# **Regeneron Corporate Presentation**

November 2022

# **REGENERON**<sup>®</sup>

This non-promotional presentation is intended for the investor audience and contains investigational data as well as forward-looking statements; actual results may vary materially

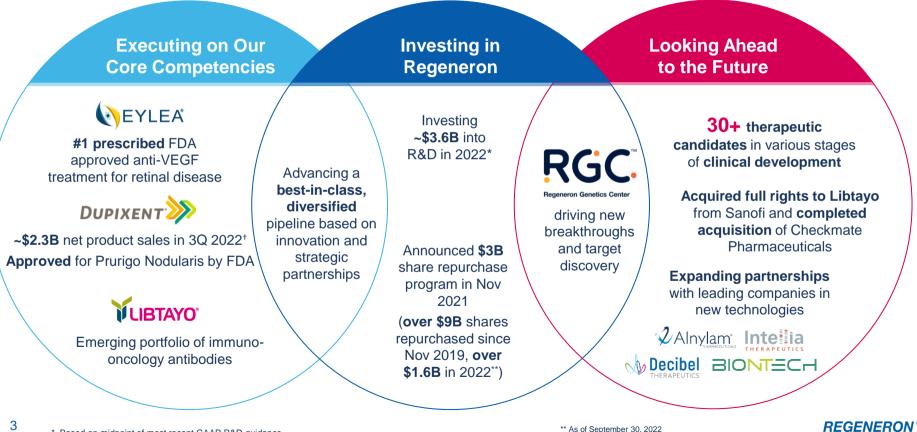
## Note regarding forward-looking statements & non-GAAP financial measures

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® (aflibercept) Injection, Dupixent® (dupilumab), Libtavo® (cemiplimab), Praluent® (alirocumab), Keyzara® (sarilumab), Evkeeza® (evinacumab), Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebon), REGEN-COV® (casirivimab, and imdevimab), affibercept 8mg, pozelimab, odronextamab, itepekimab, fianlimab, garetosmab, linvoseltamab, REGN5713-5714-5715, Regeneron's and its collaborators' other oncology programs (including its costimulatory bispecific portfolio), Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of 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; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates: competing drugs and product candidates that may be superior to, or more cost effective than. Regeneron's Products and Regeneron's Product Candidates: uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regenero Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's Product Candidates: the availability and extent of reimbursement of Regeneron's Products from third-party pavors, including private pavor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors; 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 sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA. Praluent, and REGEN-COV), 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; and 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. 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 forwardlooking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise,

This presentation uses total revenues excluding REGEN-COV and non-GAAP net income per share, or non-GAAP EPS, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). These and other non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP"). These and other non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP"). These and other non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP". On-GAAP adjustments also include the income period based on factors that are not within the Company's control, such as the Company's stock price on the dates share-based grants are issued. Management uses 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, 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 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. A reconciliation of the non-GAAP financial measures used in this presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of the non-GAAP financial measures used in this presented to accordance with GAAP.

#### **REGENERON**°

# REGENERON



\* Based on midpoint of most recent GAAP R&D guidance † Sanofi records global net product sales of Dupixent

~\$1.2 billion remaining in authorization as of September 30, 2022

# **Delivering Results Across the Organization**



### Notable R&D Pipeline Advancements

Positive pivotal data for 8mg aflibercept for wAMD an DME presented at AAO

Granted pediatric exclusivity, extending regulatory exclusivity through May 17, 2024

sBLA accepted for ROP with priority review (PDUFA Feb 11, 2023)

sBLA approved for PN, first and only medicine indicated for this disease

Positive Phase 3 data for pediatric patients (6mo - 5yr) AD published in The Lancet

Encouraging Phase 1 data at ESMO 2022 for fianlimab+Libtavo, MUC16xCD3, METxMET

Positive Phase 2 data at ESMO 2022 for Libtayo in neoadjuvant CSCC and published in NEJM

Initial Phase 1 data for NTLA-2001\* in ATTR-CM presented by Intellia

Disclosed initial Phase 1 data for ALN-HSD^



See reconciliation of non-GAAP measure on slide 26 Prurigo Nodularis: AD - Atopic Dermatitis: EoE - Eosinophilic Esophagitis: ROP - retinopathy of prematurity; sBLA - supplemental biologics license application; ATTR-CM - transthyretin amyloidosis with cardiomyopathy: CSCC - cutaneous squamous cell carcinoma

\*In collaboration with Intellia An collaboration with Alnvlam

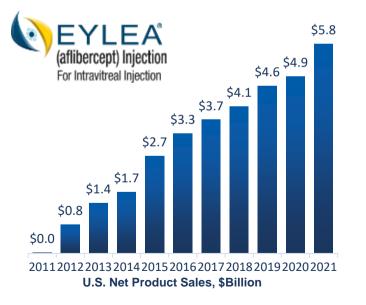
EYLEA

This slide contains investigational products not yet approved by regulatory authorities

# **EYLEA®: 10+ Years of Patient Impact**

Extending leadership position based on efficacy and safety that has transformed millions of lives; **55+ million doses** administered worldwide since launch

Developed using our proprietary Trap technology, development on aflibercept began in 2004 and became Regeneron's second FDA-approved treatment in November 2011 as **EYLEA** 



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

3Q22 U.S. net product sales of \$1.63B (+11% YoY, +12% YTD)

Well-established leadership based on safety/efficacy experience

- ~75% share of U.S. branded category; ~50% share of total category
- Breadth of indications, flexible dosing regimens, with established real-world safety

Demographic trends expected to drive future opportunity

- Increasing prevalence of diabetes which can lead to diabetic eye disease
- Aging population with increasing diagnosis of wAMD

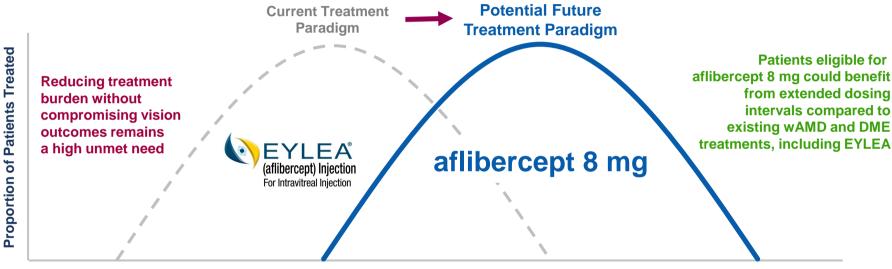
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#### **REGENERON**°

# Aflibercept 8 mg has the Potential to Shift Treatment Paradigm

**Illustrative** 

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### **Shorter Dosing Interval**

**Longer Dosing Interval** 

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By extending dosing intervals, aflibercept 8 mg has the potential to reduce treatment burden for eligible patients

wAMD = Wet age-related macular degeneration; DME = Diabetic macular edema

Aflibercept 8 mg is an investigational product and has not been approved for use by any regulatory authority.

# Retinal Franchise Poised for Sustainable Long-Term Growth and Value Creation





EYLEA is the #1 prescribed FDA approved anti-VEGF treatment for retinal disease

~50% of U.S. anti-VEGF category share; ~75% of U.S. branded share

U.S. demographic trends support mid-tohigh-single-digit category growth Plan to submit new Biologics License Application for wAMD and DME indications in late 2022

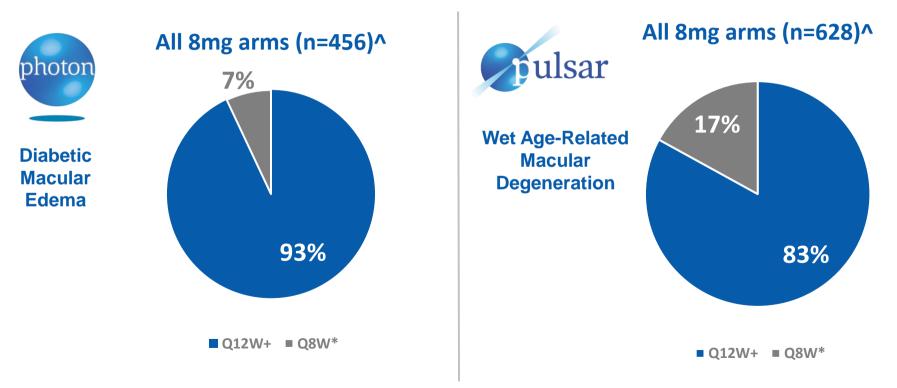
Using a Priority Review Voucher to expedite review process

Launch planning underway for potential 2H23 launch

7 Aflibercept 8 mg is an investigational product and has not been approved for use by any regulatory authority. VEGF = Vascular endothelial growth factor; wAMD = Wet age-related macular degeneration; DME = Diabetic macular edema

#### REGENERON

# At 48 Weeks Vast Majority of Aflibercept 8 mg Patients Maintained Q12W+ Dosing Intervals

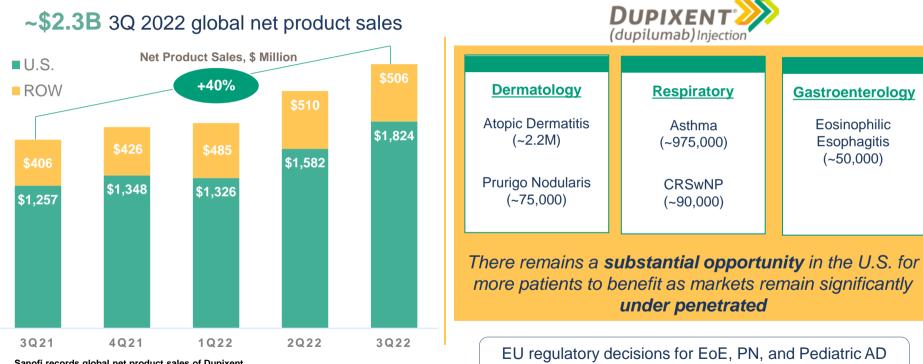


8 \*Patients shortened based on DRM assessments at some point through Week 48 ^Patients completing Week 48

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Aflibercept 8 mg is an investigational product and has not been approved for use by any regulatory authority.

# Dupixent<sup>®</sup>: Strong Performance Across All Approved Indications With Significant Opportunity For Sustained Growth



Sanofi records global net product sales of Dupixent

Figures represent U.S. biologic-eligible target population; Source - Regeneron Internal Epidemiology Data CRSwNP - Chronic Rhinosinusitis with Nasal Polyposis; EoE - Eosinophilic Esophagitis

(6mo-5yr) expected in 1H23



# Dupixent<sup>®</sup> & Itepekimab (anti IL-33) COPD Phase 3s Underway

Two-pronged approach against uncontrolled, moderate-to-severe COPD

### Dupixent potential to address Type 2 COPD

Achieved prespecified efficacy milestone in interim analysis of first Phase 3 study which triggered second Phase 3 study

Eosinophils ≥300/µI

Both former and current smokers

Two Phase 3 trials ongoing – BOREAS fully enrolled, NOTUS enrolling

Pivotal data from BOREAS expected 2023

### Itepekimab potential also for non-Type 2 COPD

In a Phase 2 study\*, itepekimab demonstrated 42% exacerbation reduction vs. placebo in former smokers

No eosinophil restriction

Focus on former smokers

Two Phase 3 trials ongoing

Pivotal data expected 2024

10 Dupixent and Itepekimab are developed in collaboration with Sanofi; COPD – Chronic Obstructive Pulmonary Disease \* Rabe et al. Lancet Respir Med. 2021

^ US, EU and Japan epidemiology, patient populations exclude never smokers (Regeneron Internal Epidemiology Data)

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

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



This slide contains investigational products not yet approved by regulatory authorities

# **Continued Progress & Developments Across Oncology Pipeline**

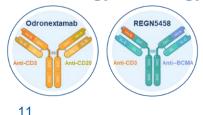
Regeneron positioned to enhance and extend treatment benefit across many cancer settings



### **Solid tumors**



### Hematology-Oncology



#### **Dermato-Oncology**

- First-in-class leading approved systemic treatment for advanced CSCC; approved in 2L+ advanced BCC
- · Phase 2 neoadjuvant CSCC data presented at ESMO, published in NEJM
- BioNTech FixVax combination in post-PD-1 melanoma Phase 2 underway

#### Non-Small Cell Lung Cancer

- Approved as monotherapy in 1L advanced NSCLC with ≥50% PD-L1
- 1L NSCLC in combination with chemotherapy under FDA review
- Fianlimab (LAG-3) Phase 3 study in 1L metastatic melanoma with Libtayo ongoing, Phase 1 data presented at ESMO
- REGN5678 (PSMAxCD28) Dose escalation with Libtayo in mCRPC ongoing; reported initial first-in-human data
- Ubamatamab (MUC16xCD3) Dose escalation with Libtayo in ovarian cancer ongoing; FIH monotherapy data
  presented at ESMO
- REGN5668 (MUC16xCD28) Dose escalation in combination with Libtayo or MUC16xCD3 in ovarian cancer ongoing
- REGN4336 (PSMAxCD3) Dose escalation in mCRPC ongoing
- REGN7075 (EGFRxCD28) Dose escalation with Libtayo in advanced cancers ongoing
- REGN5093 (METXMET) Dose expansion in MET-altered NSCLC ongoing; FIH data presented at ESMO
- REGN5093-M114 (METXMET ADC) Dose escalation in MET-overexpressing NSCLC ongoing
- Odronextamab (CD20xCD3) Granted Fast Track designation in R/R FL and DLBCL; potentially pivotal Phase 2 ongoing
- Linvoseltamab (BCMAxCD3) Potentially pivotal Phase 2 in multiple myeloma fully enrolled
- Both assets to enter combination studies with corresponding costimulatory (CD28) bispecifics

CSCC – Cutaneous Squamous Cell Carcinoma BCC – Basal Cell Carcinoma mCRPC – metastatic Castration-Resistant Prostate cancer ESMO – European Society for Medical Oncology NSCLC – Non-Small Cell Lung Cancer

R/R – Relapsed/Refractory FL – Follicular Lymphoma DLBCL – Diffuse B-Cell Lymphoma NEJM – New England Journal of Medicine

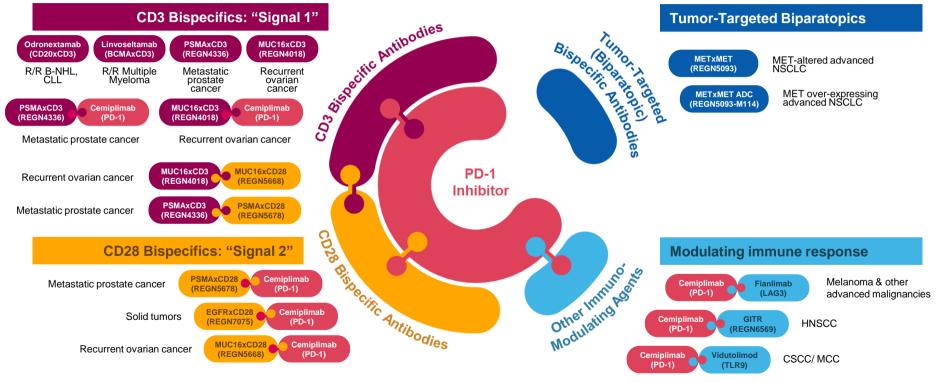


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# Unique Flexibility of Internally-Developed Pipeline Drives Potential for Novel and Differentiated Combinations

#### So aspecific Antibodies CD3 Bispecifics: "Signal 1" **Tumor-Targeted Biparatopics** Designed to bridge tumor-associated Designed to disrupt cellular signaling antigens on cancer cells with CD3and/or deliver a cytotoxic drug to expressing T cells, resulting in potential tumor cells local T-cell activation and cvtotoxicity libodies PD-1 Inhibitor Coze Bispecific Antibodies **CD28 Bispecifics: "Signal 2"** Modulating immune response Other Innuno ... Modulating Agents Designed to overcome the tumor Designed to increase the activity suppressive microenvironment of T cells that recognize tumor antigens by augmenting costimulatory signals

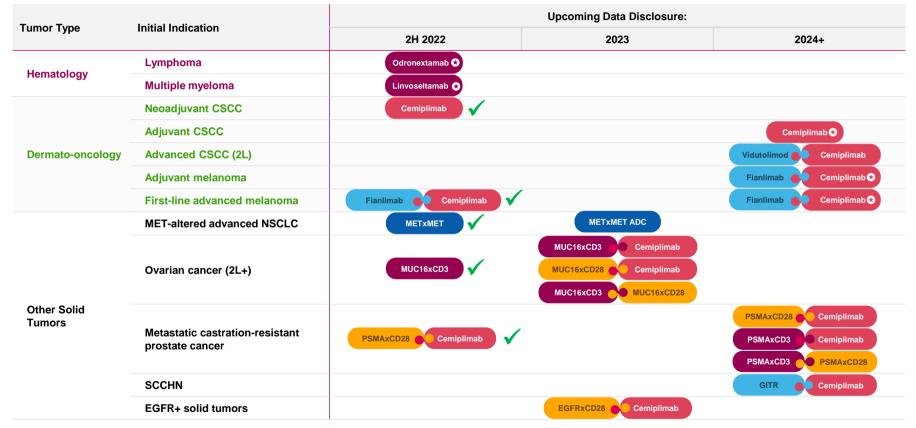
# Unique Flexibility of Internally-Developed Pipeline Drives Potential for Novel and Differentiated Combinations



EGFR = Epidermal growth factor receptor; MUC16 = Mucin 16; PSMA = Prostate-specific membrane antigen; R/R = Relapse/refractory; B-NHL = B-cell Non-Hodgkin lymphoma; BCMA = B-cell maturation antigen; NSCLC = Non-small cell 13 Jung cancer; SCCHN = Squamous cell carcinoma of the head and neck; CSCC = Cutaneous squamous cell carcinoma; ADC = Antibody drug conjugate; LAG-3 = Lymphocyte-activation gene 3; GITR = Glucocorticoid-induced TNFR-related protein; MCC = Merkel cell carcinoma

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

# **Key Data Read-Outs Expected Beginning in 2H 2022**



14 S indicates potentially pivotal study ✓ indicates data readout

CSCC = Cutaneous squamous cell carcinoma; NSCLC = Non-small cell lung cancer; 2L+ = Second line and beyond; SCCHN = Squamous cell carcinoma of the head and neck; EGFR = Epidermal growth factor receptor; MUC16 = Mucin 16; PSMA = Prostate-specific membrane antigen; BCMA = B-cell maturation antigen

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

# **Bispecifics for Heme-Onc Malignancies: Upcoming New Data at ASH 2022**

Combinations with costimulatory bispecifics and other agents entering clinic soon



### Odronextamab (CD20xCD3)\*

**Summary** – A **single, off-the-shelf bispecific**, effective in both indolent and aggressive lymphomas, including patients who failed CAR-Ts

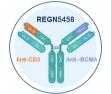
- Upcoming ASH 2022 abstract data:
  - R/R FL: ORR=81% CR=75% (N=85)
  - R/R DLBCL: ORR=53% CR=37% (N=90)
- Durable responses (median DOR was 18.2 months in FL)
- Improved safety profile observed with revised step-up dosing

#### **Progress to Date:**

- Received Fast Track designation in FL and DLBCL
- Pivotal Phase 2 data accepted for oral presentations at ASH 2022

#### **Upcoming Milestones:**

- U.S. regulatory submission in FL and DLBCL (2H23)
- Initiate dosing with subcutaneous formulation
- Initiate OLYMPIA Phase 3 program and additional combinations, including TAAxCD28 costim



### Linvoseltamab (BCMAxCD3)\*

Efficacy – Preliminary early, deep, and durable responses; ASH 2022 abstract:

- 75% ORR at higher doses (≥200mg, N=24) vs. 41% at lower doses (<200mg, N=49)</li>
- Responses deepened over time with 37.5% of patients with ≥CR
- Median DOR not reached

Safety – Generally acceptable safety and tolerability observed to date:

- 1 Grade 3 CRS, no Gr4+ CRS, no discontinuations due to CRS
- CRS reported in 48% patients, vast majority of events were Gr1
- 98% patients experienced some grade of TEAEs; 78% were Gr3+; only 3% of patients discontinued treatment due to TRAEs

#### **Progress to Date:**

- Potentially pivotal Phase 1/2 data accepted at ASH 2022
- Potentially pivotal Phase 2 study fully enrolled

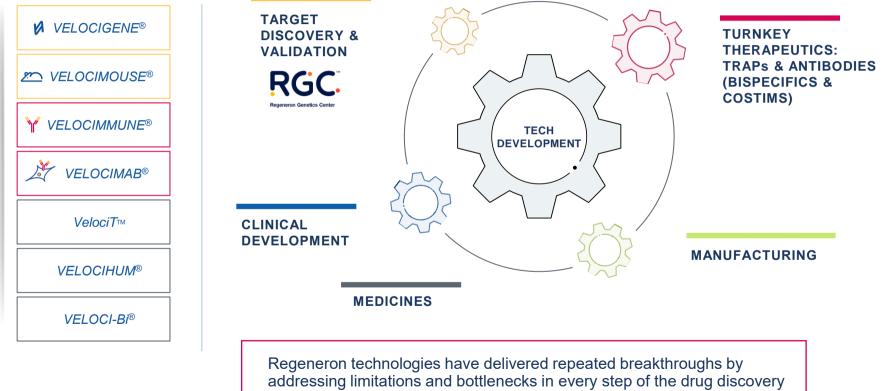
#### **Upcoming Milestones:**

- Potential U.S. regulatory submission R/R MM (2023)
- Initiate additional combinations with TAAxCD28 costim



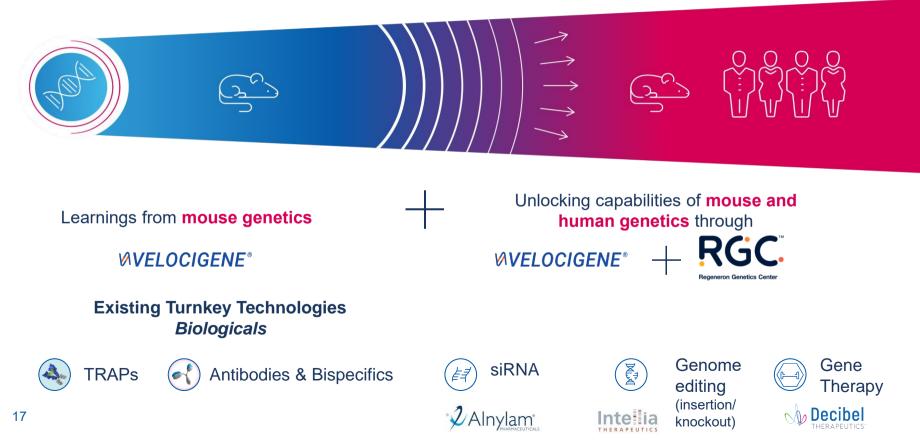
<sup>15</sup> DLBCL, Diffuse Large B Cell Lymphoma; FL, Follicular Lymphoma; ORR, objective response rate; VGPR, very good partial response; CR, complete response; DOR, duration of response; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; SOC, standard of care

# **Regeneron Technologies Power Our Pipeline: TRAPs, Antibodies and Bispecifics**



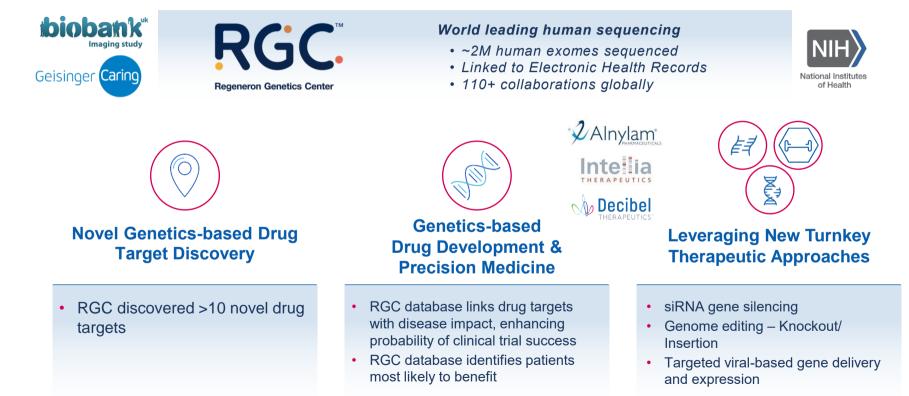
REGENERON®

# Synergistic Collaborations Supercharge Regeneron's Future Turnkey Genetics Therapeutics Platforms



# **Regeneron Genetics Medicines**

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



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

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

#### Several near-term opportunities emerging from Regeneron Genetics Medicines:

- Reported landmark TTR genome editing data in 2021; latest data update by Intellia in Sep 2022
- C5 combo program Phase 3 initiations (Myasthenia Gravis and PNH)
- HSD17B13 siRNA initial data from NASH patients reported in Sep 2022
- APP siRNA Ph1 initiated for early onset Alzheimer's
- DB-OTO gene therapy (hearing loss) Ph1/2 start • in 2023

# REGENERON GENETICS MEDICINES

### **Building the Pipeline for the Future**

### **Pre-IND**

### **Clinical Development**

**FACTOR 8 GENE INSERTION<sup>2</sup>** CRISPR/Cas9 + AAV **Transgene Insertion** Hemophilia A

### PNPLA3<sup>1</sup>

#### **PNPLA3 siRNA**

 Nonalcoholic Steatohepatitis

**GAA GENE INSERTION<sup>2</sup>** CRISPR/Cas9 + AAV **Transgene Insertion** 

ADDITIONAL PROGRAMS

30+ Programs in Research and Candidate Selection

#### Pompe Disease

#### DB-OTO3 OTOF AAV Dual Vector Gene Therapy

#### OTOF Related Hearing Loss

**FACTOR 9 GENE INSERTION<sup>2</sup>** CRISPR/Cas9 + AAV **Transgene Insertion** 

Hemophilia B

#### Myasthenia Gravis Paroxysmal Nocturnal Hemoalobinuria

C5 Antibody + C5 siRNA

#### **CEMDISIRAN<sup>1</sup>** C5 siRNA

POZELIMAB +

**CEMDISIRAN<sup>1</sup>** 

 Immunoalobulin A Nephropathy

### AI N-APP1

#### **APP siRNA**

 Cerebral Amyloid Angiopathy, Alzheimer's Disease

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

AI N-HSD<sup>1</sup>

HSD17B13 siRNA

Steatohepatitis

Nonalcoholic

NTLA-2001<sup>2</sup>

(ATTR)

CRISPR/Cas9

Transthyretin

Amyloidosis

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

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# **Regeneron-Discovered, Approved and Investigational Medicines Across a Wide and Diverse Set of Diseases**

PHASE 1	PHASE 2	PHASE 3	APPROVED OR AUTHORIZED
fianlimab (LAG-3) REGN4336 (PSMAxCD3) REGN5093 (METxMET)	cemiplimab (PD1) vidutolimod (TLR9) ubamatamab (MUC16xCD3)	cemiplimab (PD1) fianlimab (LAG-3)	Arcalyst (rilonacept) EYLEA (aflibercept) Injection
REGN5093-M114 (METxMET ADC)           REGN5668 (MUC16xCD28)           REGN5678 (PSMAxCD28)           REGN6569 (GITR)           REGN7075 (EGFRxCD28)	odronextamab (CD20xCD3) cemdisiran <sup>‡</sup> (C5) pozelimab (C5) linvoseltamab (BCMAxCD3)	pozelimab + cemdisiran ‡ (C5xC5) alirocumab (PCSK9) aflibercept° (VEGF) aflibercept 8mg° (VEGF) garetosmab (Activin A)	ZALTRAP* (ziv-aflibercept) Injection for thitakerous Infusion     Proluence       DUPIXENT     KEVZARA
odronextamab (CD20xCD3) linvoseltamab (BCMAxCD3) REGN5459 (BCMAxCD3) REGN7257 (IL-2Rg) REGN9933 (Factor XI) REGN7999 (TMPRS6)	mibavademab (LEPR) REGN5381/REGN9035 (NPR1) sarilumab* (IL-6R) dupilumab* (IL-4R)	dupilumab* (IL-4R) itepekimab* (IL-33) REGN5713-5714-5715 (Bet v 1)	(dupilumab) Injection       (sarilumab) injection         200mg - 300mg       200 mg   150 mg         Vicinity Complimation       200 mg   150 mg         (complimation - rwlc)       Immazeb (atoltivinab, maftivinab, and odestimab - ebgn) Injection         Vicinity Complimation       REGEN-COV*
NTLA-2001# (TTR) REGN5381/REGN9035 (NPR1) ALN-HSD ‡ (HSD17B13) ALN-APP ‡ (APP) "Next-Gen" COVID Antibodies (SARS-CoV-2)			(evinacumab-dgnb) Injection In collaboration with: * Sanofi ^ Roche ‡ Alnylam # Intellia « Ultragenyx ° Bayer
•	Over 30 product candidates	; <u> </u>	<b>→</b>

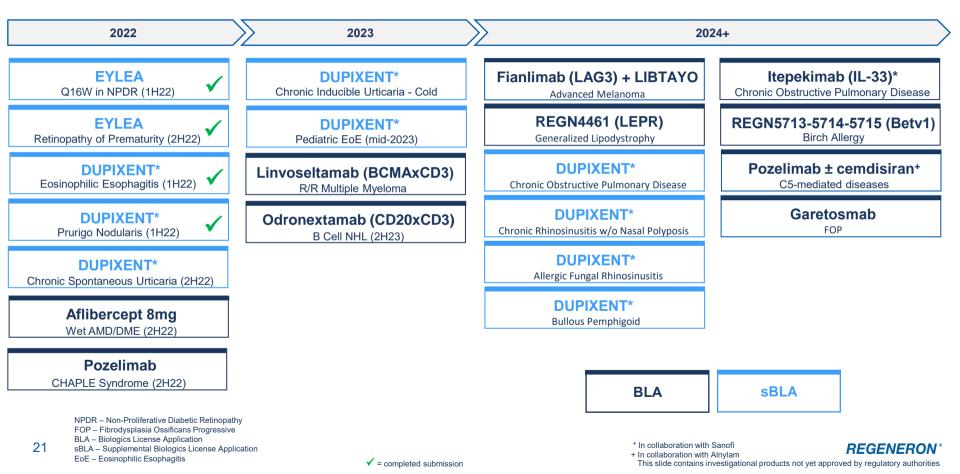
20 SOLID ORGAN ONCOLOGY HEMATOLOGY GENERAL MEDICINE

\*\*Based on the most recent Emergency Use Authorization (EUA) modification, REGEN-COV cannot currently be used anywhere in the U.S. As of November 3, 2022

#### REGENERON

This slide contains investigational products not yet approved by regulatory authorities

# Multiple Potential FDA Submissions: 2022-2024+



# **Key Upcoming Milestones (Next 12 Months)**

#### Ophthalmology

- Submit BLA for 8mg aflibercept in DME and wAMD (2H22)
- FDA decision for EYLEA in ROP (PDUFA 2/11/2023)
- FDA decision for EYLEA for 16-week dosing in DR (PDUFA 2/28/2023)

### Dupixent

- EC decision on pediatric AD (6mo 5yr) (1H23)
- EC decision on EoE for adults and adolescents (1H23)
- EC decision on PN (1H23)
- Submit sBLA for pediatric EoE (mid-2023)
- Report data for Phase 3 studies in CINDU-Cold (1H23), COPD (1H23)

### Libtayo

• Regulatory decisions for 1L advanced NSCLC chemotherapy combination

### Pozelimab (anti-C5 antibody)

• Submit BLA for CD55-deficient protein-losing enteropathy (CHAPLE) (2H22)

### Solid Organ Oncology

- Initiate Phase 3 for fianlimab with Libtayo in 1L adjuvant melanoma
- Report data from FIH study of fianlimab with Libtayo in 1L NSCLC
- · Report additional data for PSMAxCD28 with Libtayo
- · Additional and initial data expected across solid organ oncology

#### Odronextamab (CD20xCD3)

- · Update potentially pivotal Phase 2 results in B-NHL
- · Initiate dosing with subcutaneous formulation
- Initiate OLYMPIA Phase 3 program and additional combinations

#### Linvoseltamab (BCMAxCD3)

- Report potentially pivotal Phase 2 results in multiple myeloma
- · Initiate studies with subcutaneous formulation
- · Initiate Phase 3 studies in earlier lines of therapy



# **Strong Financial Position Enabling Critical Investments**

Capital allocation priorities reflect business priorities

### **Internal Investment**

in our world-class R&D capabilities and capital expenditures to support sustainable growth \$1.8B investment in Tarrytown R&D facilities announced in July 2021Continued investments in manufacturing capacity

### **Business Development**

to expand pipeline and maximize commercial opportunities



Improved economics and flexibility on existing and future external collaborations involving Libtayo combinations Recent acquisition of Checkmate Pharmaceuticals to expand immuno-oncology pipeline

Continue to **deploy excess cash** to opportunistically repurchase shares

**Over \$9B** in share repurchases since November 2019 and **over \$1.6B** in 2022\*

# Three Responsibility Focus Areas all Reflect "Doing Well by Doing Good" Ethos



Improve the lives of people with serious diseases

Foster a culture of integrity and excellence Build sustainable communities

### **Our Mission:**

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

REGENERON

# There is much to be proud of, but our job is never done

Select 2022 Honors

Newsweek: America's Most Responsible Companies Civic 50: Most Community-Minded Companies in the Nation Prix Galien Award: Best Biotechnology Product Award (Inmazeb) Science: #3 Top Employer

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# Reconciliation of Non-GAAP Results and Total Revenue Excluding REGEN-COV (casirivimab and imdevimab)

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

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2022		2021		2022	_	2021
GAAP R&D	\$	911.3	\$	665.4	\$	2,549.4	\$	2,122.5
R&D: Stock-based compensation expense		93.7		73.1		275.8		213.7
R&D: Acquisition-related integration costs		1.0		—		15.6		_
Non-GAAP R&D	\$	816.6	\$	592.3	\$	2,258.0	\$	1,908.8
GAAP SG&A	s	529.1	\$	445.0	\$	1,455.4	\$	1,265.3
SG&A: Stock-based compensation expense		59.8		48.7		178.0		149.1
SG&A: Acquisition-related integration costs and other		2.0		5.6		3.1		5.6
Non-GAAP SG&A	\$	467.3	\$	390.7	\$	1,274.3	\$	1,110.6
GAAP COGS	\$	141.3	\$	238.8	\$	497.8	\$	961.4
COGS: Stock-based compensation expense		12.8		15.1		39.2		50.5
COGS: Intangible asset amortization expense		15.1		_		15.1		_
COGS: Charges related to REGEN-COV		4.9		_		62.9		_
Non-GAAP COGS	\$	108.5	\$	223.7	\$	380.6	\$	910.9
GAAP other income (expense), net	\$	286.1	\$	(30.6)	\$	(58.0)	\$	515.3
Other income/expense: (Gains) losses on investments		(253.5)		29.3		117.3		(524.6)
Non-GAAP other income (expense), net	\$	32.6	\$	(1.3)	\$	59.3	\$	(9.3)
GAAP net income	\$	1,315.7	\$	1,632.2	\$	3,141.3	\$	5,846.3
Total of GAAP to non-GAAP reconciling items above		(64.2)		171.8		707.0		(105.7)
Income tax effect of GAAP to non-GAAP reconciling items		18.9		(31.3)		(133.4)		36.3
Non-GAAP net income	\$	1,270.4	\$	1,772.7	\$	3,714.9	\$	5,776.9
Non-GAAP net income per share - basic	\$	11.88	\$	16.69	\$	34.65	\$	54.76
Non-GAAP net income per share - diluted	\$	11.14	\$	15.37	\$	32.39	\$	50.99
Shares used in calculating:								
Non-GAAP net income per share - basic		106.9		106.2		107.2		105.5
Non-GAAP net income per share - diluted		114.0		115.3		114.7		113.3

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2022		2021		2022		2021
Revenue reconciliation:								
Total revenues		2,936.2	\$	3,452.8	\$	8,758.5	\$	11,120.0
REGEN-COV net product sales in the United States		_		676.7		_		3,530.1
Global gross profit payment from Roche in connection with sales of Ronapreve		6.4		127.1		230.9		361.8
Total revenues excluding REGEN-COV and Ronapreve	\$	2,929.8	\$	2,649.0	\$	8,527.6	\$	7,228.1

