# Modeling Support: Post-Libtayo Transaction

November 2022

**REGENERON®** 

# 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. Risks that may cause these forward-looking statements to be inaccurate include, among others: risks related to the Company's ability to realize the anticipated benefits of the restructuring") of the Company's Immuno-oncology Collaboration with Sanofi related to Libtayo® (cemiplimab-rwlc) described in this presentation, including the possibility that the expected benefits from the Restructuring will not be realized or will not be realized within the expected time period; the impact of the Restructuring on Regeneron's business, operating results, and financial condition; 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 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 Libtayo as a monotherapy treatment or in combination with chemotherapy or certain of the Company's investigational assets referenced in this presentation; 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: 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; 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; the ability of Regeneron and/or its collaborators to manufacture and manage supply chains for multiple products and product candidates; 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 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 Product 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; 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, collaboration, or supply 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 (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection. Praluent® (alirocumab). and REGEN-COV® (casirivimab and imdevimab)), 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, including its Form 10-K for the year ended December 31, 2022 and its Form 10-Q for the quarterly period ended September 30, 2022. 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 statements made by Regeneron. 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 COGS, 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 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 measure used in this presentation is provided on slide 9.

# Regeneron Acquired Global Rights to Libtayo

#### **Summary of Key Financial Terms**

**Upfront & Milestone Payments** 

- \$900 million upfront
- \$100 million regulatory milestone upon achievement of FDA approval of Libtayo in combination with chemotherapy for first-line treatment of advanced NSCLC
- \$65 million sales milestone in 2022 and \$35 million sales milestone in 2023, payable upon achieving \$475 million of global net sales of Libtayo in each year

Royalty Payment

 11% of global net sales of Libtayo monotherapy and the Libtayo portion of any combination products

Development Balance Re-Payment

- I/O: 0.5% royalty on Libtayo global net sales until ~\$35 million balance is paid
- Antibody: Increase to 20% of Regeneron's share of profits generated by products from the Antibody Collaboration (previously 10%) until ~\$3.1 billion¹ balance is paid

Future R&D and SG&A Expenses

Regeneron to fund 100% of future Libtayo R&D and commercialization expenses

# **Summary of Revenue Impacts**



U.S. Net Sales	No change (Regeneron continues to record)
Ex-U.S. Net Sales	Regeneron now records

**Net Sales of Future Combination Products** 

Regeneron records global net sales<sup>1</sup>

(Previously recorded by Sanofi)



#### Sanofi Collaboration Revenue

Antibody Collaboration

Development balance repayment increased to 20% of Regeneron's share of profits

(Previously 10%)



Immuno-oncology Collaboration

Regeneron no longer records Immunooncology collaboration revenue

#### **Net Product Sales**

(In millions)	Three Months Ended June 30,			
Net Product Sales in the United States		2022		2021
EYLEA <sup>®</sup>	\$	1,621.2	\$	1,424.7
Libtayo <sup>®*</sup>		90.9		78.0
Praluent <sup>®</sup>		31.2		41.9
REGEN-COV <sup>®**</sup>		_		2,591.2
Evkeeza®		11.1		2.0
ARCALYST®***		_		
	\$	1,754.4	\$	4,137.8

		Three Months Ended September 30,			
(In millions)			2022		2021
EYLEA®	U.S.	\$	1,629.4	\$	1,473.4
Libtayo <sup>®(a)</sup>	U.S.		94.7		78.4
	ROW <sup>(b)</sup>		31.0		_
Praluent®	U.S.		29.7		44.8
REGEN-COV <sup>®(c)</sup>	U.S.		_		676.7
Evkeeza®	U.S.		13.6		6.6
Inmazeb®	U.S.		3.0		_
ARCALYST <sup>®(d)</sup>	U.S.		_		_
		\$	1,801.4	\$	2,279.9

Effective July 1<sup>st</sup>, 2022, Regeneron records global (U.S. and Rest of World) net sales of Libtayo.

Previously, Regeneron recorded only U.S. net sales and Sanofi recorded net sales outside of the U.S.

#### **Sanofi Collaboration Revenue**

		Three Mon Jun		
(In millions)		2022		2021
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	s	496.6	\$	327.6
Sales-based milestone earned		_		_
Reimbursement for manufacturing of commercial supplies <sup>(a)</sup>		145.5		110.9
Other		28.9		_
Total Antibody		671.0		438.5
Immuno-oncology:				
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States		3.9		(3.5)
Reimbursement for manufacturing of ex-U.S. commercial supplies <sup>(a)</sup>		2.6		2.7
Total Immuno-oncology		6.5		(0.8)
Total Sanofi collaboration revenue	\$	677.5	\$	437.7

	Three Mor Septem		
(In millions)	2022		2021
Antibody:			
Regeneron's share of profits in connection with commercialization of antibodies	\$ 551.1	s	387.0
Sales-based milestone earned	_		50.0
Reimbursement for manufacturing of commercial supplies <sup>(a)</sup>	160.5		144.7
Other	(0.2)		_
Total Antibody	711.4		581.7
Immuno-oncology:		Г	
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	_		(3.0
Reimbursement for manufacturing of ex-U.S. commercial supplies <sup>(a)</sup>	_		3.1
Total Immuno-oncology	_		0.1
Total Sanofi collaboration revenue	\$ 711.4	\$	581.8

The Immuno-oncology collaboration was amended effective July 1<sup>st</sup>, with Regeneron obtaining global rights to Libtayo. The companies are not collaborating on any other immuno-oncology products.

## **Non-GAAP Operating Expenses**

Regeneron now records all R&D and SG&A expenses related to Libtayo

Regeneron now records its full 50% share of development expenses for the antibody collaboration (primarily Dupixent and itepekimab) as incurred

 Previously Regeneron generally recognized 20% of Dupixent development expenses and 0% of itepekimab development expenses as incurred, with the remaining share of expenses added to the antibody development balance, and ultimately reflected as a reduction to Collaboration revenue when repaid

As of July 1, 2022, Sanofi was no longer entitled to a share of Libtayo U.S. gross profits; this expense was previously recorded in Cost of Goods Sold

The impact of the transaction on Non-GAAP Expenses (R&D, SG&A, COGS) as described above is reflected in Regeneron's latest 2022 financial guidance

## **Development Balance Repayment**

Q2 2022	Three Months Ended June 30,			
(In millions)		2022		2021
Dupixent and Kevzara net product sales	\$	2,174.1	\$	1,565.7
Regeneron's share of collaboration profits	\$	551.7	\$	364.5
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation		(55.1)		(36.9)
Regeneron's share of profits in connection with commercialization of antibodies	\$	496.6	\$	327.6
Regeneron's share of collaboration profits as a percentage of Dupixent and Kevzara net product sales		23%		21%

Q3 2022	Three Mont Septemb		
(In millions)		2022	2021
Dupixent and Kevzara net product sales	\$	2,418.8	\$ 1,760.7
Regeneron's share of collaboration profits	\$	686.7	\$ 425.8
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation		(78.7)	(38.8)
One-time payment in connection with amendment to the Antibody License and Collaboration Agreement		(56.9)	
Regeneron's share of profits in connection with commercialization of antibodies	\$	551.1	\$ 387.0
Regeneron's share of collaboration profits as a percentage of Dupixent and Kevzara net product sales		23%	22%

\$78.7M DB Repayment (*Contra Revenue in Above Tables*) + Incremental Antibody R&D Expenses

 $\approx$ 

20%

\$686.7M Share of Profits

Regeneron's share of profits used to reimburse Sanofi for previously funded R&D expenses (i.e., development balance reimbursement obligation) increased from **10% to 20%.** 

The 20% quarterly development balance repayment is primarily reflected as:

- (1) reduction to antibody collaboration revenue
- (2) incremental antibody R&D expense (see Slide 7)

Therefore, the reduction to antibody collaboration revenue is currently less than 20% of Regeneron's share of antibody profits.

Repayment of the antibody development balance is now expected to be completed 3-5 years earlier, increasing antibody collaboration revenue in outer years.\*

The antibody development balance was **\$3.1B** as of June 30, 2022.

# Balance Sheet Intangible Asset and Non-GAAP Adjustment

	2022	June 30, 2022
	ASSETS	
Current assets:		
Cash and cash equivalents		\$ 3,395.1
Marketable securities		4,171.3
Accounts receivable, net		5,161.4
Inventories		2,218.5
Prepaid expenses and other current assets		583.6
Total current assets		 15,529.9
Marketable securities		6,415.9
Property, plant, and equipment, net		3,637.7
Deferred tax assets		1,352.4
Other noncurrent assets		269.9
Total assets		\$ 27,205.8

Q3 2022	September 30, 2022
ASSETS	
Current assets:	
Cash and cash equivalents	\$ 3,491.3
Marketable securities	3,530.4
Accounts receivable, net	5,548.3
Inventories	2,412.2
Prepaid expenses and other current assets	446.4
Total current assets	15,428.6
Marketable securities	5,968.6
Property, plant, and equipment, net	3,704.2
Intangible assets, net	804.1
Deferred tax assets	1,452.1
Other noncurrent assets	320.2
Total assets	\$ 27,677.8

The upfront payment and contingent consideration (i.e., milestones and royalties) are **capitalized to the Balance Sheet** as an Intangible Asset.

This will be amortized through the Income Statement within the **Cost of Goods Sold** line over the estimated useful life of the asset.

Amortization expense is excluded from Non-GAAP results.

GAAP COGS	\$ 149.2
COGS: Stock-based compensation expense	12.0
COGS: Charges related to REGEN-COV	-
Non-GAAP COGS	\$ 136.0

GAAP COGS	\$ 141.3
COGS: Stock-based compensation expense	12.8
COGS: Intangible asset amortization expense	15.1
COGS: Charges related to REGEN-COV	4.9
Non-GAAP COGS	\$ 108.5