# **REGENERON**<sup>®</sup> SCIENCE TO MEDICINE<sup>®</sup>

# CORPORATE PRESENTATION

FEBRUARY 2020

## 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," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products") and Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), fasinumab, evinacumab, garetosmab, pozelimab, Regeneron's immuno-oncology programs (including its costimulatory bispecific portfolio), Regeneron's earlier-stage product candidates, and the use of human genetics in Regeneron's research programs; the extent to which the results from Regeneron's research programs or preclinical testing may lead to advancement of product candidates to clinical trials or therapeutic applications; unforeseen safety issues resulting from the administration of Regeneron's Products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for Regeneron's Products including without limitation EYLEA, Dupixent, Libtayo, Praluent, Kevzara, fasinumab, evinacumab, REGN-EB3, garetosmab, pozelimab, and REGN1979; 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 or its collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's Products (such as EYLEA, Dupixent, Libtayo, Praluent, and Kevzara), 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 product candidates; competing drugs and product candidates that may be superior to Regeneron's Products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products and product candidates; the availability and extent of reimbursement of Regeneron's Products from third-party pavers, including private paver 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; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and 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 Dupixent and Praluent), 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, Baver, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success. 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, including its Form 10-K for the fiscal year ended December 31, 2019 in the section thereof captioned "Item 1A. Risk Factors." 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 any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

This presentation uses non-GAAP net income per share, or non-GAAP EPS, which is a financial measure that is not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). This and other non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP financial measure. Non-GAAP adjustments also include the 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. For example, adjustments may be made for items that fluctuate from period to 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 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 measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measures may not be comparable with GAAP. A reconciliation of the Company's fourth quarter 2019 and full year 2019 non-GAAP to GAAP net income per share is provided on slide 24.

# **CONTINUED EXECUTION AND PIPELINE PROGRESS**

## 4Q19 Top- and Bottom-line Growth

<u>Revenues of \$2.17 Bn, +13% y/y</u> EYLEA<sup>®</sup> U.S. net product sales of \$1.22 Bn, +13% y/y Dupixent<sup>®</sup> global net product sales\* of \$752 MM, +136% y/y Non-GAAP EPS\*\* of \$7.50, +10% y/y

Announced intent to simplify the Sanofi Antibody Collaboration

## **Significant Pipeline Advancements**

Eylea - High-dose Ph2 study start

Dupixent – EU approval for CRSwNP; U.S. and EU filings for AD in children 6-11 years <u>Oncology Updates</u> – REGN1979 in lymphoma and REGN5458 in multiple myeloma; Ph2 for REGN1979 expanded to include DLBCL, other lymphomas <u>Pozelimab</u> – Positive top-line results from Ph2 in PNH announced

<u>Garetosmab</u> – Encouraging results from Ph2 in FOP announced



CRSwNP – Chronic Rhinosinusitis with Nasal Polyposis AD – Atopic Dermatitis FOP – Fibrodysplasia Ossificans Progressiva

# **REGENERON'S NEAR-TERM GROWTH DRIVERS**

EV	
	LEA

- Execute in wet AMD and diabetic eye diseases
- Maximize DR and prefilled syringe launches
- Explore high-dose formulation for less frequent dosing

**REGENERON**<sup>®</sup>

• Pursue gene therapy and other novel approaches

## **Dupixent\***

- Transform the treatment of Type 2 inflammatory diseases
- Maximize launches in AD, asthma, and CRSwNP
- Expand to pediatric AD and asthma patients
- Execute expanded Ph3
   development program

## Oncology

- Realize potential for best-in-class immunotherapy treatments
- <u>Compete</u>, <u>Enhance</u>, and <u>Extend</u> benefits of immunotherapy to broader patient populations

# Specialized growth opportunities:

Fasinumab (NGF) Osteoarthritis pain

Pozelimab +/- siRNA<sup>†</sup> (C5) C5-mediated diseases

Evinacumab (ANGPTL3) HoFH

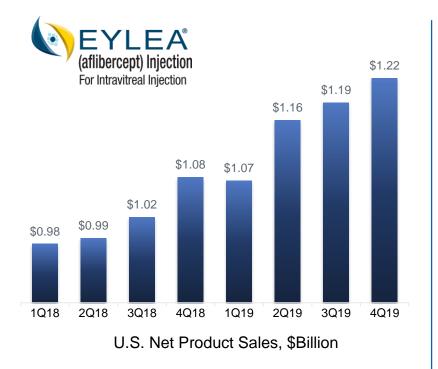
Garetosmab (Activin A) FOP

DR – Diabetic Retinopathy; AD – Atopic Dermatitis; CRSwNP – Chronic Rhinosinusitis with Nasal Polyposis; HoFH – Homozygous familial hypercholesterolemia; FOP – Fibrodysplasia ossificans progressiva

\* In collaboration with Sanofi † In collaboration with Alnylam

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# **EYLEA®: STRENGTHENING MARKET LEADERSHIP POSITION**



U.S. EYLEA Net Product Sales		Y/Y Change	
4Q19	\$1.22Bn	+13%	
2019	\$4.64Bn	+14%	

Launched EYLEA pre-filled syringe

Initiated high-dose EYLEA program

# **EYLEA®: BUILDING UPON LEADERSHIP IN TREATING RETINAL DISEASES**

### **Opportunities in Diabetic Eye Diseases**

### Diabetic Macular Edema (DME)

Targeted commercial strategy to increase anti-VEGF penetration

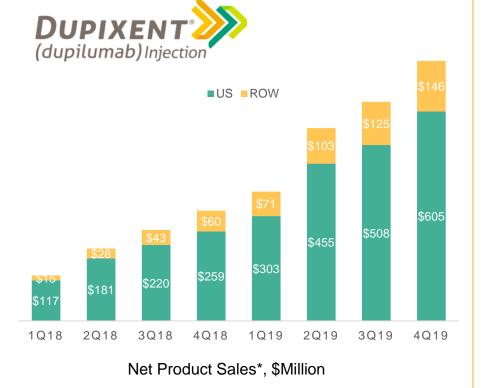
### Diabetic Retinopathy (DR)

- EYLEA is approved for all stages of diabetic retinopathy reducing the risk of blindness
- PANORAMA trial two-year results:
  - By two years, 58% of untreated patients developed vision-threatening events, and EYLEA reduced this risk by at least 75%

### **Next-Generation Strategy**

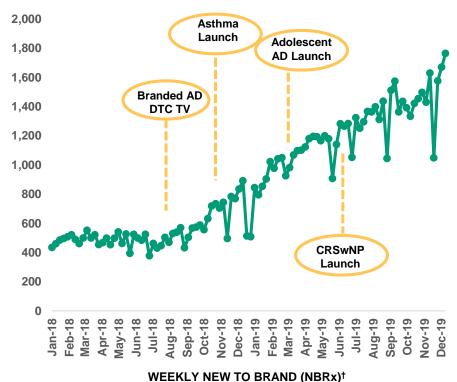
- High-Dose Formulation of EYLEA
- Other new molecular entities and technologies

# **DUPIXENT®: STRONG EXECUTION ACROSS MULTIPLE INDICATIONS**



Sanofi records global net product sales of Dupixent

REGENERON



† Source: IQVIA National Source of Business

AD – Atopic Dermatitis; CRSwNP – Chronic Rhinosinusitis with Nasal Polyposis

## **DUPIXENT®: DELIVERING ON THE "PIPELINE IN A PRODUCT" PROMISE**

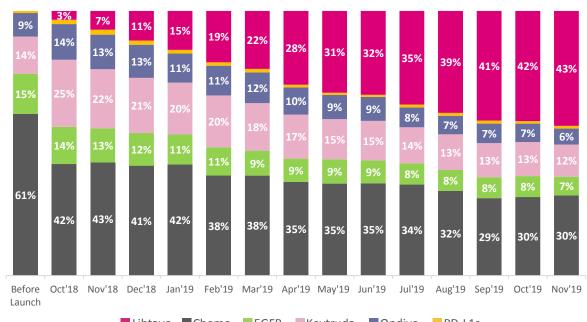
US APPROVED INDICATIONS*	Moderate-to-Severe Atopic Dermatitis	✓ Approved in Adults and Adolescents (12+ years)		
	Moderate-to-Severe Asthma	✓ Approved in Adults and Adolescents (12+ years)		
INDIGATIONS	Chronic Rhinosinusitis with Nasal Polyposis	✓ Approved in Adults		
	Atopic Dermatitis in Pediatrics (6–11 years)	Filed in the U.S., submitted in the EU		
NEAR-TERM OPPORTUNITIES	Eosinophilic Esophagitis	Ph2 readout mid-2020; Ph3 ongoing		
	Chronic Obstructive Pulmonary Disease (COPD)	Ph3 ongoing		
	Asthma in Pediatrics (6–11 years)	Ph3 readout 2H20		
	Atopic Dermatitis in Pediatrics (6 months-5 years)	Ph3 readout 2022		
LONGER-TERM OPPORTUNITIES	Airborne Allergies	Ph2 Grass Allergy data in 1H20		
	Food Allergies	Ph2 in Peanut Allergy readout 1H21		
	Additional Indications	Chronic Spontaneous Urticaria (Ph3 initiated 4Q19), Prurigo Nodularis (Ph3 initiated 4Q19), Bullous Pemphigoid (Ph3 initiated 1Q20), and others		
REGENERON®	* In the EU, Dupixent is approved in three indications: moderate-to-severe Atopic Dermatitis, severe Asthma, and severe Chronic Rhinosinusitis with	8		

Nasal Polyposis

This slide contains investigational indications not yet approved by regulatory authorities

# LIBTAYO®: LEADING TREATMENT FOR ADVANCED CSCC IN U.S.





Advanced CSCC – Total U.S. Patient Share by Products<sup>†</sup>

■ Libtayo ■ Chemo ■ EGFR ■ Keytruda ■ Opdivo ■ PD-L1s

# **ONCOLOGY STRATEGY:** <u>COMPETE</u>, ENHANCE, EXTEND

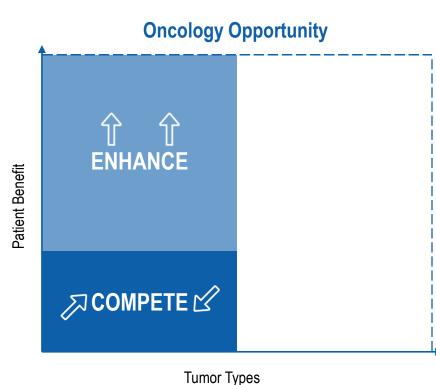


**COMPETE:** Libtayo in tumors "responsive" to PD-1 checkpoint inhibition (e.g., skin & NCSLC)

PD-(L)1 market: >\$21Bn, +42% YoY growth\*

Tumor Types

# **ONCOLOGY STRATEGY: COMPETE, <u>ENHANCE</u>, EXTEND**



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**ENHANCE:** Even for "responsive" tumors, more than half of patients do not respond to IO treatment

• Studying addition of novel therapeutics to Libtayo to "enhance" responsiveness for these tumors

# **ONCOLOGY STRATEGY: COMPETE, ENHANCE, <u>EXTEND</u>**



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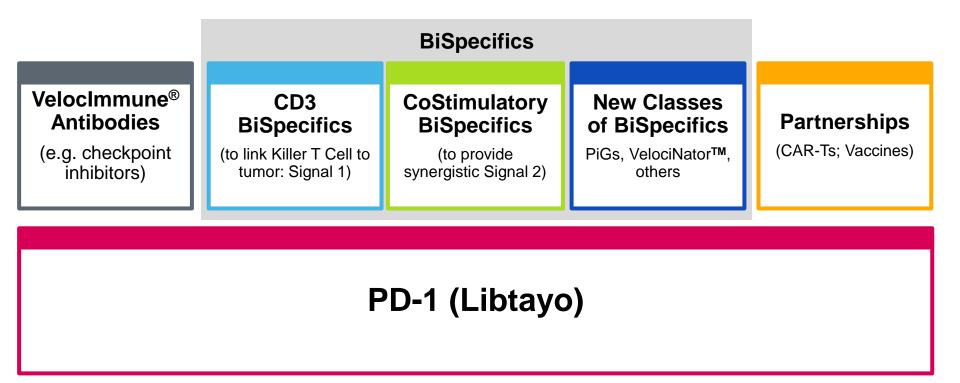
• Studying addition of novel therapeutics to Libtayo to "enhance" responsiveness for these tumors

**EXTEND:** For tumor settings with limited response to checkpoint inhibition

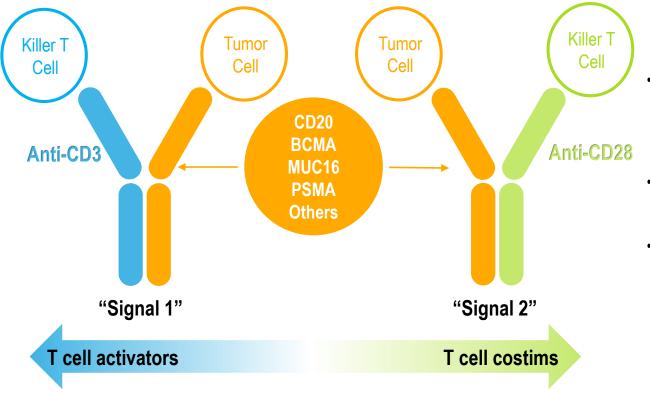
• Novel therapeutics to "*extend*" responsiveness to these tumor settings – e.g., BiSpecifics

Tumor Types

## REGENERON ONCOLOGY TOOLKIT LEVERAGES MULTIPLE PLATFORMS TO CREATE COMBINATORIAL FLEXIBILITY



# **REGENERON'S VELOCI-BI® APPROACH CAN CREATE, MANUFACTURE, AND DEVELOP HIGH-QUALITY BISPECIFICS OF ANY DESIRED SPECIFICITY**



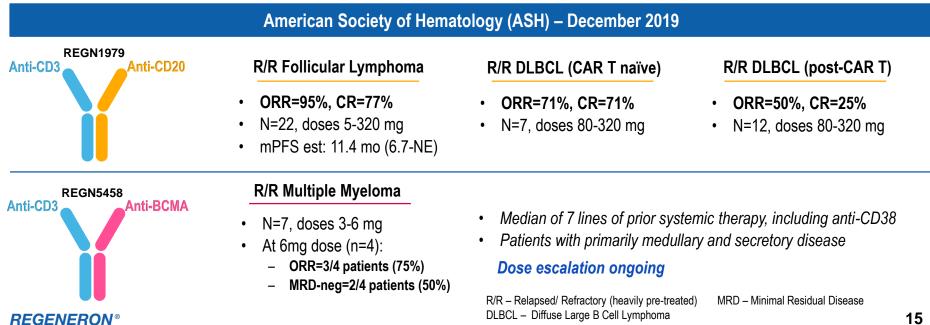
**REGENERON**<sup>®</sup>

### **VELOCI-BI**®

- VelociGene<sup>®</sup> and VelocImmune<sup>®</sup> technologies are fundamental
  - Foundation for Dupixent, Praluent, Libtayo, and other Regeneron-discovered medicines
- Next-generation VelocImmune<sup>®</sup> makes several distinct classes of BiSpecifics, with varying specificity and affinity
- Regeneron BiSpecific approach is unique
  - No linkers or artificial sequences
  - Ease of manufacturing using same process as regular antibodies
  - Similar PK to regular antibodies

## REGENERON'S CD3 BISPECIFICS SHOW SIGNIFICANT ANTI-TUMOR ACTIVITY

- REGN1979 links CD20 on tumor cells to CD3 on killer T cells
  - First BiSpecific in our portfolio: required careful approach to safely escalate doses of a potent immunostimulatory agent to provide benefit to patients
- Encouraging data seen with REGN5458 (BCMAxCD3) in early dose cohorts



## BREADTH OF REGENERON'S ONCOLOGY PIPELINE REFLECTS COMBINATORIAL FLEXIBILITY

	BiSpecifics			
		CD2 DiSpesifies	Costims New classes	Dorthoushing
	VelocImmune <sup>®</sup> Antibodies	CD3 BiSpecifics	BiSpecifics	Partnerships
	REGN3767 (LAG-3) Solid/hematologic cancers	REGN5458* (BCMAxCD3) Multiple myeloma	REGN5678 (PSMAxCD28) Prostate cancer	ISA101b + Libtayo (ISA) HNSCC
EARLY DEVELOPMENT	GITR <sup>†</sup> Solid tumors	REGN5459* (BCMAxCD3) Multiple myeloma	REGN5093 (METxMET) MET-altered NSCLC	Voyager-V1 + Libtayo (Vyriad) Solid tumors
		REGN4018* (MUC16xCD3) Ovarian cancer	PiG (Peptide in HLA Groove) <sup>†</sup> Solid tumors	
POTENTIALLY		REGN1979 (CD20xCD3) B cell NHL		RP1 + Libtayo (Replimune) CSCC
PIVOTAL	Libtayo* NSCLC	Libtayo* BCC	Libtayo* Cervical	Libtayo* Adjuvant CSCC
APPROVED	Libtayo* CSCC			
REGENERON®	Additional BiSpecifics and combinations expected to enter the clinic in 2020 N * In collaboration with Sanofi † Preclinical This slide contains investigational products not yet approved by regulatory authorities 16			

# **2019 KEY ADVANCEMENTS IN ONCOLOGY**

## PD-1

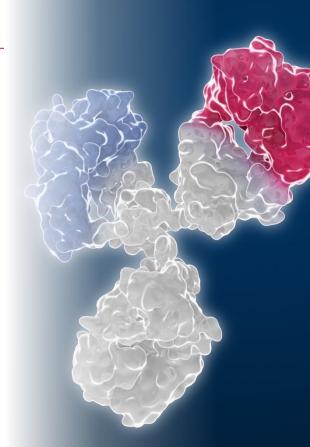
- Libtayo became the #1 systemic treatment in CSCC
- Released promising interim response data for Libtayo vs. chemotherapy in 1L NSCLC

## BISPECIFICS

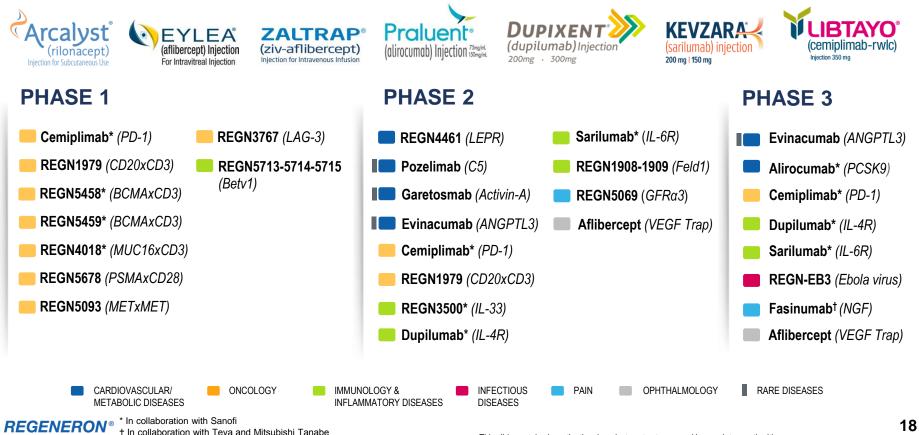
- Updated REGN1979 (CD20xCD3) data; potentially pivotal Phase 2 study initiated
- Presented first-time REGN5458 (BCMAxCD3) data
- Dosed first patient with REGN5678 (PSMAxCD28) costimulatory bispecific
- Initiated clinical studies with additional bispecifics

## **BUSINESS DEVELOPMENT**

- · Initiated collaborations with Vyriad, Inc. and BioNTech SE
- Advanced collaborations with bluebird bio Inc., Adicet Bio Inc., Replimune Group, Inc., and ISA Pharmaceuticals B.V.



# **REGENERON-DISCOVERED APPROVED AND INVESTIGATIONAL MEDICINES**



## **MULTIPLE POTENTIAL REGULATORY SUBMISSIONS: 2020-2022+**

2020	2021	2022+		
Evinacumab Homozygous Familial Hypercholesterolemia	<b>Fasinumab</b> <sup>†</sup> Osteoarthritis Pain	REGN5458 (BCMAxCD3)* Relapsed/Refractory Multiple Myeloma	DUPIXENT* Pediatric Atopic Dermatitis (6 mo-6 yr)	
REGN-EB3 Ebola Virus Infection			Eosinophilic Esophagitis Bullous Pemphigoid Chronic Spontaneous Urticaria Allergic Bronchopulmonary Aspergillosis	
Garetosmab FOP (to be discussed with regulators)	DUPIXENT* Prurigo Nodularis	High-Dose EYLEA Wet AMD and DME	Chronic Obstructive Pulmonary Disease	
LIBTAYO* Basal Cell Carcinoma	DUPIXENT* Pediatric Asthma (6-11 yr)		PRALUENT Pediatric HeFH	
PRALUENT Homozygous Familial Hypercholesterolemia		9 (CD20xCD3) Cell NHL		
LIBTA 1L Non-Small Ce				
			<u>KEY</u>	
			New Molecule	

New Indication

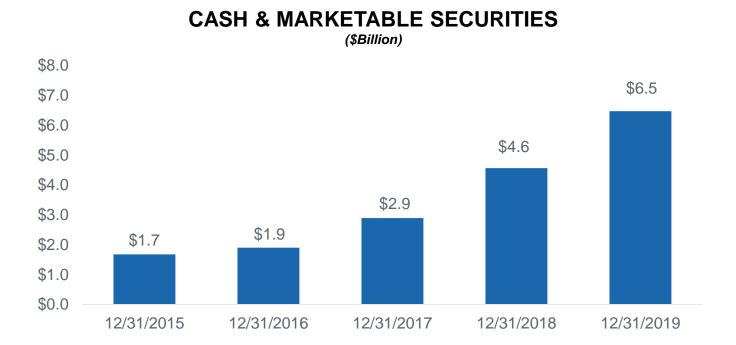
**REGENERON**<sup>®</sup> <sup>\*</sup> In collaboration with Sanofi † In collaboration with Teva and Mitsubishi Tanabe

## **CAPITAL ALLOCATION FRAMEWORK AND PRIORITIES**

FUND INTERNAL R&D	<ul> <li>Consistently high return on R&amp;D Investments</li> <li>Broad preclinical and early/late-stage clinical pipeline</li> </ul>			
BUSINESS DEVELOPMENT	<ul> <li>&gt; \$950MM in upfront and equity investments in last 18 months</li> <li>Restructured Sanofi IO agreement</li> </ul>			
RETURN CASH TO SHAREHOLDERS	<ul> <li>New share repurchase program*</li> <li>Separately, Sanofi may reimburse Regeneron for certain R&amp;D funding obligations by selling shares of Regeneron common stock**</li> </ul>			

\* As of Dec 31<sup>st</sup>, 2019, -\$250MM in shares have been repurchased and -\$750MM remain under existing authorization.
\*\* Since Jan 2018, ~530K shares purchased by Regeneron from Sanofi in satisfaction of certain of Sanofi's funding obligations under the IO and Antibody Collaborations; ~870K remaining shares may be sold by Sanofi and purchased by Regeneron (if it elects) under this arrangement.

## **REGENERON'S BALANCE SHEET ENABLES OPPORTUNITY**



~\$250 MM worth of shares repurchased in 4Q2019

# **ANTIBODY AGREEMENT RESTRUCTURING**



• Terms unchanged



KEVZAR

- Regeneron to have sole U.S. rights
- Sanofi to have sole ex-U.S. rights; Regeneron to receive royalties on ex-U.S. net sales
- Sanofi to have sole global rights
- Regeneron to receive royalties on global net sales

Regeneron Benefits of Anticipated Changes to the Antibody Agreement

(Transaction expected to be finalized in 1Q20; 2020 guidance expected in 1Q20)

- Improve profitability
- Increase efficiency of Praluent and Kevzara operations
- Simplify the Antibody Collaboration

# **KEY UPCOMING 2020 MILESTONES**

## **KEY REGULATORY APPROVALS & SUBMISSIONS**

Dupixent (IL-4/IL-13) Regulatory action for pediatric Atopic Dermatitis (age 6-11 years)
 Evinacumab (ANGPTL3) Regulatory submission for Homozygous Familial Hypercholesterolemia (HoFH)
 REGN-EB3 (Ebola) Complete rolling BLA submission for Ebola; regulatory action
 Garetosmab (Activin-A) Regulatory submission for Fibrodysplasia Ossificans Progressiva (FOP)

## **KEY DATA READOUTS**

Libtayo (PD-1)

Ph3 OS interim analysis in 1L NSCLC Ph2 pivotal study in advanced Basal Cell Carcinoma

Dupixent (IL-4/IL-13)

Ph3 study in pediatric Asthma (ages 6-11 years)

Ph2 portion of the Ph2/3 study in Eosinophilic Esophagitis (EoE)

Fasinumab (NGF) Ph3 long-term safety and efficacy studies

Pozelimab (C5) Interim results from Ph2 study in Paroxysmal Nocturnal Hemoglobinuria (PNH)

REGN1979 (CD20xCD3) and REGN5458 (BCMAxCD3) Updated results from first-in-human studies

### **REGENERON®**

## **RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME**

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
GAAP net income	\$ 792.0	\$ 820.4	\$ 2,115.8	\$ 2,444.4
Adjustments:				
R&D: Non-cash share-based compensation expense R&D: Up-front payments related to license and	72.4	68.2	250.4	229.0
collaboration agreements	30.0	_	430.0	_
SG&A: Non-cash share-based compensation				
expense	45.4	50.8	167.7	169.2
SG&A: Restructuring-related expenses	35.2	_	35.2	_
SG&A: Litigation contingencies	60.0	30.0	70.0	30.0
COGS and COCM: Non-cash share-based				
compensation expense	15.7	7.8	46.2	29.2
Other income/expense: (Gains) losses on				
investments in equity securities	(189.0)	62.9	(118.3)	41.9
Income tax effect of reconciling items above	(4.1)	(36.2)	(169.9)	(92.1)
Income tax expense: Impact of sale of assets				
between foreign subsidiaries	_	(162.1)	_	(162.1)
Income tax expense: Adjustment to previously recorded charge related to enactment of U.S. Tax		(,		(
Reform Act	_	(56.1)	_	(68.0)
Non-GAAP net income	\$ 857.6	\$ 785.7	\$ 2,827.1	\$ 2,621.5
Non-GAAP net income per share - basic	\$ 7.85	\$ 7.26	\$ 25.89	\$ 24.30
Non-GAAP net income per share - diluted	\$ 7.50	\$ 6.84	\$ 24.67	\$ 22.84
Shares used in calculating:				
Non-GAAP net income per share - basic	109.2	108.2	109.2	107.9
Non-GAAP net income per share - diluted	114.3	114.9	114.6	114.8

### **REGENERON®**

\* See slide 2 for additional important information regarding non-GAAP financial measures included in this presentation 24