

**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 9, 2023 (January 9, 2023)**

**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)**

**13-3444607  
(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 Instructions 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 9, 2023, at the 41st Annual J.P. Morgan Healthcare Conference, Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”), and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron, are providing a corporate update.

The presentation includes information regarding the Company’s preliminary (unaudited) U.S. net product sales of EYLEA<sup>®</sup> (afibercept) Injection of approximately \$6.26 billion for the full year 2022 (based on preliminary (unaudited) fourth quarter 2022 U.S. net product sales of EYLEA of approximately \$1.50 billion). With respect to the preliminary (unaudited) fourth quarter 2022 U.S. net product sales of EYLEA, the presentation further notes the following:

- Negatively impacted by a short-term shift to off-label use of compounded Avastin<sup>®</sup> (bevacizumab)
- Temporary closing in Q4 2022 of fund that provides patient co-pay assistance
- Most recent Q4 2022 market data suggests that shift to off-label Avastin is already beginning to reverse

The presentation also includes information regarding the Company’s current expectation 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 2022 and full year 2022 will include an acquired in-process research and development (“IPR&D”) charge of approximately \$30 million relating to an up-front payment in connection with the Company’s previously announced collaboration and licensing agreement with CytomX 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 2022 by approximately \$0.21.

Regeneron’s results for the fourth quarter and full year 2022 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., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron Pharmaceuticals, Inc., at the 41st Annual J.P. Morgan Healthcare Conference.](#)

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

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### **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® (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 in the quarterly period ended December 31, 2022 and its expected impact on GAAP and non-GAAP net income per diluted share for the quarterly period then ended as discussed in this Report; and the potential for any license, collaboration, or supply agreement, including Regeneron’s agreement with CytomX 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 includes 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.*

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**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 thereunto duly authorized.

**REGENERON PHARMACEUTICALS, INC.**

/s/ Joseph J. LaRosa

Joseph J. LaRosa

Executive Vice President, General Counsel and Secretary

Date: January 9, 2023

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# J.P. Morgan Healthcare Conference

January 9, 2023

**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 2023

## Strategy & Business Update



**Leonard S. Schleifer, MD, PhD**  
Co-Founder, President &  
Chief Executive Officer

## 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies; Regeneron's and its collaborators' ability to continue to conduct research and clinical programs; Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of 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® (alirocumab) Injection, Kevzara® (sarilumab) Injection, Evkeeza® (evinacumab), Imzabz® (atoltivimab, maffivimab, and odesivimab-ebgn), aflibercept 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 (including REGN14287, Regeneron's "next generation" COVID-19 antibody discussed in this presentation), and the use of human genetics in Regeneron's research programs; 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), including the studies discussed or referenced in this presentation, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including without limitation those listed above; the likelihood and timing of achieving any of the anticipated milestones described 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; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer 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 payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (including those discussed or referenced in this presentation) may be replicated in other studies and/or lead to advancement of product candidates to clinical trials or therapeutic applications; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, licensees, 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; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; 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 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 U.S. Securities and Exchange Commission. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

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# 2022 progress across key strategic priorities positions Regeneron to deliver long-term shareholder value



Positive **afibercept 8 mg** data position retinal franchise for prolonged leadership

Exceptional **Dupixent clinical profile and commercial execution**, now approved to treat five Type 2 allergic diseases and in AD patients as young as 6 months

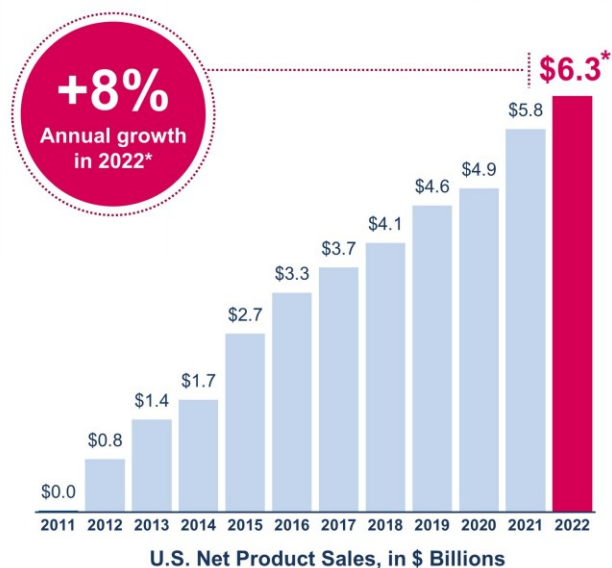
Strengthened **immuno-oncology** platform with Libtayo acquisition, advances for CD3 bispecifics, promising costimulatory bispecific data, and robust LAG-3 program

Potential breakthrough advance for **COVID-19** treatment and prevention with a novel monoclonal antibody



# Maintaining U.S. leadership with 2022 revenue growth continuing to outpace anti-VEGF category growth

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



## #1 anti-VEGF treatment for retinal diseases

- FY 2022 U.S. net product sales of \$6.26B (+8% YoY)\*
- Q4 2022 U.S. net product sales of \$1.50B (-3% YoY)\*
  - Negatively impacted by a short-term shift to off-label use of compounded Avastin
  - Temporary closing in Q4 2022 of fund that provides patient co-pay assistance
  - Most recent Q4 2022 market data suggests that shift to off-label Avastin is already beginning to reverse

~75% **branded** category share in December 2022, consistent with prior 2022 quarters†

Demographic trends expected to drive future category growth

5

\* Based on preliminary, unaudited results  
 † Symphony Health, as of December 23, 2022.

REGENERON

# Aflibercept 8 mg has potential to shift treatment paradigm; positions Regeneron's retinal franchise for prolonged leadership



**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**

**BLA submission completed in December 2022**

**Using priority review voucher to expedite FDA review**

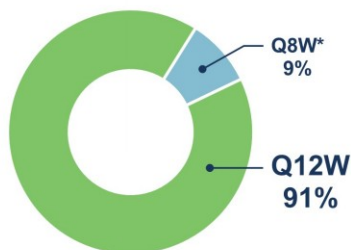
**Pre-launch planning underway with potential FDA approval by late August 2023**



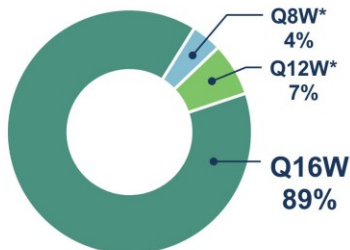
# 93% of aflibercept 8 mg DME patients maintained dosing intervals $\geq 12$ weeks through week 48

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

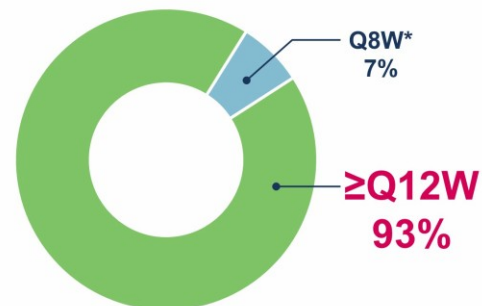
Aflibercept 8 mg Q12W  
(N=300<sup>^</sup>)



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>

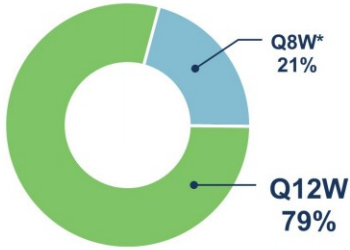
Aflibercept 2 mg (Q8W)	7.7
Aflibercept 8 mg (Q12W)	5.7
Aflibercept 8 mg (Q16W)	4.9

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

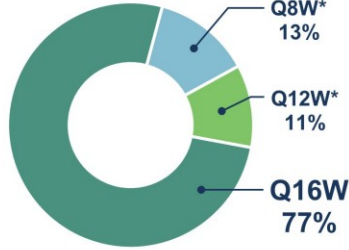


Aflibercept 8 mg 12- and 16-week dosing regimens achieved non-inferior vision gains compared to aflibercept 2 mg 8-week dosing regimen

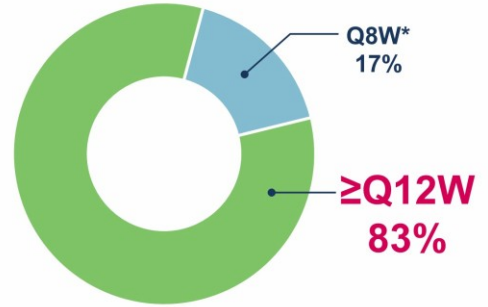
**Aflibercept 8 mg Q12W**  
(N=316<sup>^</sup>)



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



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



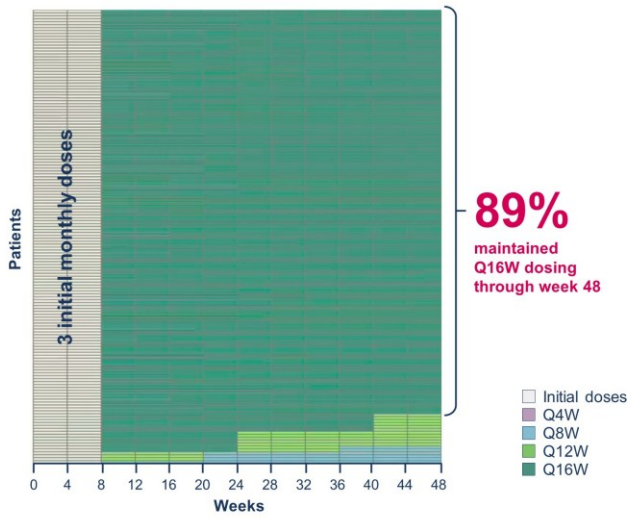
**Safety of aflibercept 8 mg comparable to that of aflibercept 2 mg**

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

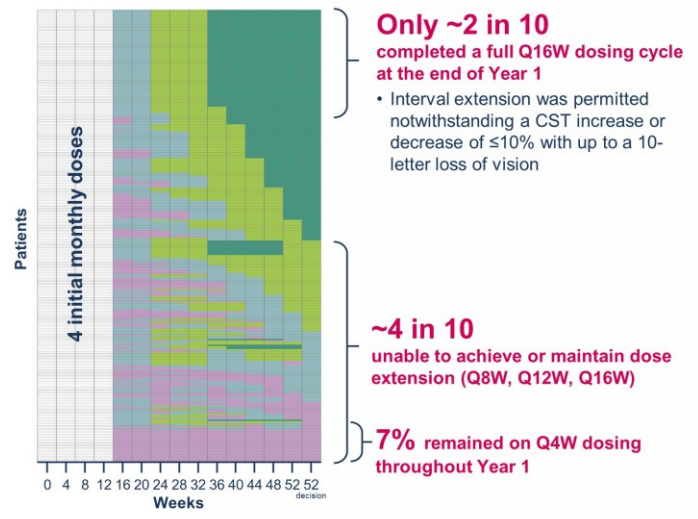
Aflibercept 2 mg (Q8W)	6.9
Aflibercept 8 mg (Q12W)	6.1
Aflibercept 8 mg (Q16W)	5.2

# Cross-trial comparison of aflibercept 8 mg and faricimab in DME patients

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



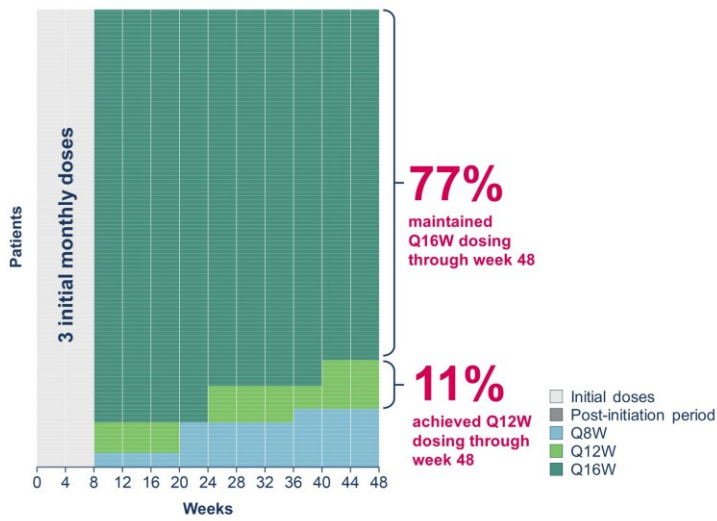
Dosing intervals of DME patients randomized to faricimab 6 mg PTI arm (N=286) in YOSEMITE study, through 52 weeks\*



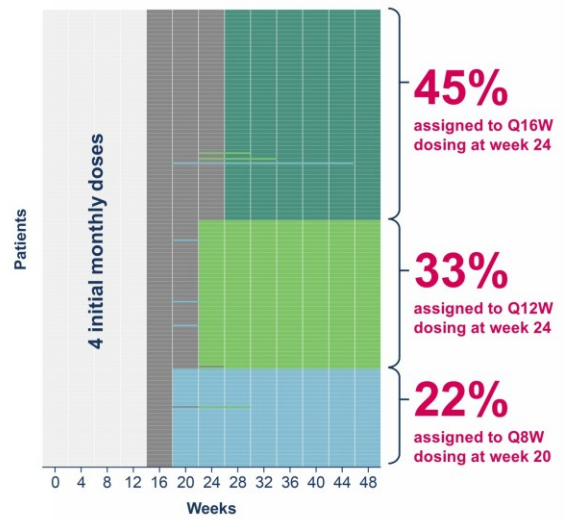
9 \*Wycoff C et al. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. *Lancet* 2022; 399: 741–55. Colors modified for consistency.

# Cross-trial comparison of aflibercept 8 mg and faricimab in wAMD patients

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

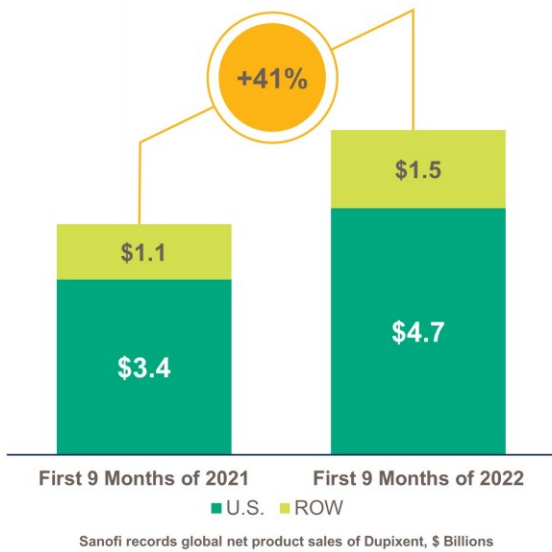


Dosing intervals of wAMD patients randomized to faricimab 6 mg in TENAYA and LUCERNE studies (n=665)\*  
 (Dose interval shortening was not permitted in Year 1 per studies' protocols)



# In first 9 months of 2022, Dupixent global net product sales grew 41% and exceeded \$6.2 billion

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



## 2022 regulatory progress across 5 diseases:

### Atopic Dermatitis

- ✓ Approved by FDA as **first biologic** medicine for AD patients aged **6 months to 5 years**; EU submission under review

### Asthma

- ✓ Approved by EC for patients aged 6 to 11 years

### Eosinophilic Esophagitis

- ✓ Approved by FDA as **first and only** treatment; recommended for EU approval by the CHMP

### Prurigo Nodularis

- ✓ Approved by FDA and EC as **first and only** treatment

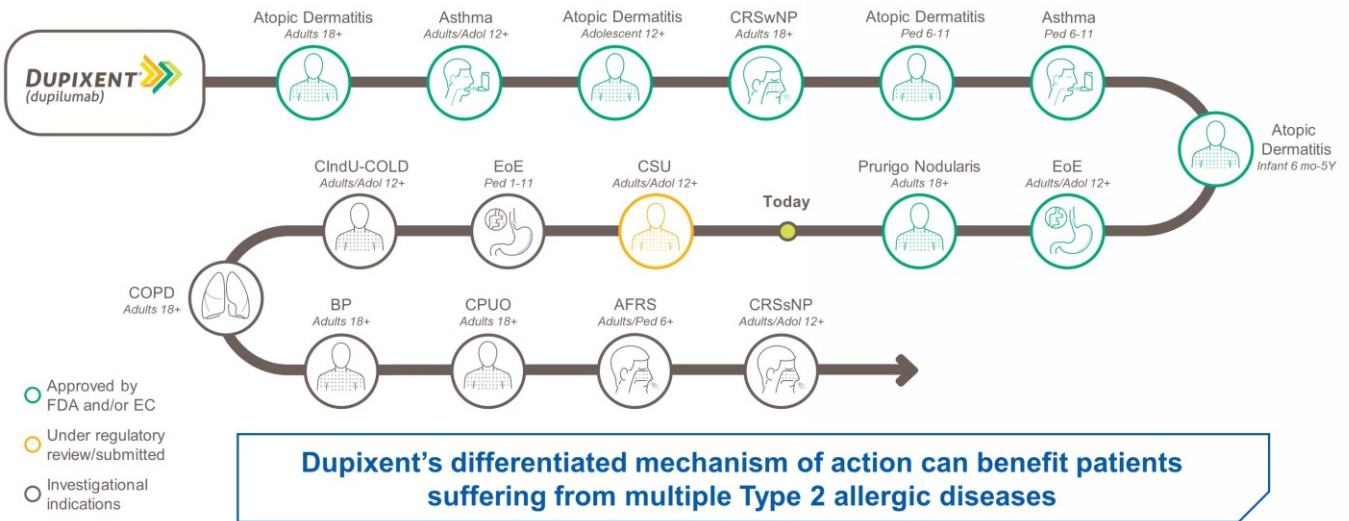
### Chronic Spontaneous Urticaria

- ✓ sBLA submitted to FDA for **biologic-naïve** patients

**2022 approvals expected to make meaningful revenue growth contributions starting in 2023**

# 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





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



- Potential to address **Type 2 COPD** in both **current and former smokers**
- Two Phase 3 studies ongoing:
  - ✓ BOREAS fully enrolled
  - ✓ NOTUS enrolling
- BOREAS **achieved pre-specified interim efficacy threshold**, triggering initiation of NOTUS study
- Key inclusion criteria: **Eosinophils  $\geq 300/\mu\text{l}$**
- BOREAS pivotal data expected in 1H 2023, NOTUS in 1H 2024

	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	—

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

## Itepekimab (anti IL-33)

- Potential to address **COPD** in **former smokers**
- Two Phase 3 studies ongoing:
  - ✓ AERIFY-1 enrolling
  - ✓ AERIFY-2 enrolling
- Demonstrated **42% reduction in exacerbations** vs. placebo in Phase 2 study of former smokers
- No inclusion criteria for eosinophil count
- Pivotal data from both AERIFY studies expected in 2024

# Meaningful advances in oncology in 2022

Tumor Type	Initial Indication	Data Disclosures	
		2H 2022	
Hematology	Lymphoma	Odronexamab	✓
	Multiple myeloma	Linvoseltamab	✓
Dermato-oncology	Neoadjuvant CSCC	Cemiplimab	✓
	First-line advanced melanoma	Fianlimab, Cemiplimab	✓
Other Solid Tumors	MET-altered advanced NSCLC	METxMET	✓
	Advanced NSCLC	Fianlimab, Cemiplimab	✓
	Ovarian cancer (2L+)	Ubamatamab	✓
	Metastatic castration-resistant prostate cancer	PSMAxCD28, Cemiplimab	✓

🔵 Indicates pivotal or potentially pivotal study ✓ indicates data readout



A FIRST-LINE TREATMENT OPTION IN  
**ADVANCED NSCLC**

FDA approved in November 2022  
for first-line use in combination  
with platinum-based  
chemotherapy

One of two PD-1/L1 antibodies  
FDA-approved for use in  
combination with chemotherapy  
irrespective of histology or  
PD-L1 expression levels

## Research & Pipeline Update



**George D. Yancopoulos, MD, PhD**  
Co-Founder, President &  
Chief Scientific Officer

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

1988

COMMITMENT TO MOUSE GENETICS



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

Regeneron is founded

2014

UNLOCKING POWER OF HUMAN GENETICS



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

## Biologicals: 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

# Meaningful advances across therapeutic areas in 2022

## Ophthalmology

### EYLEA (VEGF Trap)

- Received six months of **pediatric exclusivity**
- sBLA accepted for Priority Review in **Retinopathy of Prematurity**

### AFLIBERCEPT 8 MG (VEGF Trap)

- Positive pivotal data in **wet Age-related Macular Degeneration** and **Diabetic Macular Edema**
- BLA submitted, with priority review voucher

## Immunology

### DUPIXENT (anti-IL-4/IL-13)

- FDA and EC approval as **first and only** treatment indicated for **Prurigo Nodularis**
- FDA approval as **first treatment** indicated for **Eosinophilic Esophagitis**; recommended for EU approval by the CHMP
- FDA approval as **first biologic** for pediatric (6mos – 5yrs) **Atopic Dermatitis**
- EC approval in pediatric (6 – 11yrs) **Asthma**
- sBLA submitted for **Chronic Spontaneous Urticaria**

## Oncology

### LIBTAYO (anti-PD-1)

- FDA approval in combination with chemotherapy for **1L advanced NSCLC**
- EC and Japan approval in **2L Cervical Cancer**

### OTHER ONCOLOGY

- Positive data presented for **fianlimab + Libtayo** in advanced **Melanoma** and advanced **NSCLC**
- Initial data presented for **novel bispecifics in solid tumors** (METxMET, ubamatamab)
- First data for **PSMAxCD28 + Libtayo** showed encouraging anti-tumor activity in **mCRPC**
- Potentially pivotal Phase 2 data presented for **odronextamab** in **B-NHL** and **linvoseltamab** in **Myeloma**

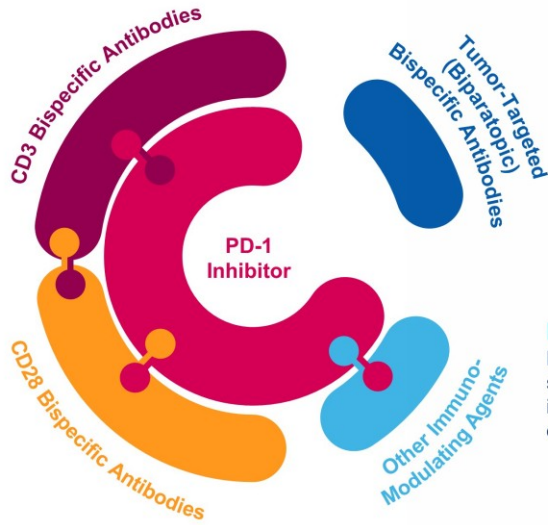
## Broader Pipeline

- sBLA accepted for priority review for Evkeeza in **pediatric HoFH**
- BLA submitted for **pozelimab** in **CHAPLE**
- Reported rapid, deep, and sustained TTR reduction after single dose of **NTLA-2001**
- Preliminary data reported for **siRNA for HSD17B13** in NASH showing robust target knockdown
- Discovered rare mutations in **CIDEB** gene that protect against liver disease; published in **NEJM**
- **Inmazeb** won prestigious “Best Biotechnology Product” **Prix Galien** award for treatment of **Ebola**

# 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

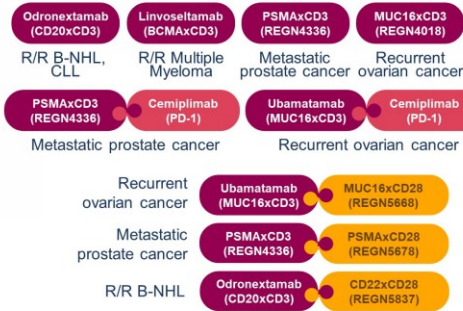


**Tumor-Targeted Biparatopics**  
Designed to disrupt cellular signaling and/or deliver a cytotoxic drug to tumor cells

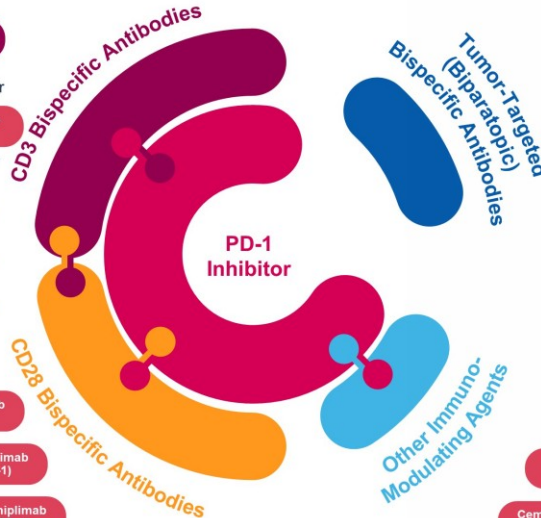
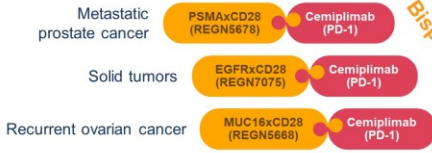
**Modulating immune response**  
Designed to overcome the tumor suppressive microenvironment (e.g., by inhibition of checkpoints, or targeted delivery of immuno-modulators)

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

## CD3 Bispecifics: "Signal 1"



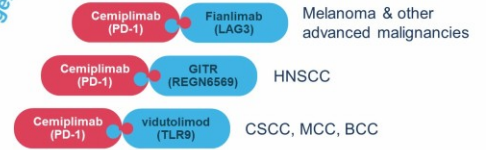
## CD28 Bispecifics: "Signal 2"



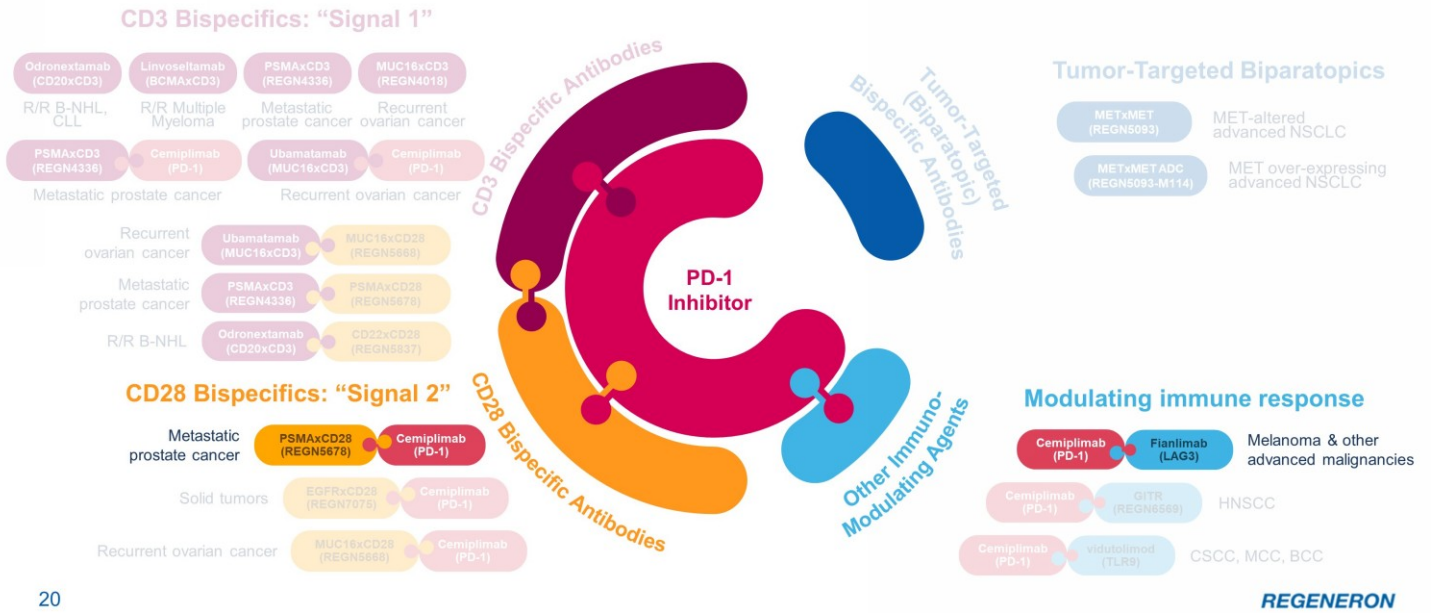
## Tumor-Targeted Biparatopics



## Modulating immune response



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

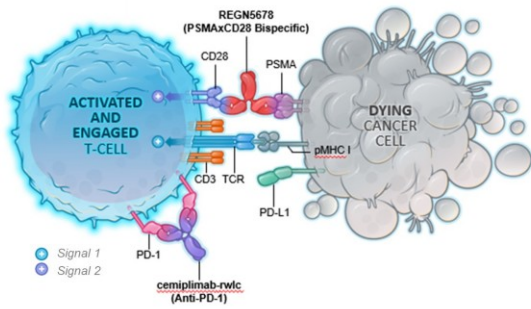




# Costim bispecifics may allow “cold” tumors to respond to immunotherapy

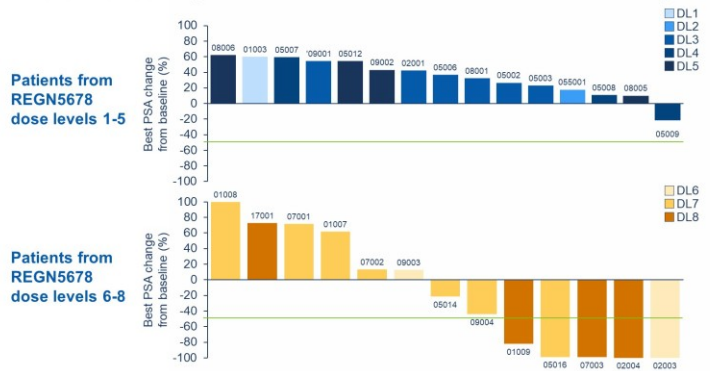
Initial PSMAxCD28 + Libtayo clinical data show responses in tumors resistant to anti-PD-1 monotherapy

## REGN5678 (PSMAxCD28) + Libtayo (PD-1 antibody) Mechanism of Action



- PSMA is highly expressed on prostate tumors
- The combination of REGN5678 and Libtayo is designed to further increase the antitumor activity of T cells that recognize cancer cells by augmenting costimulatory “Signal 2” and blocking cancer cells from using the PD-1 pathway to suppress T-cell activation

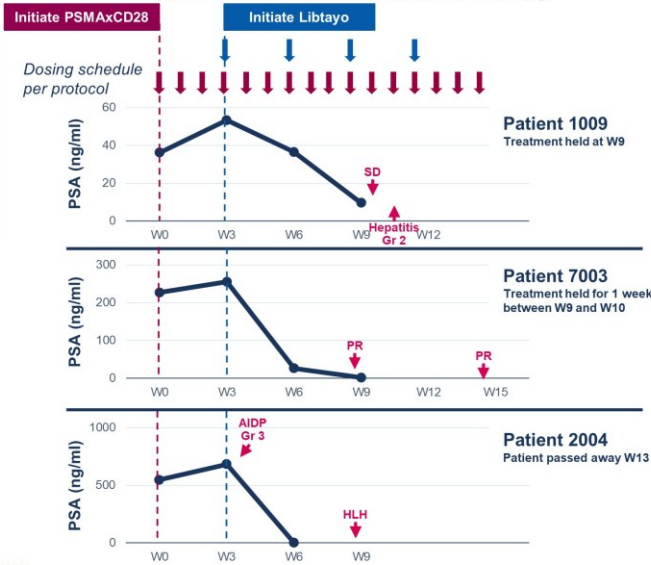
## REGN5678 + Libtayo: Initial Phase 1/2 data show dose-dependent anti-tumor activity for PSMAxCD28 when combined with Libtayo



- **REGN5678: Potential to overcome mCRPC resistance to PD-1 inhibition**
  - DL 1-5 (n=17): Minimal anti-tumor activity and no  $\geq$ G3 irAEs
  - DL 6-8 (n=16): Dose-dependent responses observed with correlated irAEs
- $\geq$ Grade 3 immune-related adverse events only occurred in certain patients with anti-tumor activity

# PSMAxCD28 + Libtayo demonstrated profound anti-tumor activity in tumor type historically resistant to anti-PD-1 monotherapy

At DL8, 3 of 4 patients showed profound PSA responses upon initiation combination therapy



## “Index patient” (DL6) experiencing ongoing response ~1.5 years after initial dosing\*

- Maintained PSA levels below the limit of detection<sup>^</sup>
- Disappearance of soft tissue disease
- Normalizing bone scan with negative PSMA PET scan<sup>^</sup>

## Key takeaways from initial PSMAxCD28 data

- Minimal PSMAxCD28 anti-tumor activity at lower doses, as predicted by preclinical models
- Anti-tumor activity amplified with Libtayo initiation
- ≥Gr 3 immune-related adverse events only occurred in certain patients with anti-tumor activity

\* Patient discontinued therapy after 7 weeks due to a Gr3 irAE of the skin that resolved with treatment  
<sup>^</sup> Per physician report

# Costimulatory bispecifics platform: status and next steps

Costimulatory bispecifics will be combined with both Libtayo and a growing list of CD3 bispecifics



## Prostate Cancer

### PSMAxCD28 (REGN5678) + Libtayo

- Share initial Phase 1 data
- Present Phase 1 data at a medical meeting in 1H23
- Select go-forward dose(s) in 2023

### PSMAxCD28 (REGN5678) + PSMAxCD3 (REGN4336)

- Phase 1 study planned
- Initial data in 2024+



## Ovarian Cancer

### MUC16xCD28 (REGN5668) + Ubamatamab (MUC16xCD3)

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

### MUC16xCD28 (REGN5668) + Libtayo

- Initiate Phase 1 (dose escalation)
- Initial data in 2023



## EGFR + Solid Tumors

### EGFRxCD28 (REGN7075) + Libtayo

- Phase 1 early dose escalation data presented at SITC 2022
- Present updated data in 2023



## Hematology

### CD22xCD28 (REGN5837) + Odronextamab (CD20xCD3)

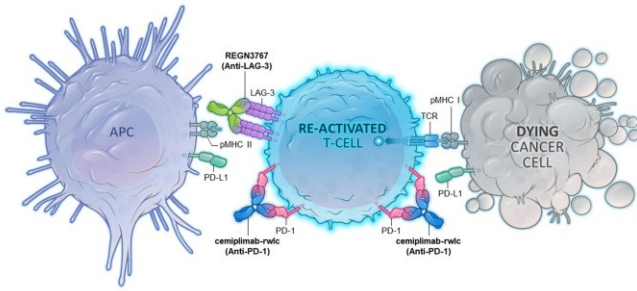
- Supportive preclinical data presented at SITC 2022\*
- Phase 1/2 study in DLBCL to initiate 1H 2023

### TAAxCD28 + Linvoseltamab (BCMAxCD3)

- Phase 1 study in 3L+ multiple myeloma to initiate in 2023

# Dual LAG-3 and PD-1 blockade may provide enhanced immune activation vs. anti-PD-1 alone

Robust clinical development program underway



- Lymphocyte-activation gene 3 (LAG-3) is an immune checkpoint receptor that delivers an inhibitory signal to activated T cells
- LAG-3 expression in melanoma biopsies has been shown to be associated with therapeutic resistance to anti-PD-1, suggesting that inhibiting LAG-3 in addition to PD-1 may enhance the anti-tumor effect

## Fianlimab (anti-LAG-3) + Libtayo (anti-PD-1)

### Melanoma

- Two metastatic melanoma cohorts showed a consistent and strong efficacy signal
- Phase 3 studies in 1L advanced melanoma and adjuvant melanoma ongoing
- Phase 3 study in perioperative melanoma initiating in 1H 2023

### NSCLC

- Promising early data presented from expansion cohort of the FIH study
- Phase 2/3 studies initiating in 1L advanced NSCLC (1H 2023) and perioperative NSCLC (2H 2023)

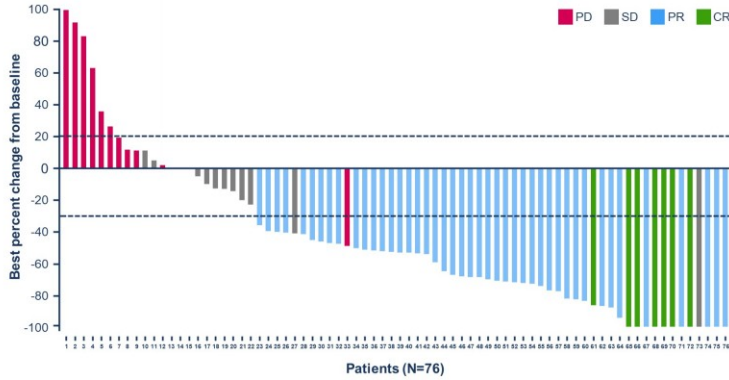
### Exploring additional indications

- Neoadjuvant breast cancer: I-SPY study of fianlimab+Libtayo+paclitaxel, data presented in 2H 2022
- Science-led development for potential additional indications

# Fianlimab + Libtayo: competitive efficacy in 1L metastatic melanoma

Data from second anti-PD-(L)1-naïve metastatic melanoma cohort confirmed strong efficacy signal observed in first cohort

**Tumor response waterfall plot by investigator assessment**  
(melanoma anti-PD-(L)1-naïve patients, cohorts 6 and 15)



% (n), unless otherwise stated	Cohort 6* (N=40)	Cohort 15* (N=40)	Cohort 6 + 15 (N=80)	RELATIVITY-047 (nivolumab & relatlimab-rmbw) (N=355)†
<b>ORR, % (95% CI)</b>	<b>62.5 (45.8, 77.3)</b>	<b>65.0 (48.3, 79.4)</b>	<b>63.8 (52.2, 74.2)</b>	<b>43 (38, 48)</b>
Complete response	15.0 (6)	2.5 (1)	8.8 (7)	16 (58)
Partial response	47.5 (19)	62.5 (25)	55.0 (44)	27 (95)
Stable disease	17.5 (7)	15.0 (6)	16.3 (13)	17 (61)
Progressive disease	15.0 (6)	15.0 (6)	15.0 (12)	30 (105)
NE/Unknown	5.0 (2)	5.0 (2)	5.0 (4)	8 (27)
DCR	80.0 (32)	80.0 (32)	80.0 (64)	62.8 (223)
<b>KM-estimated PFS, median (95% CI), mos</b>	<b>24 (4.2, NE)</b>	<b>NR (7.5, NE)</b>	<b>24 (9.9, NE)</b>	<b>10.2 (6.5, 14.8)</b>
DOR, median (95% CI), mos	NR (11.9, NE)	NR (6.3, NE)	NR (22.6, NE)	NR (29.6, NR)
OS, HR (95% CI)	-	-	-	0.80 (0.64, 1.01)

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

\*Anti-PD-1/PD-L1 naïve cohorts, Fianlimab 1600 mg + cemiplimab 350 mg IV every 3 weeks, for up to 51 weeks. Prior systemic therapies, including prior adjuvant therapies, excluded for cohort 15. Data cut-off date: 1 Jul 2022.

† Long, G. (March 2022). Abstract 360385: Relatlimab and nivolumab versus nivolumab in previously untreated metastatic or unresectable melanoma: Overall survival and response rates from RELATIVITY-047 [Presentation]. ASCO Plenary Series 2022.

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This slide contains investigational drug candidates that have not been approved by any regulatory authority. No direct head-to-head data available – caution advised when comparing results of different clinical studies.

# Poised to advance oncology pipeline in 2023 and beyond

Tumor Type	Initial Indication	Upcoming Expected Data Disclosure		
		2023	2024+	
Hematology	Lymphoma	Odronextamab		
	Multiple myeloma	Linvoseltamab		
Dermato-oncology	Neoadjuvant CSCC	Cemiplimab		
	Adjuvant CSCC		Cemiplimab	
	Advanced CSCC (2L)		Vidutolimod, Cemiplimab	
	Perioperative and adjuvant melanoma		Fianlimab, Cemiplimab	
	First-line advanced melanoma	Fianlimab, Cemiplimab	Fianlimab, Cemiplimab	
Other Solid Tumors	MET-altered advanced NSCLC		METxMETADC	
	Perioperative and advanced NSCLC		Fianlimab, Cemiplimab	
	Ovarian cancer (2L+)	Ubamatamab, Cemiplimab		
		MUC16xCD28, Cemiplimab		
	Metastatic castration-resistant prostate cancer	PSMAxCD28, Cemiplimab		Ubamatamab, MUC16xCD28
				PSMAxCD3, Cemiplimab
				PSMAxCD3, PSMAxCD28
SCCHN		GITR, Cemiplimab		
EGFR+ solid tumors	EGFRxCD28, Cemiplimab			

26 \* indicates pivotal or potentially pivotal study

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

REGENERON

# Next-gen COVID antibody binds outside variable RBD and has demonstrated high neutralization activity against all known variants and lineages

## Differentiated vs. prior antibody approaches

- Binding site outside of immunodominant, highly variable RBD and NTD regions, lowering 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 known SARS-CoV-2 variants and 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 <sup>‡</sup>	Bebtelovimab <sup>§</sup>	REGN14287
	D614G	✓✓✓	✓✓	✓✓✓	✓✓✓	✓✓✓
	BA.2	✓	✓	■	✓✓✓	✓✓✓
	BA.4/5	✓	✓	✓✓	✓✓✓	✓✓✓
Omicron	BA.4.6	✗	✗	✗	✓✓✓	✓✓✓
	BA.2.75	✗	✓	■	✓✓✓	✓✓✓
	BQ.1	✗	✓	✗	✗	✓✓✓
	BQ.1.1	✗	✗	✗	✗	✓✓✓
	XBB	✗	✓	✗	✗	✓✓✓

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

✓✓✓ High neutralizing activity (IC50<10<sup>-10</sup> M)
✓ Limited neutralizing activity (10<sup>-10</sup> M<IC50<10<sup>-9</sup> M)
✓ Low neutralizing activity (10<sup>-9</sup> M<IC50<10<sup>-8</sup> M)
✗ No neutralizing activity (IC50>10<sup>-8</sup> M)
■ Not evaluated for neutralizing activity

**Anticipate initiating REGN14287 clinical trial in 2023, pending regulatory discussions**

\* REGEN-COV (casirivimab (REGN10933) and imdevimab (REGN10987)) 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.

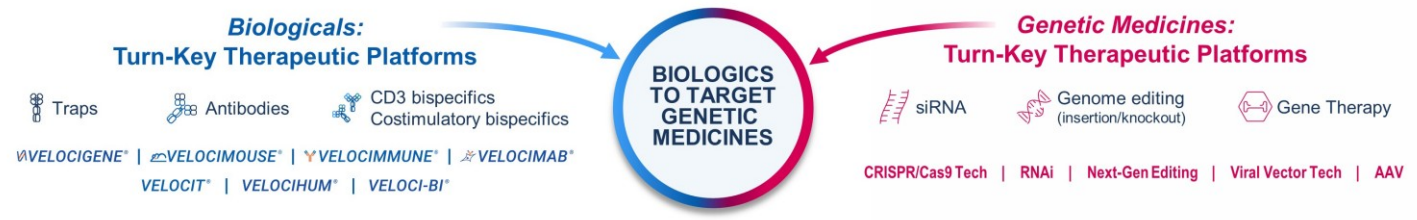
‡ Evusheld (AZD7442, combination of tixagevimab (AZD8895) and cilgavimab (AZD1061)) was discovered by Vanderbilt University Medical Center and licensed to AstraZeneca.

§ 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.

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

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





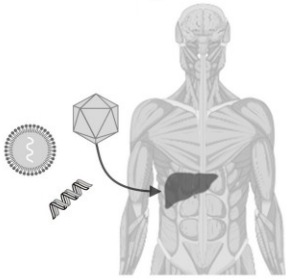
# Optimizing genetic medicines with antibody-targeted delivery

Improving delivery technologies to create the next generation of genetic medicines

Capitalizing on Regeneron's expertise in biologics by deploying antibody technologies that more efficiently deliver payloads to potentially address challenging genetic diseases

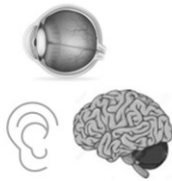
## Current options for genetics medicines delivery

Systemic delivery mostly targets the liver

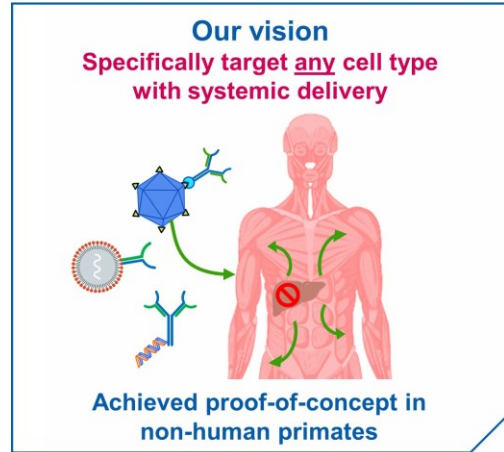


Liver "overloaded" when attempting to target other organs

Local delivery

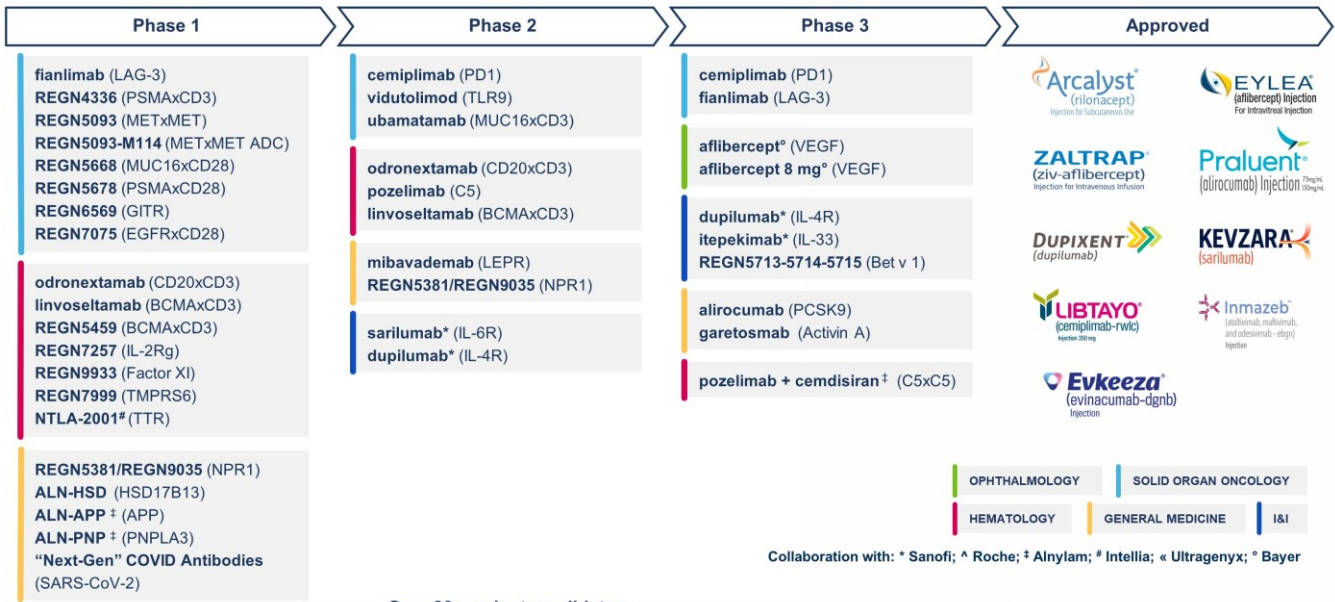


or



REGENERON

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



# Multiple potential FDA submissions: 2022-2024+

2022	2023	2024+
<b>EYLEA</b> ✓ Retinopathy of Prematurity	<b>DUPIXENT*</b> CINDU-Cold (2H)	<b>LIBTAYO</b> Adjuvant CSCC
<b>DUPIXENT*</b> ★ Eosinophilic Esophagitis	<b>DUPIXENT*</b> Pediatric EoE (mid)	<b>DUPIXENT*</b> Type 2 COPD
<b>DUPIXENT*</b> ★ Prurigo Nodularis	<b>PRALUENT</b> Pediatric HeFH (mid)	<b>DUPIXENT*</b> CRSsNP
<b>DUPIXENT*</b> ✓ Chronic Spontaneous Urticaria	<b>Odronextamab</b> B-Cell NHL (2H)	<b>DUPIXENT*</b> CPUO
<b>EVKEEZA</b> ✓ Pediatric HoFH	<b>Linvoseltamab</b> R/R Multiple Myeloma (2H)	<b>DUPIXENT*</b> Bullous Pemphigoid
<b>KEVZARA*</b> ✓ Polymyalgia Rheumatica		<b>Aflibercept 8 mg</b> RVO
<b>Aflibercept 8 mg</b> ✓ ⌚ Wet AMD/DME		
<b>Pozelimab</b> ✓ CHAPLE Syndrome		

★ Submission accepted and approved in 2022  
 ✓ Accepted submission  
 ✓ Submission complete, pending acceptance  
 ⌚ Using priority review voucher

**BLA**      **sBLA**

**REGENERON**

\* In collaboration with Sanofi. \* In collaboration with Alnylam.  
 An sBLA for an every 16-week dosing regimen for EYLEA (aflibercept 2 mg) in patients with diabetic retinopathy was withdrawn from FDA review in January 2023.

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

## 2023 key upcoming milestones

### Ophthalmology

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

### Dupixent

- sBLA acceptance for CSU (Q1)
- EC decision on pediatric AD (6mo – 5yr) and EoE (1H)
- Report data for Phase 3 studies in CINDU-Cold and Type 2 COPD (1H)
- Submit sBLA for pediatric EoE (mid) and CINDU-Cold (2H)
- FDA decision on CSU (Q4)

### Pozelimab (anti-C5 antibody)

- BLA acceptance (1H) and FDA decision (2H) on CHAPLE

### Solid Organ Oncology

- Initiate Phase 3 study for fianlimab+Libtayo in perioperative melanoma (1H) as well as Phase 2/3 studies in 1L advanced NSCLC (1H) and perioperative NSCLC (2H)
- Report additional data for PSMAxCD28+Libtayo
- 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)

### Odronextamab (CD20xCD3)

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

### Linvoseltamab (BCMAxCD3)

- Initiate confirmatory studies in MM, including in earlier lines (1H)
- Initiate Phase 1 study in combination with TAAxCD28 in MM (2H)
- Submit BLA in 3L+ MM (2H)

# 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



## Our mission:

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

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## Q&A



**Leonard S. Schleifer, MD, PhD**  
Co-Founder, President &  
Chief Executive Officer



**George D. Yancopoulos, MD, PhD**  
Co-Founder, President &  
Chief Scientific Officer



**Marion McCourt**  
EVP, Head of Commercial

# Allocated ~\$3.4 billion\* to business development and share repurchases in 2022

## 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
- Acquisition of Checkmate Pharmaceuticals and collaboration with CytomX to **expand immuno-oncology pipeline**

## Repurchase Shares



- Deploy excess cash to opportunistically repurchase shares
- Approximately **\$9.8 billion\*** in share repurchases since November 2019, including **~\$2.1 billion\*** in 2022

## Recast GAAP Income Statement including IPR&D for Q4 2021

	Q1 2021	Q2 2021	Q3 2021	Q4 2021	FY 2021	Q1 2022	Q2 2022	Q3 2022
<b>Revenues:</b>								
Net product sales	\$ 1,724.3	\$ 4,137.8	\$ 2,279.9	\$ 3,975.2	\$12,117.2	\$ 1,638.6	\$ 1,754.4	\$ 1,801.4
Collaboration revenue	754.4	954.7	1,073.9	890.3	3,673.3	1,232.5	1,043.6	1,050.6
Other revenue	50.0	46.0	99.0	86.2	281.2	94.0	59.2	84.2
	<u>2,528.7</u>	<u>5,138.5</u>	<u>3,452.8</u>	<u>4,951.7</u>	<u>16,071.7</u>	<u>2,965.1</u>	<u>2,857.2</u>	<u>2,936.2</u>
<b>Expenses:</b>								
Research and development	742.9	714.2	665.4	737.6 <sup>*</sup>	2,860.1 <sup>*</sup>	843.8 <sup>*</sup>	794.3 <sup>*</sup>	911.3
Acquired in-process research and development	—	—	—	48.0 <sup>*</sup>	48.0 <sup>*</sup>	28.1 <sup>^</sup>	197.0 <sup>†</sup>	—
Selling, general, and administrative	405.6	414.7	445.0	559.6	1,824.9	450.0	476.3	529.1
Cost of goods sold	183.2	539.4	238.8	811.7	1,773.1	207.3	149.2	141.3
Cost of collaboration and contract manufacturing	124.8	154.3	214.4	170.9	664.4	197.6	147.9	176.5
Other operating (income) expense, net	(40.5)	(31.3)	42.0	(15.8)	(45.6)	(20.2)	(17.4)	(45.7)
	<u>1,416.0</u>	<u>1,791.3</u>	<u>1,605.6</u>	<u>2,312.0</u>	<u>7,124.9</u>	<u>1,706.6</u>	<u>1,747.3</u>	<u>1,712.5</u>
Income from operations	1,112.7	3,347.2	1,847.2	2,639.7	8,946.8	1,258.5	1,109.9	1,223.7
<b>Other income (expense):</b>								
Other income (expense), net	154.9	420.0	(16.4)	(122.2)	436.3	(183.8)	(133.6)	301.4
Interest expense	(14.6)	(14.4)	(14.2)	(14.1)	(57.3)	(13.6)	(13.1)	(15.3)
	<u>140.3</u>	<u>405.6</u>	<u>(30.6)</u>	<u>(136.3)</u>	<u>379.0</u>	<u>(197.4)</u>	<u>(146.7)</u>	<u>286.1</u>
Income before income taxes	1,253.0	3,752.8	1,816.6	2,503.4	9,325.8	1,061.1	963.2	1,509.8
Income tax expense	137.8	653.9	184.4	274.4	1,250.5	87.6	111.1	194.1
Net income	<u>\$ 1,115.2</u>	<u>\$ 3,098.9</u>	<u>\$ 1,632.2</u>	<u>\$ 2,229.0</u>	<u>\$ 8,075.3</u>	<u>\$ 973.5</u>	<u>\$ 852.1</u>	<u>\$ 1,315.7</u>
Net income per share - basic	\$ 10.58	\$ 29.51	\$ 15.37	\$ 20.99	\$ 76.40	\$ 9.12	\$ 7.90	\$ 12.31
Net income per share - diluted	\$ 10.09	\$ 27.97	\$ 14.33	\$ 19.69	\$ 71.97	\$ 8.61	\$ 7.47	\$ 11.66
Weighted average shares outstanding - basic	105.4	105.0	106.2	106.2	105.7	106.8	107.9	106.9
Weighted average shares outstanding - diluted	110.5	110.8	113.9	113.2	112.2	113.1	114.0	112.8

In Q4 2022, Regeneron expects to record an acquired in-process research and development (IPR&D) charge of approximately \$30 million<sup>‡</sup> related to an up-front payment in connection with the Company's collaboration with CytomX Therapeutics, Inc. which is expected to negatively impact each GAAP and non-GAAP diluted earnings per share by approximately \$0.21<sup>‡</sup>

<sup>\*</sup> Beginning with the first quarter of 2022, the Company added a new line item, Acquired in-process research and development, to its Condensed Consolidated Statements of Operations. This line item includes in-process research and development acquired in connection with asset acquisitions as well as up-front/opt-in payments related to license and collaboration agreements. Amounts recorded to Acquired in-process research and development would have historically been recorded to Research and development expenses.

<sup>^</sup> IPR&D charge primarily related to \$34 million aggregate up-front payments in connection with our collaboration agreement with Nykode Therapeutics.

<sup>†</sup> IPR&D charge primarily related to a \$20 million opt-in payment in connection with a product candidate under our collaboration agreement with Adicet Bio, Inc.

<sup>‡</sup> Based on preliminary, unaudited results.



# Abbreviations and Definitions

Abbreviation	Definition	Abbreviation	Definition	Abbreviation	Definition
1L	Front line	FIH	First in human	PSA	Prostate-specific antigen
2L+	Second line and beyond	FL	Follicular lymphoma	PSMA	Prostate-specific membrane antigen
3L+	Third line and beyond	FOP	Fibrodysplasia ossificans progressive	PTI	Personalized treatment interval
AD	Atopic dermatitis	GAAP	Generally accepted accounting principles	RBD	Receptor binding domain
AFRS	Allergic fungal rhinosinusitis	GITR	Glucocorticoid-induced TNFR-related protein	ROP	Retinopathy of prematurity
BCC	Basal cell carcinoma	HeFH	Heterozygous familial hypercholesterolemia	ROW	Rest of world
BCMA	B-cell maturation antigen	HN5CC	Head and neck squamous cell carcinoma	RVO	Retinal vein occlusion
BLA	Biologics license application	HoFH	Homozygous familial hypercholesterolemia	sBLA	Supplemental biologics license application
B-NHL	B-cell non-Hodgkin's lymphoma	HR	Hazard ratio	SCCHN	Squamous cell carcinoma of the head and neck
BP	Bullous pemphigoid	IC50	Half maximal inhibitory concentration	SD	Stable disease
CHAPLE	CD55-deficient protein-losing enteropathy	irAE	Immune-related adverse event	TAA	Tumor-associated antigen
CHMP	Committee for medicinal products for human use	LAG-3	Lymphocyte-activation gene 3	TCR	T-cell receptor
CI	Confidence interval	M	Molar	TTR	Transthyretin protein
CIndU-COLD	Chronic inducible urticaria – cold	mCRPC	Metastatic castration-resistant prostate cancer	VEGF	Vascular endothelial growth factor
CLL	Chronic lymphocytic leukemia	MCC	Merkel cell carcinoma	wAMD	Wet age-related macular degeneration
COPD	Chronic obstructive pulmonary disease	MM	Multiple myeloma		
CPUO	Chronic pruritis of unknown origin	MUC16	Mucin 16		
CR	Complete response	NASH	Non-alcoholic steatohepatitis		
CRL	Complete response letter	NE	Not estimable		
CRSsNP	Chronic sinusitis without nasal polyposis	NEJM	New England Journal of Medicine		
CRSwNP	Chronic sinusitis with nasal polyposis	NR	Not reached		
CSCC	Cutaneous squamous cell carcinoma	NSCLC	Non-small cell lung cancer		
CSU	Chronic spontaneous urticaria	NTD	N-terminal domain		
DCR	Duration of complete response	OS	Overall survival		
DL	Dose level	PD-1/PD-(L)1	Programmed cell death protein/(ligand) 1		
DLBCL	Diffuse large B-cell lymphoma	PET scan	Positron emission tomography scan		
DME	Diabetic macular edema	PFS	Progression-free survival		
DOR	Duration of response	pMHC	Peptide-major histocompatibility complex class I		
EC	European Commission	PMR	Polymyalgia rheumatica		
EGFR	Epidermal growth factor receptor	PN	Prurigo nodularis		
EoE	Eosinophilic esophagitis	PR	Partial response		