Regeneron Provides Update on Commercial and Pipeline Progress at J.P. Morgan Healthcare Conference

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TARRYTOWN, N.Y., Jan. 7, 2019 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) will provide a strategic business update to the investor community today at the 37th Annual J.P. Morgan Healthcare Conference. Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer, and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer, will discuss commercial and pipeline progress across the company's portfolio. Slides and a webcast from the presentation may be accessed from the "Investors & Media" page of Regeneron's website at http://investor.regeneron.com/events.cfm.

"Regeneron continues to advance an innovative, homegrown portfolio of marketed and investigational therapies for patients with a range of serious diseases," said Dr. Schleifer. "In 2018, we saw continued strong growth for EYLEA® (aflibercept) Injection in retinal diseases and Dupixent® (dupilumab) Injection in atopic dermatitis, as well as a positive initial reception to our two new launches – Libtayo® (cemiplimab-rwlc) Injection for advanced cutaneous squamous cell carcinoma and Dupixent for asthma. On the development front, we now have more than 20 investigational candidates in human clinical trials and look forward to entering several more this year, as we continue to leverage our cutting-edge science and technology to bring new hope to patients in need."

EYLEA: Strengthening Market Leadership Position

- EYLEA† achieved $4.07 billion in 2018 U.S. net sales (based on preliminary, unaudited fourth quarter 2018 U.S. net sales of $1.07 billion), representing approximately 10 percent growth over 2017.*(1)*
- The U.S. Food and Drug Administration (FDA) has assigned an action date of May 13, 2019 for a new EYLEA indication in diabetic retinopathy.
- Regeneron is also advancing next-generation ophthalmology treatments, such as a high-dose formulation of EYLEA, which is expected to enter clinical trials in 2019.

Dupixent: Continued Growth and New Indications

- Dupixent*† uptake continues to accelerate in both its FDA-approved indications with positive trends in new-to-brand prescriptions following a direct-to-consumer television campaign for moderate-to-severe atopic dermatitis and the 2018 asthma launch.
- Additional important regulatory milestones are expected for Dupixent this year, including a March 11, 2019FDA action date for adolescent atopic dermatitis (age 12-17), a European Medicines Association (EMA) decision for asthma and an FDA filing for chronic rhinosinusitis with nasal polyps.
- In 2019, Regeneron also expects to report results from a Phase 3 study of Dupixent in pediatric patients (age 6-11) with atopic dermatitis and initiate a Phase 2/3 program in Chronic Obstructive Pulmonary Disease. Phase 2 studies in grass allergy and peanut allergy are ongoing, as are combination studies with REGN3500* (IL-33 antibody) in atopic dermatitis and asthma.

Immuno-Oncology Platform

- Regeneron has seen encouraging early uptake from the U.S. launch of Libtayo*† for advanced cutaneous squamous cell carcinoma (CSCC). An EMA decision on Libtayo for advanced CSCC is expected in the first half of 2019, and pivotal and earlier studies in other cancers are continuing to enroll.
- Regeneron's CD20xCD3 bispecific antibody, REGN1979, continues to progress with a potentially pivotal Phase 2 study in Follicular Lymphoma anticipated to begin in the first half of 2019 and a potentially pivotal Phase 2 study in Diffuse Large B-Cell Lymphoma anticipated to begin in the second half of 2019.
- Supported by Regeneron's proprietary science and technology platforms, the company is advancing a new class of costimulatory bispecific antibodies for cancer, with two candidates expected to enter human clinical studies in 2019. These therapies have the potential to be used in combination with other Regeneron immuno-oncology therapies to address difficult-to-treat cancers.
- Earlier today, Regeneron and Sanofi announced a restructuring of their 2015 Immuno-oncology Discovery and Development Agreement. Regeneron and Sanofi have selected two investigational bispecific antibodies (MUC16xCD3 for mucin16-expressing cancers and BCMAxCD3 for multiple myeloma) for continued collaborative development. Regeneron will retain exclusive rights to all its other immuno-oncology programs, including additional xCD3 bispecifics and the new class of costimulatory bispecific antibodies. The bispecific antibody REGN1979 (CD20xCD3) remains exclusively owned by Regeneron.

"Over the last few years, we've made excellent progress with our immuno-oncology portfolio, which includes Libtayo, the first and only approved treatment for advanced cutaneous squamous cell carcinoma, as well as our first clinical-stage bispecific antibody, REGN1979," said Dr. Yancopoulos. "Regeneron now has one approved and five clinical-stage immuno-oncology therapies for a range of targets and modalities, which have the opportunity to be used as monotherapy or in combination with other agents. We're particularly encouraged to be entering two new therapies into the clinic this year from our costimulatory bispecific portfolio. Building on our deep antibody engineering expertise, this new class of bispecific agents has the promise to treat certain cancers where other classes of immunotherapy have proven inadequate."

Additional Research and Development Updates

- In 2018, Regeneron entered four new molecules into the clinic: REGN4018, a MUC16xCD3 bispecific antibody for cancer; REGN4461, a leptin receptor (LEPR) agonist for lipodystrophy and obesity; REGN4659, a CTLA-4 antibody for cancer; and REGN5069, a GFRa3 antibody for pain.
- In 2019, four to six new molecules are expected to enter clinical development, including REGN5458, the BCMAxCD3 bispecific antibody which has already initiated a Phase 1 study, as well as two costimulatory bispecific antibodies for cancer.
- The Regeneron Genetics Center (RGC) continues to make important discoveries, including validating the genetic role of IL-33 in asthma and identifying a new genetic variant that protects against chronic liver disease. The RGC has now sequenced over 500,000 human exomes linked to detailed patient electronic health records and anticipates sequencing up to 500,000 more exomes in 2019.

2019 Financial Guidance[(2)]

Sanofi Collaboration Revenue Reimbursement of Regeneron Commercialization-Related Expenses	**$510 – 560 Million**
Non-GAAP Unreimbursed R&D[(3)(4)]	**$1,590 – 1,710 Million**
Non-GAAP SG&A[(3)(4)]	**$1,500 – 1,600 Million**
Effective Tax Rate	**14 – 16%**
Capital Expenditures	**$410 – 490 Million**

(1)Regeneron records net product sales of EYLEA in the United States. Outside the United States, EYLEA net product sales comprise sales by Bayer in countries other than Japan and sales by Santen Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with an affiliate of Bayer. The Company recognizes its share of the profits (including a percentage on sales in Japan) from EYLEA sales outside the United States within "Bayer collaboration revenue" in its Statements of Operations.

(2)The Company's 2019 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(3)This press release uses non-GAAP unreimbursed R&D and non-GAAP SG&A, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). These 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 estimated income tax effect of reconciling items.

The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. 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 or changes in the fair value of the Company's equity investments) or items that are not associated with normal, recurring operations (such as changes in applicable laws and regulations). Management uses these non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of these and other 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.

(4)A reconciliation of full year 2019 non-GAAP to GAAP financial guidance is included below:

	Projected Range	
(In millions)	**Low**	**High**
GAAP unreimbursed R&D [(5)]	$ 1,855	$ 2,000
R&D: Non-cash share-based compensation expense	(265)	(290)
Non-GAAP unreimbursed R&D	$ 1,590	$ 1,710
GAAP SG&A	$ 1,700	$ 1,830
SG&A: Non-cash share-based compensation expense	(200)	(230)
Non-GAAP SG&A	$ 1,500	$ 1,600

(5) Unreimbursed R&D represents R&D expenses reduced by R&D expense reimbursements from the Company's collaborators and/or customers.

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neuromuscular diseases, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*® which produces optimized fully-human antibodies, and ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Regeneron Forward-Looking Statements and Use of Digital Media
This press release 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 nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, Libtayo® (cemiplimab-rwlc) Injection, fasinumab, evinacumab, 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 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 marketed products, including without limitation EYLEA, Dupixent, Praluent, Kevzara, Libtayo, fasinumab, and evinacumab; the likelihood and timing of achieving any of the anticipated milestones described in this press release; 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 marketed products (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo), 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 the Company'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; 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 to perform 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, including financial guidance relating to Sanofi collaboration revenue, non-GAAP unreimbursed R&D, non-GAAP SG&A, effective tax rate, and capital expenditures; risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation proceedings relating to EYLEA, Dupixent, and Praluent, the ultimate outcome of any such litigation proceeding, 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), 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, 2017 and its Form 10-Q for the quarterly period ended September 30, 2018, including 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 any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is

routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

Non-GAAP Financial Measures
This press release includes amounts that are considered non-GAAP financial measures under U.S. Securities and Exchange Commission rules. Please refer to important information about these measures, as well as a reconciliation of the non-GAAP financial measures included in this press release to the most directly comparable GAAP measures, in the notes above.

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[*] Collaboration program with Sanofi
[†] See full prescribing information

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