan-Meier curve	SC	Subcutaneous
CRSwNP	Chronic sinusitis with nasal polyposis	LAG-3	Lymphocyte-activation gene 3	sCR	Stringent compl
CSCC	Cutaneous squamous cell carcinoma	LDH	Lactate dehydrogenase	siRNA	Small interfering
CSU	Chronic spontaneous urticaria	LEPR	Leptin receptor	T2DM	Type 2 diabetes
dB HL	Decibel hearing loss	MAA	Marketing authorization application	TAA	Tumor-associat
DCR	Duration of complete response	MCC	Merkel cell carcinoma	TRx	Total prescriptic
DLBCL	Diffuse large B-cell lymphoma	mCRPC	Metastatic castration-resistant prostate cancer	TTR	Transthyretin pr
DME	Diabetic macular edema	MM	Multiple myeloma	UC	Ulcerative coliti
DR	Diabetic retinopathy	MOA	Mechanism of action	ULN	Upper limit of n
DXA	Dual-energy X-ray absorptiometry	mPFS	Median progression-free survival	VEGF	Vascular endoth
EC	European Commission	MUC16	Mucin 16	wAMD	Wet age-related
EGFR	Epidermal growth factor receptor	NASH	Non-alcoholic steatohepatitis		
EoE	Eosinophilic esophagitis	NBRx	New to Brand Prescriptions		
EoG	Eosinophilic gastroenteritis	NHP	Non-human primate		