

May 5, 2016

Regeneron Reports First Quarter 2016 Financial and Operating Results

- -- First quarter 2016 EYLEA® (aflibercept) Injection U.S. net sales increased 44% to \$781 million versus first quarter 2015
- -- First quarter 2016 EYLEA global net sales(1) increased 44% to \$1.20 billion versus first quarter 2015
- -- Raised estimated full year 2016 EYLEA U.S. net sales growth guidance to 20% 25% over 2015, from the previous guidance of approximately 20%
- -- Positive dupilumab topline results reported from two Phase 3 trials in atopic dermatitis

TARRYTOWN, N.Y., May 5, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2016 and provided a business update.

Financial Highlights

(\$ in millions, except per share data)	Three Months Ended March 31,					
	20)16	20	15	% Change	
EYLEA U.S. net product sales	\$	781	\$	541	44%	
Total revenues	\$	1,201	\$	870	38%	
Non-GAAP net income ⁽²⁾	\$	293	\$	336	(13%)	
Non-GAAP net income per share - diluted ⁽²⁾	\$	2.57	\$	2.88	(11%)	
GAAP net income	\$	166	\$	76	118%	
GAAP net income per share - diluted	\$	1.45	\$	0.66	120%	

[&]quot;The year is off to a very productive start at Regeneron. This quarter, we saw continued strong sales growth with EYLEA, made additional launch progress with Praluent, prepared for the potential launch of sarilumab, and reported important new data across our pipeline," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Our innovative new therapy dupilumab showed positive results across two Phase 3 trials in moderate-to-severe atopic dermatitis, a debilitating disease with very limited treatment options, and we look forward to submitting a Biologics License Application to the U.S. FDA in the third quarter."

Business Highlights

Marketed Product Update

EYLEA® (aflibercept) Injection for Intravitreal Injection

- In the first quarter of 2016, net sales of EYLEA in the United States increased 44% to \$781 million from \$541 million in the first quarter of 2015. Overall distributor inventory levels remained within the Company's one- to two-week targeted range.
- Bayer commercializes EYLEA outside the United States. In the first quarter of 2016, net sales of EYLEA outside of the United States⁽¹⁾ were \$419 million, compared to \$292 million in the first quarter of 2015. In the first quarter of 2016, Regeneron recognized \$146 million from its share of net profit from EYLEA sales outside the United States, compared to \$89 million in the first quarter of 2015.
- A Phase 3 study of EYLEA for the treatment of non-proliferative diabetic retinopathy in patients without diabetic macular edema (DME) was initiated in the first quarter of 2016.

Praluent® (alirocumab) Injection for the Treatment of High Low-Density Lipoprotein (LDL) Cholesterol

- In the first quarter of 2016, net sales of Praluent were \$13 million. Product sales for Praluent are recorded by Sanofi, and the Company shares in any profits or losses from the commercialization of Praluent. Praluent was launched in the United States in the third quarter of 2015 and in certain countries in the European Union commencing in the fourth quarter of 2015.
- In March 2016, the Company and Sanofi reported data from the Phase 3 ODYSSEY ESCAPE study in patients with

heterozygous familial hypercholesterolemia (HeFH) who were undergoing LDL apheresis therapy. The trial achieved its primary endpoint, demonstrating that patients who added Praluent to their existing treatment regimen significantly reduced the frequency of their apheresis therapy by 75%, compared to placebo.

In the first quarter of 2016, the Data Monitoring Committee (DMC) of the ODYSSEY OUTCOMES study for Praluent completed the first interim analysis. In accordance with the protocol, the DMC performed a futility assessment. The DMC recommended the study continue with no changes. Regeneron remains blinded to the actual results of this analysis. The ongoing ODYSSEY OUTCOMES trial is assessing the potential of Praluent to demonstrate cardiovascular benefit.

Pipeline Progress

Regeneron has thirteen product candidates in clinical development. These consist of EYLEA and twelve fully human monoclonal antibodies generated using the Company's *VelocImmune*[®] technology, including four in collaboration with Sanofi. In addition to EYLEA and Praluent, highlights from the antibody pipeline include:

<u>Sarilumab</u>, the Company's antibody targeting IL-6R for rheumatoid arthritis, is currently being studied in the global Phase 3 SARIL-RA program.

- In March 2016, the Company and Sanofi reported results from the 24-week Phase 3 SARIL-RA-MONARCH study in adult patients with active rheumatoid arthritis who were inadequate responders to, intolerant of, or inappropriate candidates for methotrexate (MTX) therapy. The study met its primary endpoint, demonstrating that sarilumab monotherapy was superior to adalimumab monotherapy (marketed by AbbVie Inc. as HUMIRA[®]).
- In December 2015, the U.S. Food and Drug Administration (FDA) accepted for review a Biologics License Application (BLA) for sarilumab, with a target action date of October 30, 2016.

<u>Dupilumab</u>, the Company's antibody that blocks signaling of IL-4 and IL-13, is currently being studied in atopic dermatitis, asthma, nasal polyps, and eosinophilic esophagitis.

- In April 2016, the Company and Sanofi reported that the Phase 3 LIBERTY AD SOLO 1 and SOLO 2 trials evaluating dupilumab in adult patients with inadequately controlled moderate-to-severe atopic dermatitis met their primary endpoints.
- A Phase 2 study of dupilumab in pediatric patients (6-17 years of age) with moderate-to-severe atopic dermatitis is fully enrolled and ongoing.
- A Phase 3 pivotal study of dupilumab in patients with uncontrolled persistent asthma continues to enroll patients.
- A Phase 2 study of dupilumab in eosinophilic esophagitis is ongoing.

<u>Fasinumab</u>, the Company's antibody targeting Nerve Growth Factor (NGF), is currently being studied in patients with pain due to osteoarthritis and lower back pain.

- The Company recently reported results from a Phase 2/3 study evaluating fasinumab in patients with moderate-to-severe osteoarthritis pain of the hip or knee who have a history of inadequate pain relief or intolerance to current analysesic therapies. The study met its primary endpoint at 16 weeks.
- In the first quarter of 2016, the Company initiated a Phase 3 long-term safety and efficacy study of fasinumab in patients with pain due to osteoarthritis of the knee or hip, and this trial is currently enrolling patients.
- In the first quarter of 2016, the Company also initiated a Phase 2b/3 study of fasinumab in chronic lower back pain.

<u>REGN2810</u>, an antibody to programmed cell death protein 1 (PD-1), entered a potentially pivotal clinical study for the treatment of advanced cutaneous squamous cell carcinoma in the second quarter of 2016.

<u>Nesvacumab/aflibercept</u>, a combination product comprised of an antibody to angiopoietin-2 (Ang2) co-formulated with aflibercept for intravitreal injection for use in ophthalmology, entered Phase 2 clinical development for the treatment of neovascular age-related macular degeneration (wet AMD) and DME in the first quarter of 2016.

<u>Evinacumab</u>, an antibody to Angptl-3, was granted orphan-drug designation by the FDA in the first quarter of 2016. Clinical studies are ongoing for the treatment of homozygous familial hypercholesterolemia and severe forms of hyperlipidemia.

Select Upcoming 2016 Milestones

REGN2176-3 (PDGFR-beta Antibody co-formulated with aflibercept)	Report results from Phase 2 study
Praluent	DMC interim analysis of ODYSSEY OUTCOMES trialOngoing launch in additional countries
Sarilumab (IL-6R Antibody)	FDA target action date of October 30, 2016File for regulatory approvals outside the United States
Dupilumab (IL-4R Antibody)	 Report primary endpoint results from Phase 3 CHRONOS study in atopic dermatitis Complete rolling BLA submission for atopic dermatitis in the United States Initiate Phase 3 study in pediatric patients in atopic dermatitis
REGN2810 (PD-1 Antibody)	Report data from Phase 1 study in patients with cancer

Human Genetics Initiative

In the first quarter of 2016, the *New England Journal of Medicine* published a Regeneron Genetics Center paper showing that inactivating mutations of the angiopoeitin-like 4 (ANGPTL4) gene are associated with a significantly reduced risk of coronary artery disease in humans. ANGPTL4 and ANGPTL3 are thought to be related inhibitors of lipoprotein lipase (LPL).

Business Development Update

- In March 2016, the Company and Bayer entered into a collaboration agreement to jointly develop a combination therapy of the Ang2 antibody nesvacumab and aflibercept for the treatment of serious eye diseases.
- In April 2016, the Company and Intellia Therapeutics, Inc. entered into a license and collaboration agreement to advance CRISPR/Cas gene-editing technology for *in vivo* therapeutic development. In addition to the discovery, development and commercialization of new therapies, the companies will focus on technology development of the CRISPR/Cas platform.

First Quarter 2016 Financial Results

Product Revenues: Net product sales were \$784 million in the first quarter of 2016, compared to \$545 million in the first quarter of 2015. EYLEA net product sales in the United States were \$781 million in the first quarter of 2016, compared to \$541 million in the first quarter of 2015.

Total Revenues: Total revenues, which include product revenues described above, increased by 38% to \$1.201 billion in the first quarter of 2016, compared to \$870 million in the first quarter of 2015. Total revenues also include collaboration revenues of \$399 million in the first quarter of 2016, compared to \$297 million in the first quarter of 2015. Collaboration revenues in the first quarter of 2016 increased primarily due to higher reimbursement of the Company's research and development expenses under its antibody collaboration with Sanofi, an increase in the Company's net profit from commercialization of EYLEA outside the United States, and reimbursement of the Company's research and development expenses and amortization of up-front payments received in connection with the Company's July 2015 immuno-oncology collaboration with Sanofi.

Refer to Table 4 for a summary of collaboration revenue.

Research and Development (R&D) Expenses: GAAP R&D expenses were \$470 million in the first quarter of 2016, compared to \$343 million in the first quarter of 2015. The higher R&D expenses in the first quarter of 2016 were principally due to higher development costs primarily related to dupilumab and fasinumab, and higher headcount to support the Company's increased R&D activities, partly offset by lower development costs primarily related to Praluent. In addition, in the first quarter of 2016, R&D-related non-cash share-based compensation expense was \$78 million, compared to \$60 million in the first quarter of 2015.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$290 million in the first quarter of 2016, compared to \$159 million in the first quarter of 2015. The increase was primarily due to higher headcount, and higher commercialization expenses related to EYLEA and Praluent. In addition, in the first quarter of 2016, SG&A-related non-cash share-based compensation expense was \$60 million, compared to \$42 million in the first quarter of 2015.

Cost of Goods Sold (COGS): GAAP COGS was \$79 million in the first quarter of 2016, compared to \$43 million in the first quarter of 2015. COGS primarily consists of royalties as well as costs in connection with producing U.S. EYLEA commercial supplies, and various start-up costs in connection with the Company's Limerick, Ireland commercial manufacturing facility. COGS increased principally due to the increase in U.S. EYLEA net product sales, as well as an increase in Limerick start-up costs.

Income Tax Expense: In the first quarter of 2016, GAAP income tax expense was \$164 million and the effective tax rate was 49.8%, compared to \$201 million and 72.5% in the first quarter of 2015. The effective tax rate for the first quarter of 2016 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the federal statutory rate and the non-tax deductible Branded Prescription Drug Fee, partly offset by the federal tax credit for increased research activities and the domestic manufacturing deduction. The effective tax rate for the first quarter of 2015 was negatively impacted primarily by losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, the non-tax deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities.

The non-GAAP income tax adjustment in the first quarter of 2016 is primarily related to the cash taxes the Company expects to be paid or payable in 2016 in connection with the immuno-oncology up-front payment that the Company received in 2015, partly offset by the excess tax benefit associated with stock option exercises. The non-GAAP income tax adjustment in the first quarter of 2015 was primarily related to the Company's tax credit carry-forwards available for tax purposes and excess tax benefits in connection with stock option exercises.

Non-GAAP and GAAP Net Income: The Company reported non-GAAP net income of \$293 million, or \$2.81 per basic share and \$2.57 per diluted share, in the first quarter of 2016, compared to non-GAAP net income of \$336 million, or \$3.28 per basic share and \$2.88 per diluted share, in the first quarter of 2015.

The Company reported GAAP net income of \$166 million, or \$1.59 per basic share and \$1.45 per diluted share, in the first quarter of 2016, compared to GAAP net income of \$76 million, or \$0.74 per basic share and \$0.66 per diluted share, in the first quarter of 2015.

A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

2016 Financial Guidance⁽³⁾

The Company's updated full year 2016 financial guidance consists of the following components:

EYLEA U.S. net product sales	20% - 25% growth over 2015
	(previously approximately 20% growth over 2015)
Sanofi reimbursement of Regeneron	\$320 million - \$370 million
commercialization-related expenses	
Non-GAAP unreimbursed R&D ⁽²⁾	\$875 million - \$950 million (reaffirmed)
Non-GAAP SG&A ⁽²⁾	\$925 million - \$1.0 billion (reaffirmed)
Cash tax as a % of non-GAAP pre-tax income ⁽²⁾	35% - 45%* (reaffirmed)
Capital expenditures	\$550 million - \$625 million
	(previously \$580 million - \$680 million)

^{* -} Includes a non-recurring tax payment of approximately \$222 million related to the immuno-oncology upfront payment from Sanofi that the Company received in 2015.

- (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.
- This press release uses non-GAAP net income, non-GAAP net income per share, non-GAAP unreimbursed R&D, non-GAAP SG&A, and cash tax as a percentage of non-GAAP pre-tax income, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The Company believes that the presentation of these non-GAAP measures is useful to investors because they exclude, as applicable: (i) non-cash share-based compensation expense, which fluctuates 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; (ii) non-cash interest expense related to the Company's convertible senior notes, since this is not deemed useful in evaluating the Company's operating performance; and (iii) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control. Non-GAAP measures also include income tax expense adjustments to consider the tax effect of reconciling items and an adjustment from GAAP tax expense to the amount of taxes that are paid or payable in cash in respect of the current period. As there has been a significant difference between the Company's effective tax rate and actual cash income taxes paid or payable, GAAP income tax expense is not deemed useful in evaluating the Company's operating performance. Non-GAAP unreimbursed R&D represents non-GAAP R&D expenses reduced by R&D expense reimbursements from the Company's collaboration partners. 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. 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. A reconciliation of the Company's historical GAAP to non-GAAP results is included in Table 3 of this press release.

(3) The Company's 2016 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its first quarter 2016 financial and operating results on Thursday, May 5, 2016, at 8:30 AM. To access this call, dial (888) 771-4371 (U.S.) or (847) 585-4405 (International). A link to the webcast may be accessed from the "Events and Presentations" page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for 30 days.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for high LDL cholesterol, eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the Company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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; the likelihood and timing of achieving any of the anticipated milestones described in this news release; 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® (aflibercept) Injection and Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, REGN2810, nesvacumab/aflibercept, and evinacumab; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA and Praluent), 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 ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; 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 without limitation those relating to EYLEA U.S. net product sales, Sanofi reimbursement of Regeneron commercialization-related expenses, non-GAAP unreimbursed R&D, non-GAAP SG&A, cash tax as a percentage of non-GAAP pre-tax income, and capital expenditures; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. 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, 2015 and its Form 10-Q for the quarterly period ended March 31, 2016. 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 and/or the financial results attached to this press release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, Regeneron has provided reconciliations of historical non-GAAP financial measures.

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TABLE 1

REGENERON PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited) (In thousands)

	 March 31, 2016	 December 31, 2015
Assets:		
Cash and marketable securities	\$ 1,404,389	\$ 1,677,385
Accounts receivable - trade, net	1,450,572	1,152,489
Accounts receivable from Sanofi and Bayer	414,649	315,304
Inventories	303,294	238,578
Deferred tax assets	543,689	461,945
Property, plant, and equipment, net	1,666,391	1,594,120
Other assets	121,476	169,311
Total assets	\$ 5,904,460	\$ 5,609,132
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	\$ 855,412	\$ 760,619
Deferred revenue	909,371	818,166
Facility lease obligations	364,136	364,708
Convertible senior notes	10,459	10,802
Stockholders' equity	3,765,082	3,654,837
Total liabilities and stockholders' equity	\$ 5,904,460	\$ 5,609,132

Three Months Ended March 31,

	warch 31,		
	2016	2015	
Revenues:			
Net product sales	\$ 784,182	\$ 544,573	
Sanofi collaboration revenue	219,694	173,356	
Bayer collaboration revenue	179,592	123,846	
Other revenue	17,381	27,837	
	1,200,849	869,612	
Expenses:			
Research and development	470,112	343,113	
Selling, general, and administrative	289,677	158,991	
Cost of goods sold	78,942	42,570	
Cost of collaboration and contract manufacturing	32,810	41,385	
	871,541	586,059	
Income from operations	329,308	283,553	
Other income (expense), net	843	(7,030)	
Income before income taxes	330,151	276,523	
Income tax expense	(164,415)	(200,502)	
Net income	\$ 165,736	\$ 76,021	
Net income per share - basic	\$ 1.59	\$ 0.74	
Net income per share - diluted	\$ 1.45	\$ 0.66	
Weighted average shares outstanding - basic	104,290	102,227	
Weighted average shares outstanding - diluted	114,228	114,519	
5 5	•	•	

TABLE 3

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

Three Months Ended March 31,

2015 76,021 59,502 42,175 2,082
59,502 42,175
42,175
42,175
*
2,082
3,190
152,568
335,538
3.28
2.88
102,227

- (a) For diluted non-GAAP net income per share calculations, interest expense related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes were excluded since these securities were dilutive. Such interest expense was not material for the three months ended March 31, 2016 and 2015.
- (b) Weighted average shares outstanding includes the dilutive effect, if any, of employee stock options, restricted stock awards, convertible senior notes, and warrants.

TABLE 4

REGENERON PHARMACEUTICALS, INC. COLLABORATION REVENUE (Unaudited) (In thousands)

	 Three Months Ended March 31,		
	2016		2015
Sanofi collaboration revenue:			
Reimbursement of Regeneron research and development expenses	\$ 222,877	\$	169,506
Reimbursement of Regeneron commercialization-related expenses	73,274		8,458
Regeneron's share of losses in connection with commercialization of antibodies	(99,422)		(22,405)
Other	22,965		17,797
Total Sanofi collaboration revenue	219,694	_	173,356
Bayer collaboration revenue:			
Regeneron's net profit in connection with commercialization of EYLEA outside the			
United States	145,835		89,426
Sales milestones	_		15,000
Cost-sharing of Regeneron development expenses	4,639		3,911
Other	29,118		15,509
Total Bayer collaboration revenue	179,592	_	123,846
Total collaboration revenue	\$ 399,286	\$	297,202

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/regeneron-reports-first-quarter-2016-financial-and-operating-results-300263119.html

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