

**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 11, 2021 (January 11, 2021)

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 11, 2021, at the virtual 39th 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[®] (afibercept) Injection of approximately \$4.95 billion for the full year 2020 (based on preliminary (unaudited) fourth quarter 2020 U.S. net product sales of EYLEA of approximately \$1.34 billion). Overall distributor inventory levels for EYLEA in the United States remained within the Company’s one-to-two-week targeted range.

The presentation also includes information regarding the Company’s preliminary (unaudited) U.S. net product sales of casirivimab and imdevimab, the Company’s novel investigational dual-antibody therapy for COVID-19, of approximately \$184 million for the full year 2020 (based on preliminary (unaudited) fourth quarter 2020 U.S. net product sales of casirivimab and imdevimab of approximately \$144 million). The Company expects that the full 300,000 doses under the previously announced contract with the U.S. government will be fulfilled by the end of February 2021.

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 virtual 39th Annual J.P. Morgan Healthcare Conference.](#)

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, whether and to what extent Regeneron will be able to supply the remaining doses of the casirivimab and imdevimab antibody cocktail under the terms of the agreement with U.S. government referenced in this Report (the “Manufacturing and Supply Agreement”), the amount of future payments (if any) Regeneron may receive pursuant to the Manufacturing and Supply Agreement, and whether the Manufacturing and Supply Agreement is terminated by the U.S. government or otherwise prior to completion; and 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, including the casirivimab and imdevimab antibody cocktail. 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, 2019 and its Form 10-Q for the quarterly period ended September 30, 2020. 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.

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.

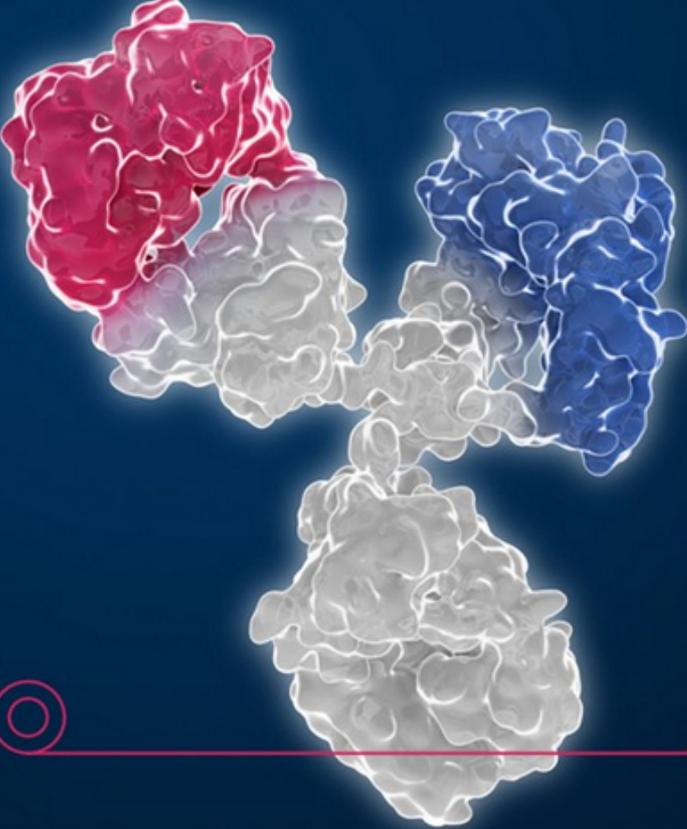
REGENERON PHARMACEUTICALS, INC.

/s/ Joseph J. LaRosa

Joseph J. LaRosa

Executive Vice President, General Counsel and Secretary

Date: January 11, 2021



REGENERON
SCIENCE TO MEDICINE®

JP MORGAN 2021
JANUARY 11TH

LEONARD S. SCHLEIFER MD, PhD
PRESIDENT & CEO

GEORGE D. YANCOPOULOS MD, PhD
PRESIDENT & CSO

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 (collectively, "Regeneron's Products"), and the global economy, the nature, timing, and possible success and therapeutic applications of 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® (alicumab), Kevzara® (sarilumab), Imzabz™ (ablitivimab), mabivimab, and odesivimab-ebgn), casirivimab and imdevimab, fasinumab, evircumab, garelsimab, Regeneron's and its collaborators' other oncology programs (including odronextamab (REGN1979) and REGN5458), Regeneron's and its collaborators' other hematology programs (including pozilimab (REGN3018)), 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 product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 EYLEA, Dupixent, Libtayo, Praluent, Kevzara, casirivimab and imdevimab, fasinumab, evircumab, garelsimab, odronextamab, REGN5458, and pozilimab; 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 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 (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, or more cost effective than, 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 payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid (including the impact of the recently issued "most-favored-nation" interim final rule); 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, 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, including, without limitation, capital expenditures, 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, 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, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's agreement with Roche relating to casirivimab and imdevimab, 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, including its Form 10-K for the fiscal year ended December 31, 2019 and Form 10-Q for the quarterly period ended September 30, 2020, in each case 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 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.

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 measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations or a perspective on how effectively the Company deploys capital. 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 Company's non-GAAP to GAAP net income and net income per share for the three months and nine months ended September 30, 2020 is provided on slide 38.

REGENERON[®]

Leonard S. Schleifer MD, PhD
President & Chief Executive Officer



REGENERON[®]

Strong and Growing Core Brands



Entering a Period of New Launches



1L Non-Small Cell Lung Cancer and Basal Cell Carcinoma



Pediatric Asthma



Casirivimab / Imdevimab

COVID-19

Evinacumab

Homozygous Familial Hypercholesterolemia (HoFH)

A Broad and Diverse Pipeline

Dupixent in pivotal trials for **eight Type 2** diseases

Advancing **immuno-oncology** pipeline and combinations

20+ Therapeutic candidates in clinical development

STRONG EXECUTION IN 2020

Total Revenues (9 months through Sept 2020)*

+29% growth



Non-GAAP EPS (9 months through Sept 2020)*

+28% growth

R&D Pipeline Advancements

DUPIXENT

EoE, Pediatric Asthma/AD

LIBTAYO

Filed in 1L NSCLC and BCC (PDUFA's 1Q21)



Leading CD3 & CD28 Bispecifics platform



Casirivimab / Imdevimab

COVID-19 antibody cocktail EUA



Inmazoleb
(atoltivimab, maftivimab, and odesivimab - ebgn)

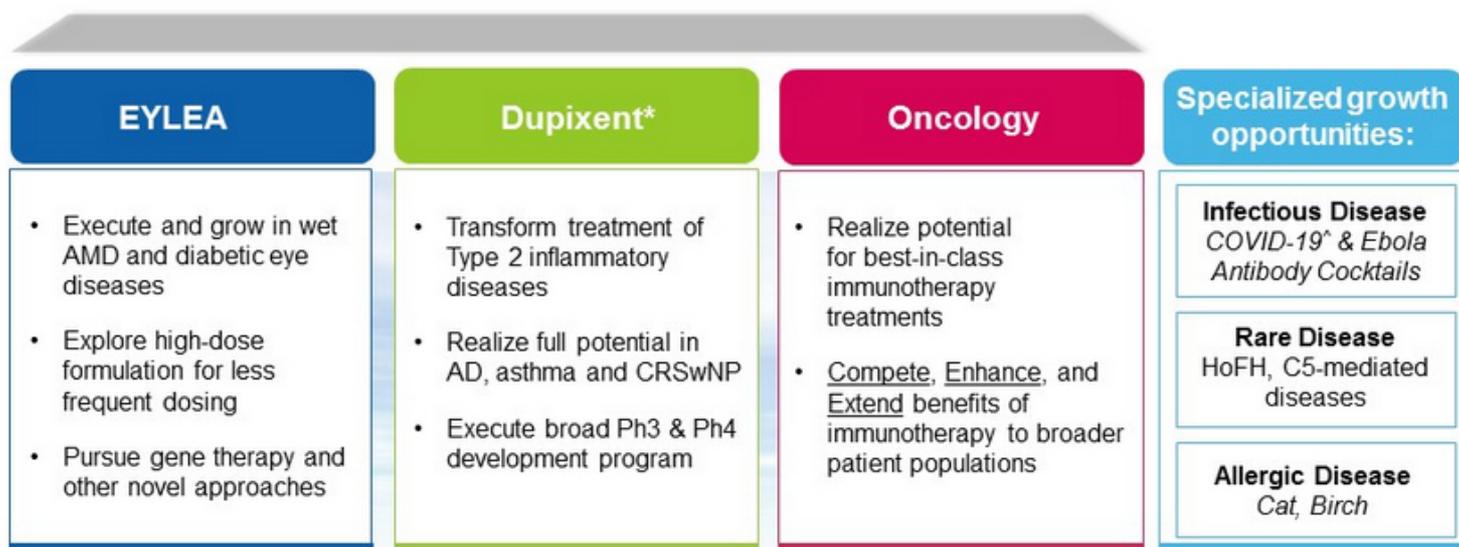
FDA-approved Treatment for Ebola

Eight new INDs

* Year-over-year growth, first nine months of 2020 vs. first nine months of 2019. See reconciliation of non-GAAP net income to GAAP net income and non-GAAP EPS to GAAP EPS on slide 38

EoE - Eosinophilic Esophagitis; AD - Atopic Dermatitis; BCC - Basal Cell Carcinoma; NSCLC - Non-Small Cell Lung Cancer; EUA - Emergency Use Authorization; IND - Investigational New Drug; PDUFA - Prescription Drug User Fee Act
This slide contains investigational products not yet approved by regulatory authorities

EYLEA, DUPIXENT, AND LIBTAYO ARE CORE TO DIVERSIFIED GROWTH STRATEGY; SPECIALIZED PROGRAMS OFFER ADDITIONAL GROWTH POTENTIAL



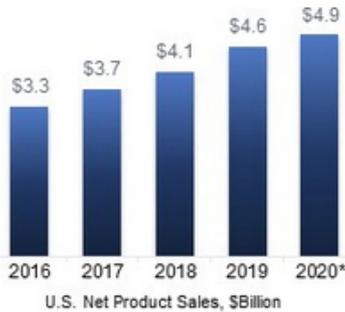
AMD – Age-Related Macular Degeneration; AD – Atopic Dermatitis; CRSwNP – Chronic Rhinosinusitis with Nasal Polyps; HoFH – Homozygous familial hypercholesterolemia

* In collaboration with Sanofi
^ In collaboration with Roche

This slide contains investigational products not yet approved by regulatory authorities

EYLEA®: EXTENDING MARKET LEADERSHIP POSITION

Setting a high bar on efficacy/safety/convenience for current and future potential competition



#1 prescribed anti-VEGF treatment

30+ million doses administered since launch

Capturing Market Growth

- 4Q20 **\$1.34Bn** (+10% YoY), FY2020 **\$4.95Bn** (+7% YoY)*
- Market share gains and favorable demographic trends



Maximize Growth Initiatives

- Realize potential in diabetic eye diseases
- Initiating DTC to drive disease awareness



Focusing on the Science

- Explore high-dose formulation for less frequent dosing
- Pursue gene therapy and other novel approaches

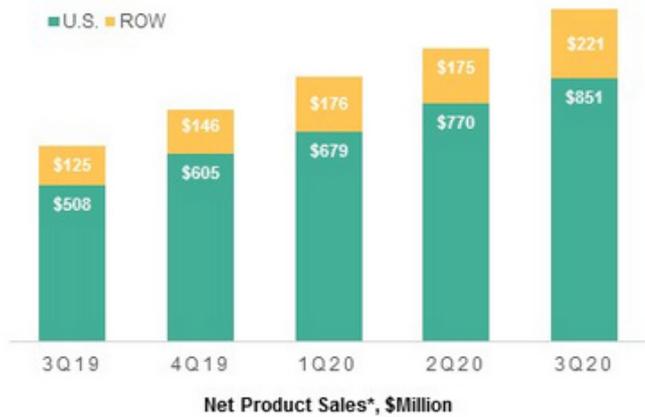


* U.S. net product sales. Based on preliminary unaudited fiscal 2020 results of \$4.95Bn; preliminary unaudited 4Q 2020 U.S. EYLEA net product sales of \$1.34Bn

DUPIXENT®: STRONG GROWTH TRAJECTORY



+69% worldwide sales growth in 3Q20 vs. 3Q19



Broad-based growth across all approved indications

Significant **market opportunities** support future growth

Advancing clinical development program across **EIGHT** Type 2 diseases

* Sanofi records global net product sales of Dupixent

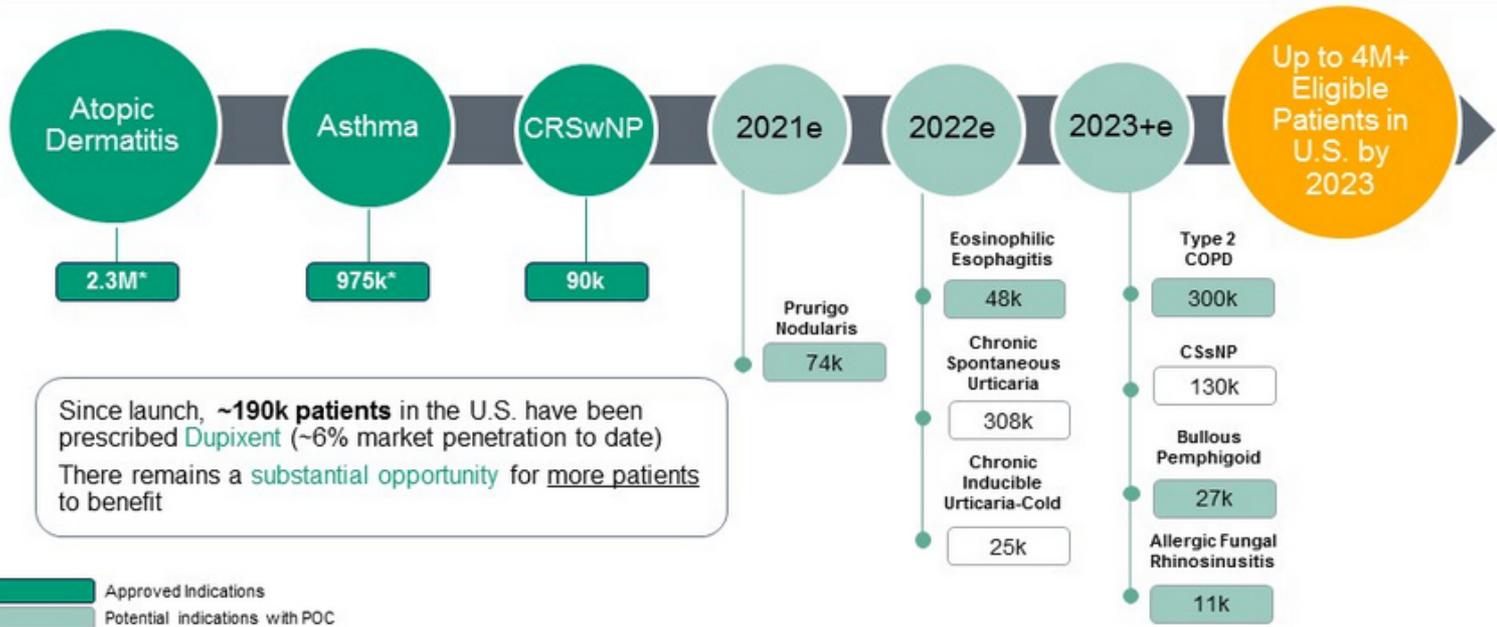
DUPIXENT®: DRIVING LEVERAGE IN COLLABORATION PROFITABILITY

Antibody Collaboration Share of Profits / (Losses)*
(in Millions)



* Share of profits/(losses) are derived from global net product sales of Praluent (up until and including 1Q20), Kevzara, and Dupixent, which are recorded by Sanofi

SUBSTANTIAL PATIENT OPPORTUNITY IN TYPE 2 INFLAMMATORY DISEASES FOR DUPIXENT®



Since launch, ~190k patients in the U.S. have been prescribed Dupixent (~6% market penetration to date)
 There remains a substantial opportunity for more patients to benefit

Approved Indications
 Potential indications with POC
 Other investigational uses
 CRSwNP - Chronic Rhinosinusitis with Nasal Polyps;
 COPD - Chronic Obstructive Pulmonary Disease;
 CSsNP - Chronic Sinusitis without Nasal Polyps

Figures represent U.S. Biologic-eligible target population (all age groups)
 *Target population includes age groups that are not currently approved but in clinical development
 Source - Regeneron Internal Epidemiology Data

This slide contains investigational indications not yet approved by regulatory authorities

ROADMAP TO LEADERSHIP IN ONCOLOGY

COMPETE, ENHANCE, and EXTEND treatment benefits in monotherapy and in combination settings

COMPETE

LEAD in dermatology

First approved anti-PD-1 in advanced **CSCC**

Accepted for **priority review** as first-in-class PD-1 in 2L+ **BCC** (PDUFA 3/3/21)

COMPETE in 1L Non-Small Cell Lung Cancer

Accepted for **priority review** in **PD-L1+ NSCLC** (PDUFA 2/28/21)



* Sanofi records net product sales of LIBTAYO outside the U.S.

REGENERON

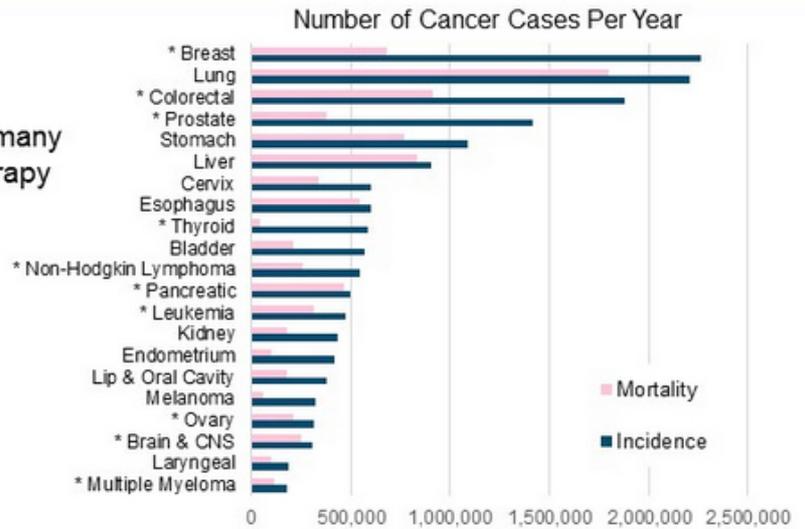
CSCC – Cutaneous Squamous Cell Carcinoma;
BCC – Basal Cell Carcinoma; NSCLC – Non-Small Cell Lung Cancer

This slide contains Investigational Indications not yet approved by regulatory authorities

SIGNIFICANT OPPORTUNITY TO ENHANCE & EXTEND TREATMENT BENEFITS

Despite the advancements in the field, there are many cancers that don't respond to anti PD-1 monotherapy

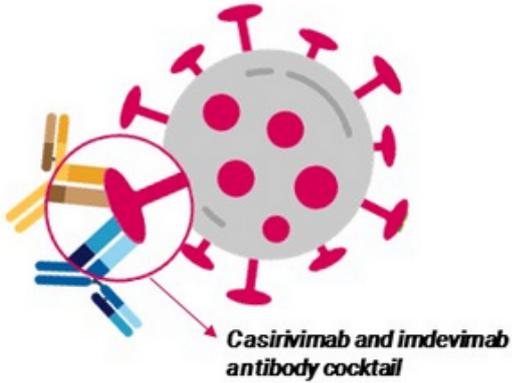
Even for those cancers that are responsive, many patients unfortunately do not benefit



Regeneron's clinical development pipeline of 12+ candidates has potential to address unmet need in the vast majority of the most prevalent cancer types

COVID-19 ANTIBODY COCKTAIL – FIRST COMBINATION THERAPY TO RECEIVE EUA; MANUFACTURING SCALE-UP ONGOING

In 4Q20, the U.S. FDA granted Emergency Use Authorization to the COVID-19 antibody cocktail casirivimab and imdevimab



Casirivimab and imdevimab is an investigational medicine. The safety and efficacy of this drug candidate are still being evaluated by regulatory authorities.

Net Product Sales

- 4Q20 Net Product Sales* of **\$144M** (**\$184M** in FY2020)

Patients

- For recently diagnosed, mild-to-moderate COVID-19 in high-risk patients

Supply/Manufacturing

- U.S. government purchased initial 300K doses
- Increasing global capacity including through Roche collaboration

Clinical Development

- Trials in both treatment and prophylactic settings ongoing, exploring lower doses

*Based on preliminary unaudited fiscal 2020 results

Evinacumab

PDUFA date 2/11/2021

Address Unmet Need in Patients with HoFH

Build Rare Disease Strategy

Apply Cardiometabolic Expertise



Found that patients with loss-of-function mutations in their ANGPTL3 gene have significantly lower levels of key blood lipids, including LDL-C. Evinacumab was designed to replicate this loss-of-function mutation effect to lower LDL-C in patients with HoFH.

Evinacumab is an investigational medicine. The safety and efficacy of this drug candidate are still being evaluated by regulatory authorities.

HoFH - Homozygous Familial Hypercholesterolemia

MULTIPLE POTENTIAL REGULATORY SUBMISSIONS: 2021-2023+

2021	2022		2023+
Casirivimab and Imdevimab COVID-19 [‡]	Odronextemab** (CD20xCD3) B Cell NHL	DUPIXENT* Eosinophilic Esophagitis	Itepekimab (IL-33)* Chronic Obstructive Pulmonary Disease
Fasinumab† Osteoarthritis Pain*	REGN5458 (BCMAxCD3)* Relapsed/Refractory Multiple Myeloma	DUPIXENT* Pediatric Atopic Dermatitis (6 mo-5 yr)	REGN1908-1909 (Feld1) Cat Allergy
Garetosmab FOP*	High-Dose EYLEA Wet AMD and DME	DUPIXENT* Chronic Inducible Urticaria – Cold	REGN5713-5714-5715 (Betv1) Birch Allergy
DUPIXENT* Prurigo Nodularis	LIBTAYO* 2L Cervical Cancer	DUPIXENT* Chronic Spontaneous Urticaria	Pozelimab ± cemdisiran* C5-mediated diseases
DUPIXENT* Pediatric Asthma (6-11 yr)	LIBTAYO* + chemo 1L Non-Small Cell Lung Cancer		DUPIXENT* Bullous Pemphigoid Chronic Obstructive Pulmonary Disease Chronic Sinusitis w/o Nasal Polyposis Allergic Fungal Rhinosinusitis
			PRALUENT Pediatric HeFH
		New Molecule	New Indication

* In collaboration with Sanofi

† Partial clinical hold pending review of additional data

** Partial clinical hold pending changes to clinical protocol

+ In collaboration with Alkermes

‡ In collaboration with Teisai and Mitsubishi Tanabe

‡ Received EUA from FDA for mild to moderate COVID-19 in high-risk non-hospitalized patients

HeFH – Heterozygous Familial hypercholesterolemia; FOP – Fibrodysplasia ossificans progressive

This slide contains investigational products not yet approved by regulatory authorities

BUSINESS SUMMARY

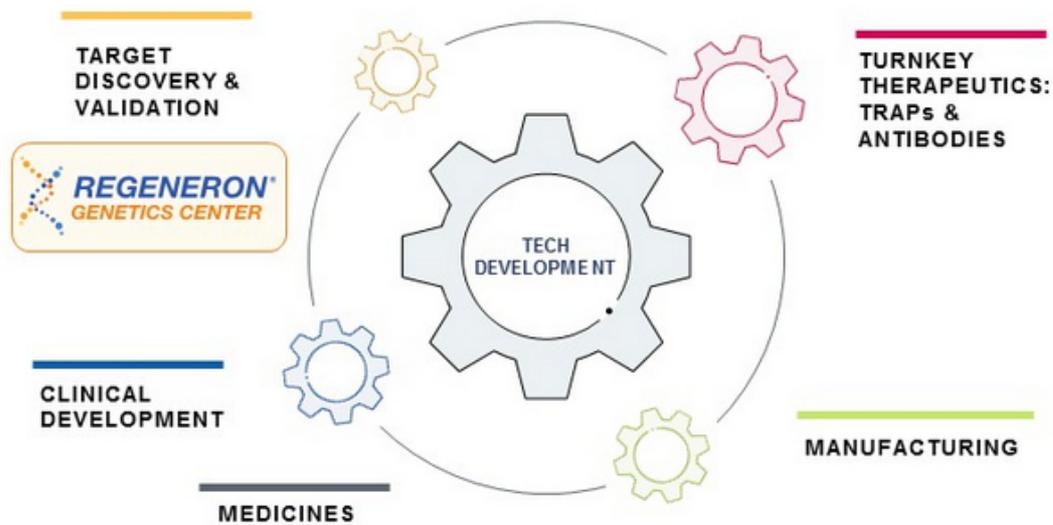
- **2020** was a **transformational** year driven by **growth**, commercial **execution** across the portfolio, **advancements/innovations** in **R&D**, strong financial **performance** and significant corporate initiatives creating **long-term value** for shareholders
- We will maintain commitment to continue the fight against COVID-19
- We are entering a period of anticipated **accelerated growth** with **several launches**
- We continue to **advance** our industry-leading **R&D pipeline** and capabilities across many therapeutic areas including **oncology** and **immunology**

George D. Yancopoulos, MD, PhD
President & Chief Scientific Officer



REGENERON[®]

REGENERON'S PROPRIETARY TECHNOLOGIES REPEATEDLY DELIVER IMPORTANT NEW THERAPEUTICS

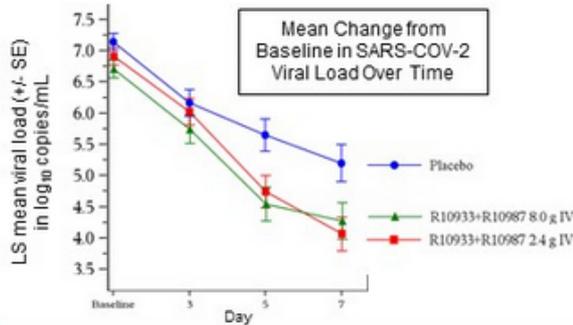


REGENERON technologies *deliver repeated breakthroughs* by addressing limitations and bottlenecks in every step of the drug discovery

THESE TECHNOLOGIES ENABLED RAPID DEVELOPMENT AND ADVANCEMENT OF OUR COVID-19 ANTIBODY COCKTAIL

Virology results

Non-hospitalized study: Statistically significant anti-viral activity against SARS-COV-2 in seronegative patients



Clinical results

Non-hospitalized study: reduction in COVID-19 related medical visits ("MVs", e.g. ER/urgent care visits, hospitalizations)

- 57% reduction in MVs in overall population (n=799)
- 84% reduction in MVs in targeted population (one or more risk factors, seronegative and high viral load)

Basis for the granted EUA

Hospitalized study: passed initial futility analysis

- 22% reduction in risk of death or mechanical ventilation in seronegative patients on low-flow oxygen (n=217; HR: 0.78; 80% CI: 0.51-1.2)

Using **VelociSuite®** technologies, discovery and preclinical validation were compressed to **MONTHS** vs. years

Casirivimab and imdevimab is an investigational medicine. The safety and efficacy of this drug candidate are still being evaluated by regulatory authorities

This project has been funded in whole or in part with Federal funds from BARDA under OT number: HHSO100201700020C

COVID-19 ANTIBODY COCKTAIL: BROAD CLINICAL DEVELOPMENT PROGRAM

Program Status Update



**STUDY 2067 Non-Hospitalized (IV)
Seamless Ph1/2/3**

- EUA granted for mild to moderate COVID-19 in high-risk patients
- Additional data (including lower 1.2g dose) in late 1Q21



**STUDY 2066 Hospitalized (IV)
Seamless Ph1/2/3
No O₂ requirement | Low Flow O₂**

- Passed futility analysis in Low Flow O₂ patients
- UK RECOVERY Trial ongoing (including patients requiring high-flow oxygen or mechanical ventilation)



**STUDY 2069 Household Contacts
Prophylaxis (SQ) Ph3**

- Data expected in 1H21



**STUDY 20145 Dose Ranging
Virology Study**

STUDY 2093 HV Multidose

- Exploring lower doses and repeated dosing

Approaching 15,000 patients enrolled to date

Casirivimab and imdevimab is an investigational medicine. The safety and efficacy of this drug candidate are still being evaluated by regulatory authorities.

This project has been funded in whole or in part with Federal funds from BARDA under OT number: HHSO100201700020C

REGENERON-DISCOVERED, APPROVED AND INVESTIGATIONAL MEDICINES ACROSS A WIDE AND DIVERSE SET OF DISEASES



PHASE 1

- Casirivimab and Imdevimab* (SARS-CoV-2)
- Cemiplimab* (PD-1)
- Oronextamab (CD20xCD3)
- REGN5459* (BCMAxCD3)
- REGN4018* (MUC16xCD3)
- REGN5678 (PSMAxCD28)
- REGN5093 (METxMET)
- REGN6569 (GITR)
- REGN3767 (LAG-3)
- REGN5381 (NPR1)
- REGN5713-5714-5715 (Betv1)
- REGN7257 (IL-2Rg)

PHASE 2

- Casirivimab and Imdevimab* (SARS-CoV-2)
- REGN4461 (LEPR)
- Pozelimumab (C5)
- Garetosmab (Activin-A)
- Evinacumab (ANGPTL3)
- Cemiplimab* (PD-1)
- Oronextamab (CD20xCD3)
- REGN5458* (BCMAxCD3)
- Dupilumab* (IL-4R)
- Sarilumab* (IL-6R)
- REGN1908-1909 (Fcd1)
- Itepekimab* (IL-33)
- Aflibercept (VEGF Trap)

PHASE 3

- Casirivimab and Imdevimab* (SARS-CoV-2)
- Aflibercept (VEGF Trap)
- Dupilumab* (IL-4R)
- Alirocumab (PCSK9)
- Cemiplimab* (PD-1)
- Fasinumab† (NGF)

- CARDIOVASCULAR/
METABOLIC DISEASES
- ONCOLOGY
- IMMUNOLOGY &
INFLAMMATORY DISEASES
- INFECTIOUS
DISEASES
- PAIN
- OPHTHALMOLOGY
- RARE DISEASES

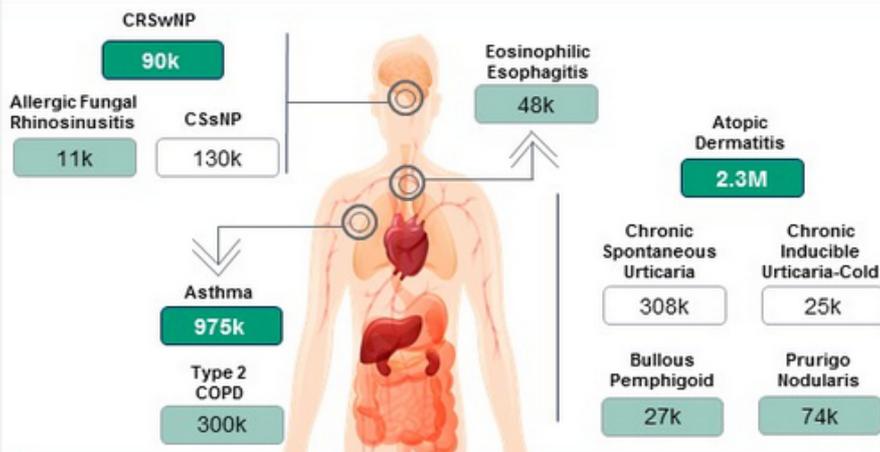
* In collaboration with Sanofi
 † In collaboration with Teva and Mitsubishi Tanabe
 ‡ In collaboration with Roche

As of 3Q20 10-Q filing
 This slide contains investigational products not yet approved by regulatory authorities

PROGRESSING AND EXPANDING DUPIXENT'S CLINICAL DEVELOPMENT PROGRAM FOR MANY TYPE 2 DISEASES

Approved indications address **3+ million** eligible patients in the U.S. with **Type 2** diseases

Dupixent is currently in pivotal trials for **EIGHT** Type 2 diseases; potential to address disease in **~1 million additional** patients



Dupixent clinical trials prove that IL-4 and IL-13 are key drivers of multiple Type 2 inflammatory conditions

- Approved Indications
- Potential indications with POC
- Other investigational uses

This slide contains investigational indications not yet approved by regulatory authorities

Figures represent U.S. Biologic-eligible target population (all age groups)

CRSwNP - Chronic Rhinosinusitis with Nasal Polyps;
COPD - Chronic Obstructive Pulmonary Disease;
CSsNP - Chronic Sinusitis without Nasal Polyps

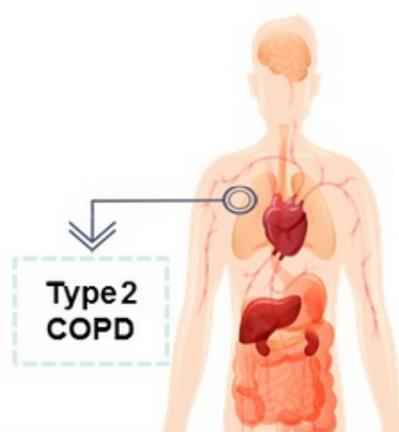
DUPIXENT & ITEPEKIMAB (ANTI IL-33) – TWO-PRONGED APPROACH AGAINST CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Dupixent addresses Type 2 COPD

Achieved prespecified efficacy milestone in interim analysis of first Ph3 study

Itepekimab addresses also non-Type 2 COPD

Ph2 proof-of-concept data indicates potential benefit in former smokers



Dupixent clinical trials prove that IL-4 and IL-13 are key drivers of multiple Type 2 inflammatory conditions

Interleukin-33 (IL-33) is a key driver of lung inflammation

ADDRESSING UNMET NEED IN COPD; PHASE 3 PROGRAMS UNDERWAY

Dupixent addresses Type 2 COPD

- Eosinophils $\geq 300/\mu\text{l}$
- Both former and current smokers
- 2 Ph3 trials ongoing
- Pivotal data expected 2023

Former Smokers
(70% of COPD patients[^])

Non-Type 2

Itepekimab only
~350K patients

Type 2

Dupixent or Itepekimab
>200K patients

Itepekimab addresses also non-Type 2 COPD

- No eosinophil restriction
- Focus on former smokers
- 2 Ph3 trials initiated
- Pivotal data expected 2024

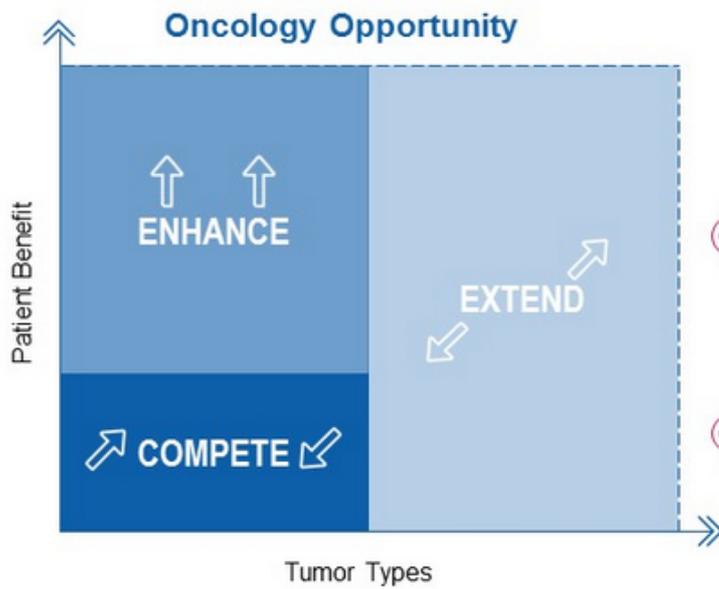
Current Smokers
(30% of COPD patients[^])

Dupixent only
~100K patients

^{*} Dupixent and Itepekimab are developed in collaboration with Sanofi
[^] US epidemiology estimates, patient populations exclude never smokers

This slide contains investigational indications not yet approved by regulatory authorities

ONCOLOGY STRATEGY: ASPIRE TO COMPETE, ENHANCE, & EXTEND



COMPETE: LIBTAYO delivers potentially 'best-in-class' data in tumors responsive to PD-1 monotherapy (e.g., skin cancers & NSCLC*)

- **Compete** in large PD-(L)1 opportunity:
 - >\$25Bn, +25% YoY growth[†]

ENHANCE: Even for PD-1 responsive tumors, more than half of patients do not respond

- **Enhance** responsiveness for these tumors by adding novel therapeutics (e.g., xCD3 & xCD28 Bispecifics)

EXTEND: Most tumor settings have limited responses to checkpoint inhibition

- **Extend** responsiveness for these tumors via addition of novel therapeutics (e.g., xCD3 & xCD28 Bispecifics)

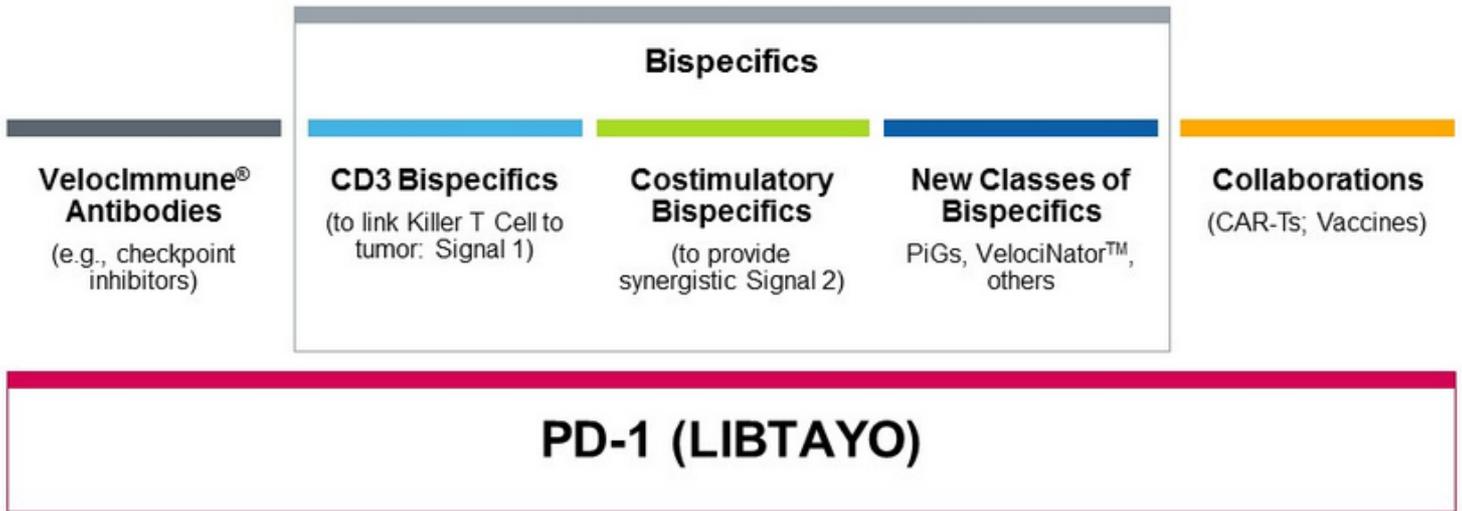
[†]If approved; under priority review with PDUFA date of 02/28/2021

REGENERON[®]

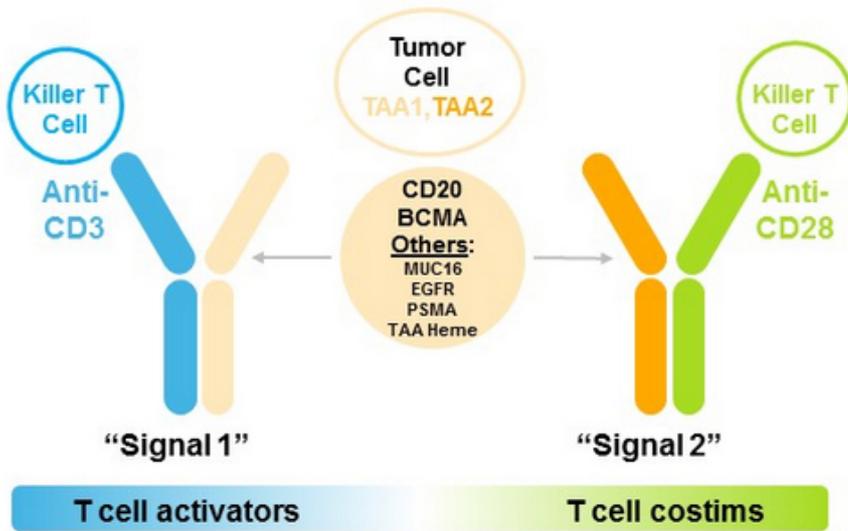
[†]Based on TTM.net product sales data for approved PD-(L)1 agents as of Sept 30, 2020

The use of LIBTAYO in any indication other than advanced CSCC is investigational and has not been fully evaluated by regulatory authorities

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



VELOCI-BI®

VelociGene® and VelocImmune® technologies are fundamental

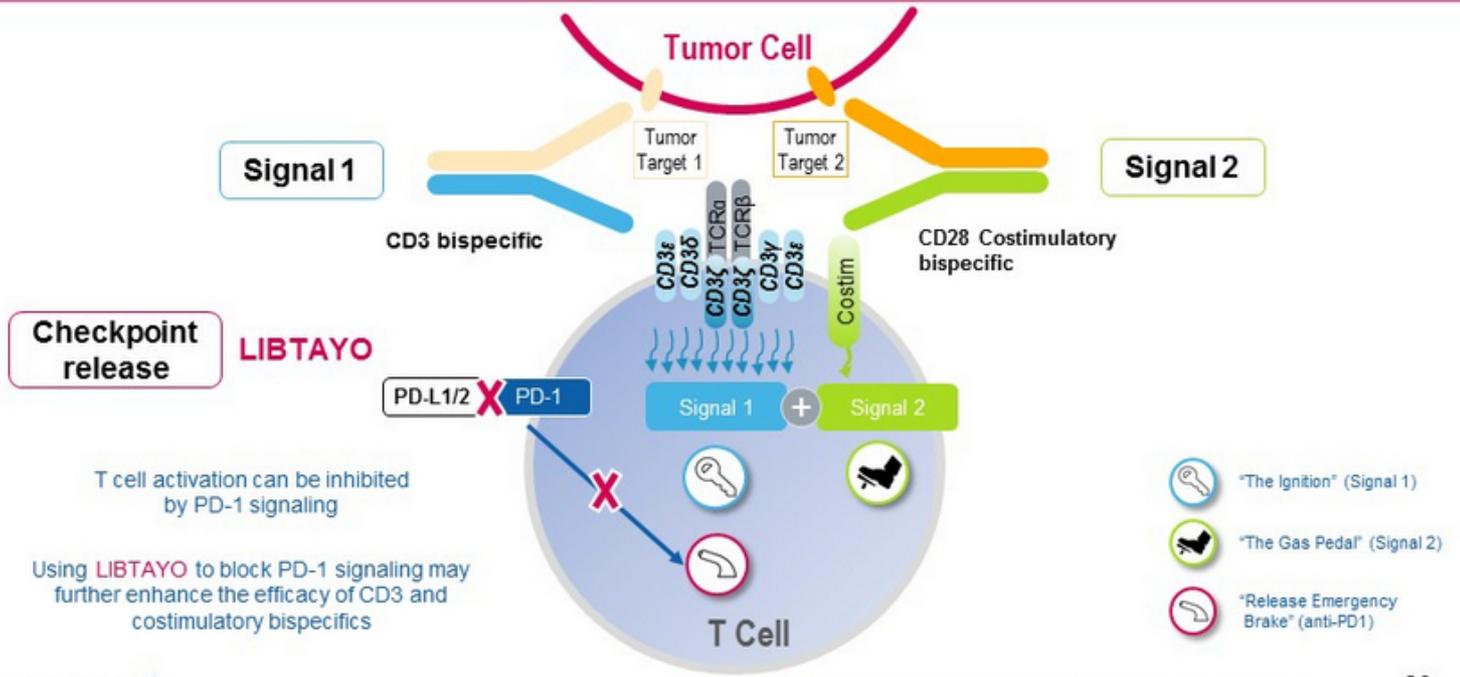
- Foundation for Dupixent, Praluent, Libtayo, REGN-EB3 (Inmazeb), COVID-19 Ab cocktail and other Regeneron-discovered medicines

Next-generation VelocImmune® used to create 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 & CD28 COSTIMULATORY BISPECIFICS ARE OFF-THE-SHELF DRUGS WITH POTENTIAL TO TURN PATIENTS' T CELLS INTO TUMOR CELL KILLERS



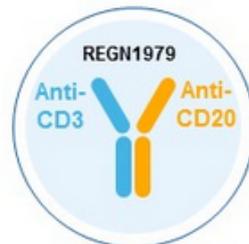
REGENERON®

Our bispecific antibodies are investigational and have not been fully evaluated by regulatory authorities.

ODRONEXTAMAB (CD20XCD3): DEEP AND DURABLE RESPONSES

- A **single bispecific**, effective in both indolent and aggressive lymphomas, including patients who failed CAR-Ts
- **Off-the-shelf** administered in outpatient setting*
- Pivotal Phase 2 enrolling rapidly – robust development plan ahead
- Over 350 patients dosed to date across program
- **Durable responses** (~3.5 years in FL)
- Acceptable safety profile

The Ph1 and Ph2 Odronextamab clinical trials are currently on partial clinical hold. The company has submitted a response to the FDA with the goal of resuming patient enrollment early in the first quarter of 2021.



American Society of Hematology (ASH) Dec 2020 update:

R/R Follicular Lymphoma	R/R DLBCL (CAR-T naïve)	R/R DLBCL (post-CAR-T)
<ul style="list-style-type: none"> • ORR=90%, CR=70% • N=30, doses 5-320 mg • CRs ongoing for up to ~3.5 years 	<ul style="list-style-type: none"> • ORR=55%, CR=55% • N=11, doses 80-320 mg • CRs ongoing for up to 21 months 	<ul style="list-style-type: none"> • ORR=33%, CR=21% • N=24, doses 80-320 mg • All CRs ongoing for up to 20 months

Durable CRs: mDoCR not reached for any indication

- Most frequent Gr ≥ 3 TEAEs (>10% of patients) included anemia (24.3%; Gr 1–3 at baseline in 22%), lymphopenia (20.6%; transient), neutropenia (18.4%; febrile in 2.2%), and hypophosphatemia (18.4%; transient)
- Nine patients (6.6%) had to discontinue odronextamab due to a TEAE, including Gr 1 cytomegalovirus infection (n=1), Gr 1 fatigue (n=1); Gr 2 pneumonia (n=1); Gr 3 hemolysis, fatigue, pneumonia, toxoplasmosis, and TLS (all n=1), plus abscess (n=1; unrelated to study treatment)
- No patients discontinued odronextamab due to CRS or neurotoxicity
- Odronextamab was administered up to 320 mg weekly without DLTs or reaching MTD; no dose-dependent increase in toxicity was observed

REGENERON[®]

R/R – Relapsed/Refractory (heavily pre-treated); DLBCL – Diffuse Large B Cell Lymphoma; ORR – Objective Response Rate; CR – Complete Response; CRS – Cytokine Release Syndrome; TEAE – Treatment-Emergent Adverse Event

*Patients are hospitalized for observation during step-up dosing and the first Q1W dose.

This slide contains investigational products not yet approved by regulatory authorities

REGN5458 (BCMAxCD3): COMPETITIVE ANTI-TUMOR ACTIVITY; POTENTIALLY REGISTRATIONAL PH2 UNDERWAY IN MULTIPLE MYELOMA

REGN5458

Our first BCMAxCD3 bispecific to enter clinic; now in potentially registrational Ph2 dose expansion

- Competitive efficacy profile in a heavily pretreated, vulnerable patient population:
 - 100% refractory to anti-CD38 and at least triple refractory
 - 67% with prior autologous transplant
 - 31% 70 years or older
- Data shown for all patients at all dose levels explored (intention to treat analysis)
 - Deep responses across all dose levels
- Acceptable safety profile
 - No Grade 3+ neurotoxicity or CRS



Phase 1 ASH Dec 2020 update:

R/R Multiple Myeloma

N=49*, doses 3-96 mg

Efficacy:

3-12mg (n=24): **ORR=29%, VGPR or better= 25%**

24-48mg (n=17): **ORR=41%, VGPR or better= 41%**

96mg (n=8): **ORR=63%, VGPR or better= 63%**

- High and deep response rates: 95% of responders achieved VGPR or better
- Among responding patients with ≥ 6 months of follow-up, 83% have ongoing responses for up to 13 months
- Responses occur early and improve over time
- Acceptable tolerability up to 96mg (dose level 6)

REGENERON[®]

*Median of 5 lines of prior systemic therapy, including anti-CD38; patients with primarily medullary and secretory disease
R/R - Relapsed/ Refractory (heavily pre-treated); ORR - Objective Response Rate;
VGPR - Very Good Partial Response; CRS - Cytokine Release Syndrome

Sanofi has opt-in rights for BCMAxCD3 bispecifics
This slide contains investigational products not yet approved by regulatory authorities

COSTIMS COMBINED WITH CD3 BISPECIFICS SHOW ENHANCEMENT IN PRECLINICAL HEMATOLOGICAL TUMOR MODELS

Our CD28 costimulatory bispecifics activate T cells only when they are bridged to cancer cells and after having received the first "recognition" signal from the CD3 engagement

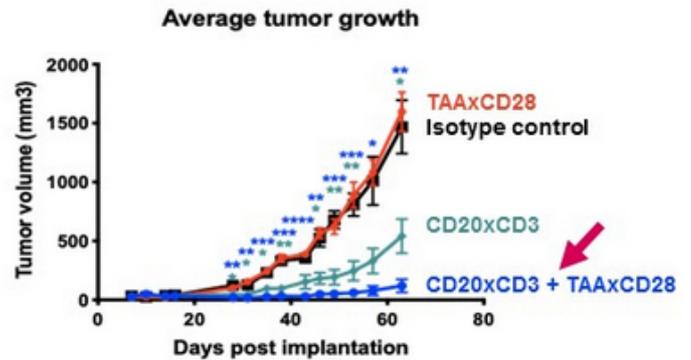


2021: (B cell TAA)xCD28 + odronextamab to enter clinic for B-NHL

2021: (Plasma cell TAA)xCD28 + REGN5458 to enter clinic for Multiple Myeloma

odronextamab + TAAxCD28 costim

odronextamab-resistant DLBCL mouse model



Complementary costimulatory bispecifics could further enhance anti-tumor effects of odronextamab and REGN5458

COSTIM COMBINATIONS: ENHANCE AND EXTEND BENEFITS OF CHECKPOINT INHIBITORS

CD28 COSTIMS IN THE CLINIC (SOLID TUMORS)

REGN5678 (PSMAxCD28)

Evaluating combination with
LIBTAYO

Prostate Cancer
(metastatic castration-resistant)



REGN5668 (MUC16xCD28)

Evaluating combination with either
MUC16xCD3 or **LIBTAYO**

Ovarian Cancer (recurrent)



REGN7075 (EGFRxCD28)

Evaluating combination with
LIBTAYO

Solid tumors, including:
Non-Small Cell Lung Cancer
Cutaneous Squamous Cell Carcinoma
Colorectal Cancer (microsatellite stable)
Triple Negative Breast Cancer



Combinations of our CD3 and CD28 bispecific antibodies and checkpoint inhibitors offer advantage of simultaneously providing multiple signals for activating T cells to kill tumors

Additional CD3 and CD28 bispecifics for all these tumors are being developed

Robust combinatorial potential and flexibility to enhance and extend treatment across many different types of cancers

POWERFUL AND DIVERSE ONCOLOGY PORTFOLIO FOR RATIONAL COMBINATIONS

	VelocImmune® Antibodies	Bispecifics		New Classes	Collaborations
		CD3 Bispecifics	Costims	Bispecifics	Other
EARLY DEVELOPMENT	REGN3767 (LAG-3) Solid/hematologic cancers	REGN5458* (BCMAxCD3) Multiple myeloma	REGN5678 (PSMAxCD28) Prostate cancer	REGN5093 (METxMET) MET-altered NSCLC	
	REGN6569 (GITR) Solid tumors	REGN5459* (BCMAxCD3) Multiple myeloma	REGN5668 (MUC16xCD28) Ovarian cancer	PIG (Peptide in HLA Groove)† Solid tumors	
		REGN4018* (MUC16xCD3) Ovarian cancer	REGN7075 (EGFRxCD28) Solid tumors	ISA101b + LIBTAYO (ISA) HNSCC	
POTENTIALLY PIVOTAL				Voyager-V1 + LIBTAYO (Vyriad) Solid tumors	
		Odronextamab* (CD20xCD3) B cell NHL		RP1 + LIBTAYO (Replimune) CSCC	
	LIBTAYO* NSCLC	LIBTAYO* BCC	LIBTAYO* Cervical	LIBTAYO* Adjuvant CSCC	
APPROVED	LIBTAYO* Advanced CSCC				

Additional bispecifics and combinations expected to enter the clinic in coming months

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* In collaboration with Sanofi
^ Currently on partial clinical hold
† Preclinical

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BROAD COMBINATIONS PIPELINE CONTINUES TO ADVANCE AND GROW

	COMBINATIONS		INDICATIONS	STATUS	
ONGOING	Odronextamab ^A (CD20xCD3)	+	LIBTAYO [*]	Lymphoma	Resubmit modified study design to FDA [*]
	REGN4018 [*] (MUC16xCD3)	+	LIBTAYO [*]	Ovarian cancer	Dose escalation ongoing
	REGN5678 (PSMAxCD28)	+	LIBTAYO [*]	Prostate cancer	Dose escalation ongoing
	REGN3767 (LAG-3)	+	LIBTAYO [*]	Advanced cancers	Expansion cohort enrolling
	REGN5668 (MUC16xCD28)	+	REGN4018 [*] / LIBTAYO [*]	Ovarian cancer	IND open
	REGN6569 (GITR)	+	LIBTAYO [*]	Solid tumors	Enrolling
	REGN7075 (EGFRxCD28)	+	LIBTAYO [*]	Solid tumors	IND open
	UPCOMING	odronextamab (CD20xCD3)	+	B cell/CD28 costim	B-NHL
REGN5458/9 [*] (BCMAxCD3)		+	Plasma cell/CD28 costim	Multiple myeloma	IND filing in 2021
TAAxCD3		+	LIBTAYO [*]	Prostate cancer	IND filing in 2021
odronextamab (CD20xCD3)		+	Standard of Care	B-NHL	Initiating in 2021
REGN5458/9 [*] (BCMAxCD3)		+	Standard of Care	Multiple myeloma	Initiating in 2021

VelocImmune[®] Antibodies

Costim BiSpecifics

CD3 BiSpecifics

Anti-PD-1

REGENERON[®]

^{*} in collaboration with Sanofi
^A Currently on partial clinical hold

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EMPOWERING OUR COLLABORATIONS TO ADVANCE THE NEXT GENERATION OF GENETICS-BASED MEDICINES



World leading human sequencing

- >1M human exomes sequenced
- linked to EHRs
- BIG DATA



VIRAL-BASED GENE THERAPY

- RGC helps discover gene targets for hearing loss
- Developing novel ways to engineer viral-based gene therapy to the ear



RNAi THERAPEUTICS

- RGC helps discover new gene targets
- First-in-class antibody/RNAi combinations (e.g. C5)



CRISPR/Cas9

- First-ever CRISPR-based systemic gene therapy (TTR)
- RGC helps discover new gene targets
- Inventing new technologies for "CRISPR-based gene knock-in"



CAR-T & OTHER CELL BASED THERAPIES

- Technologies to discover new CAR-T targets
- Creating new CARs
- Novel tumor targeting moieties (e.g. PiG Abs)

RGC – Regeneron Genetics Center; EHR – Electronic Health Records; CAR – Chimeric Antigen Receptor; PiG – Peptide in Groove

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KEY UPCOMING MILESTONES (12-18 MONTHS)

EYLEA: Ph2 data readout for High Dose formulation

Dupixent

- Regulatory submissions in pediatric asthma (6-11 years)
- Ph3 data readouts for EoE and Prurigo Nodularis

Libtayo

- Regulatory action in 1L NSCLC (PDUFA 2/28/21) and 2L+ BCC (PDUFA 3/3/21)
- Data anticipated in 1L NSCLC chemo combo and 2L Cervical

Odronextamab (CD20xCD3)

- Complete enrollment in potentially pivotal Phase 2 in NHL
- Initiate OLYMPIA Phase 3 program and evaluate combinations

REGN5458 (BCMAxCD3)

- Complete enrollment in potentially pivotal Phase 2 in Multiple Myeloma
- Evaluate combinations with standard of care and novel agents

New Bispecifics: Potential first data for MUC16xCD3 and PSMAxCD28

Evinacumab (ANGPTL3): Regulatory action for HoFH (PDUFA date 2/11/21)



NSCLC - Non-Small Cell Lung Cancer
BCC - Basal Cell Carcinoma
NHL - Non-Hodgkin's Lymphoma
HoFH - Homozygous Familial hypercholesterolemia
EoE - Eosinophilic Esophagitis

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Leonard S. Schleifer MD, PhD
President & Chief Executive Officer

George D. Yancopoulos, MD, PhD
President & Chief Scientific Officer

Marion McCourt
EVP, Head of Commercial

Robert Landry
EVP, Chief Financial Officer



RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME

REGENERON PHARMACEUTICALS, INC. RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
GAAP R&D	\$ 684.6	\$ 526.0	\$ 1,990.5	\$ 1,897.6
R&D: Non-cash share-based compensation expense	55.9	60.0	169.5	178.0
R&D: Up-front payments related to license and collaboration agreements	—	—	85.0	400.0
Non-GAAP R&D	\$ 628.7	\$ 466.0	\$ 1,736.0	\$ 1,319.6
GAAP SG&A	\$ 326.9	\$ 304.4	\$ 1,042.5	\$ 890.1
SG&A: Non-cash share-based compensation expense	35.9	40.8	114.4	122.3
SG&A: Litigation contingencies and restructuring-related expenses	—	—	28.9	10.0
Non-GAAP SG&A	\$ 291.0	\$ 263.6	\$ 899.2	\$ 757.8
GAAP COGS	\$ 131.0	\$ 115.9	\$ 312.3	\$ 253.8
COGS: Non-cash share-based compensation expense	9.4	16.3	26.6	30.5
COGS: Other	—	—	0.9	—
Non-GAAP COGS	\$ 121.6	\$ 99.6	\$ 284.8	\$ 223.3
GAAP other income (expense), net	\$ (54.8)	\$ 30.0	\$ 176.2	\$ 5.2
Other income/expense: Losses (gains) on investments	37.2	(3.4)	(162.1)	70.7
Interest expense: Other	11.2	—	12.7	—
Non-GAAP other income (expense), net	\$ (6.4)	\$ 26.6	\$ 26.8	\$ 75.9
GAAP net income	\$ 842.1	\$ 669.6	\$ 2,364.0	\$ 1,323.8
Total of GAAP to non-GAAP reconciling items above	149.6	113.7	275.9	811.5
Income tax effect of GAAP to non-GAAP reconciling items	(30.5)	(21.5)	(53.7)	(165.8)
Non-GAAP net income	\$ 961.2	\$ 761.8	\$ 2,586.2	\$ 1,969.5
Non-GAAP net income per share - basic	\$ 9.11	\$ 6.96	\$ 23.88	\$ 18.04
Non-GAAP net income per share - diluted	\$ 8.36	\$ 6.67	\$ 22.01	\$ 17.16
<i>Shares used in calculating:</i>				
Non-GAAP net income per share - basic	105.5	109.4	108.3	109.2
Non-GAAP net income per share - diluted	115.0	114.2	117.5	114.8

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