Regeneron Reports Third Quarter 2015 Financial and Operating Results

November 4, 2015

TARRYTOWN, N.Y., Nov. 4, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the third quarter of 2015 and provided an update on development programs.

Financial Highlights

($ in millions, except per share data)	Three Months Ended September 30,		
	2015	2014*	% Change
EYLEA U.S. net product sales	$ 734	$ 445	65 %
Total revenues	$ 1,137	$ 726	57 %
Non-GAAP net income (2)	$ 403	$ 295	37 %
Non-GAAP net income per share - diluted (2)	$ 3.47	$ 2.52	38 %
GAAP net income	$ 210	$ 83	153 %
GAAP net income per share - diluted	$ 1.82	$ 0.73	149 %

** See note (4) below for an explanation of revisions made to certain amounts previously reported for the three months ended September 30, 2014.*

"Our commercial business continues to advance with increased demand for EYLEA, our marketed medicine for serious retinal diseases, and continued launch progress with Praluent, our new therapy for hypercholesterolemia," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Regeneron also continues to progress the next wave of candidates from our strong pipeline, including sarilumab for rheumatoid arthritis, the BLA for which was recently submitted to the U.S. FDA, and dupilumab, which is in Phase 3 trials for atopic dermatitis and asthma."

Business Highlights

EYLEA® (aflibercept) Injection for Intravitreal Injection

- In the third quarter of 2015, net sales of EYLEA in the United States increased 65% to $734 million from $445 million in the third quarter of 2014. Overall distributor inventory levels remained within the Company's one- to two-week targeted range.
- Bayer HealthCare commercializes EYLEA outside the United States. In the third quarter of 2015, net sales of EYLEA outside of the United States(1) were $371 million, compared to $277 million in the third quarter of 2014. In the third quarter of 2015, Regeneron recognized $131 million from its share of net profit from EYLEA sales outside the United States, compared to $85 million in the third quarter of 2014.
- In October 2015, the European Commission granted marketing authorization of EYLEA for the treatment of visual impairment due to myopic choroidal neovascularization.

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

- In July 2015, following the U.S. Food and Drug Administration (FDA) approval of Praluent for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol, the Company and Sanofi commenced their launch of Praluent. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.
- In the third quarter of 2015, net sales of Praluent in the United States were $4 million. Product sales for Praluent are recorded by Sanofi, and the Company shares in any profits or losses from the commercialization of Praluent.
- In October 2015, Praluent was included in the Express Scripts National Preferred Formulary, the nation's largest formulary covering approximately 25 million Americans.
- In September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated.
- In July 2015, the Company and Sanofi reported that the Phase 3 ODYSSEY JAPAN trial met its primary endpoint.
- The Phase 3 ODYSSEY program remains ongoing.

Pipeline Progress

Regeneron has thirteen fully human monoclonal antibodies generated using the Company's *VelocImmune*® technology in clinical development, including five in collaboration with Sanofi(5). In addition to Praluent, highlights from the antibody pipeline include:

Sarilumab, the Company's antibody targeting IL-6R for rheumatoid arthritis, is currently being studied in the global Phase 3 SARIL-RA program. A Biologics License Application (BLA) in the United States was recently submitted to the FDA.

Dupilumab, 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.

- Multiple Phase 3 studies of dupilumab in atopic dermatitis are currently underway. Phase 3 pivotal trials in atopic dermatitis are fully enrolled.
- The Phase 2 study in atopic dermatitis in adolescents and children completed enrollment.
- The second pivotal study of dupilumab in patients with uncontrolled persistent asthma continues to enroll patients.

Fasinumab, an antibody targeting Nerve Growth Factor (NGF), entered Phase 2b/3 clinical development (sixteen-week study) for pain due to osteoarthritis in the second quarter of 2015. In September 2015, the Company and Mitsubishi Tanabe Pharma Corporation (MTPC) entered into a strategic collaboration providing MTPC with exclusive development and commercial rights to fasinumab in Japan and certain other countries in Asia.

REGN2222, an antibody targeting the respiratory syncytial virus (RSV), entered Phase 3 clinical development in the third quarter of 2015.

Third Quarter 2015 Financial Results

Product Revenues: Net product sales were $738 million in the third quarter of 2015, compared to $449 million in the third quarter of 2014. EYLEA net product sales in the United States were $734 million in the third quarter of 2015, compared to $445 million in the third quarter of 2014.

Total Revenues: Total revenues, which include product revenues described above, increased by 57% to $1,137 million in the third quarter of 2015, compared to $726 million in the third quarter of 2014. Total revenues also include collaboration revenues of $382 million in the third quarter of 2015, compared to $269 million in the third quarter of 2014. Collaboration revenues in the third quarter of 2015 increased primarily due to higher reimbursement of the Company's research and development expenses under its antibody collaboration with Sanofi and an increase in the Company's net profit from commercialization of EYLEA outside the United States. Refer to Table 4 for a summary of collaboration revenue.

Research and Development (R&D) Expenses: GAAP R&D expenses were $426 million in the third quarter of 2015, compared to $338 million in the third quarter of 2014. The higher R&D expenses in the third quarter of 2015 were principally due to higher development costs related to dupilumab and higher headcount to support the Company's increased R&D activities. In addition, in the third quarter of 2015, R&D-related non-cash share-based compensation expense was $64 million, compared to $46 million in the third quarter of 2014.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were $210 million in the third quarter of 2015, compared to $144 million in the third quarter of 2014. The increase in SG&A expenses was primarily due to higher headcount and headcount-related costs and higher commercialization expenses related to Praluent. These increases were partly offset by a third quarter 2014 incremental charge related to the Branded Prescription Drug Fee, based on final regulations issued by the Internal Revenue Service (IRS) in July 2014. In addition, in the third quarter of 2015, SG&A-related non-cash share-based compensation expense was $36 million, compared to $21 million in the third quarter of 2014.

Cost of Goods Sold (COGS): GAAP COGS was $67 million in the third quarter of 2015, compared to $34 million in the third quarter of 2014. 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.

Income Tax Expense: GAAP income tax expense was $183 million in the third quarter of 2015, compared to $98 million in the third quarter of 2014. The effective tax rate was 46.5% for the third quarter of 2015, compared to 54.1% for the third quarter of 2014.

Non-GAAP and GAAP Net Income: The Company reported non-GAAP net income of $403 million, or $3.90 per basic share and $3.47 per diluted share, in the third quarter of 2015, compared to non-GAAP net income of $295 million, or $2.93 per basic share and $2.52 per diluted share, in the third quarter of 2014.

The Company reported GAAP net income of $210 million, or $2.04 per basic share and $1.82 per diluted share, in the third quarter of 2015, compared to GAAP net income of $83 million, or $0.83 per basic share and $0.73 per diluted share, in the third quarter of 2014.

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

2015 Financial Guidance(3)

The Company's updated full year 2015 financial guidance consists of the following components:

EYLEA U.S. net product sales	50% - 55% growth over 2014 *(previously 45% - 50% growth over 2014)*
Non-GAAP unreimbursed R&D (2)	$540 million - $560 million *(previously $510 million - $550 million)*
Non-GAAP SG&A (2)	$630 million - $650 million *(previously $610 million - $650 million)*
Cash tax as a % of non-GAAP pre-tax income (2)	16% - 20% *(previously 15% - 22%)*

Capital expenditures	$625 million - $675 million *(previously $675 million - $750 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 HealthCare in countries other than Japan and sales by Santen Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with an affiliate of Bayer HealthCare. The Company recognizes its share of the profits (including a percentage on sales in Japan) from EYLEA sales outside the United States within "Bayer HealthCare collaboration revenue" in its Statements of Operations.

(2) 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) the incremental charge recorded in the third quarter of 2014 related to the issuance of the final IRS regulations that provide guidance on the annual fee imposed by the Patient Protection and Affordable Care Act (the final IRS regulations differed from the temporary regulations issued in 2011 which resulted in the recognition of a catch-up adjustment); (iii) 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; (iv) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control; and (v) income tax expense for 2014, which was principally a non-cash expense due primarily to utilization of net operating loss and tax credit carry-forwards, and deductions related to employee stock option exercises. In 2015, income tax expense adjustments 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 is 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 2015 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(4) Applicable amounts previously reported for the three months ended September 30, 2014 and as of December 31, 2014 have been revised to reflect certain revisions, including a correction to the Company's accounting for certain stock option awards. These revisions consisted entirely of non-cash adjustments and had no impact on the Company's previously reported non-GAAP financial measures, including non-GAAP net income and non-GAAP net income per share. Refer to the Company's Form 10-Q for the quarterly period ended September 30, 2015 (Notes 1 and 4 of the Notes to Condensed Consolidated Financial Statements) for further details.

(5) In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its third quarter 2015 financial and operating results on Wednesday, November 4, 2015, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (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; 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 Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab and REGN2222; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA® (aflibercept) Injection 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, 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, 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, 2014 and its Form 10-Q for the quarterly period ended September 30, 2015. 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.

TABLE 1

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

	September 30, 2015	December 31, 2014*
Assets:		
Cash and marketable securities	$ 1,576,968	$ 1,360,634
Accounts receivable - trade, net	1,088,207	739,379
Accounts receivable from Sanofi and Bayer HealthCare	351,108	236,993
Inventories	190,668	128,861
Deferred tax assets	406,764	315,416
Property, plant, and equipment, net	1,475,123	974,309
Other assets	94,077	82,080
Total assets	$ 5,182,915	$ 3,837,672
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 656,170	$ 619,083
Deferred revenue	833,337	209,274
Facility lease obligations	365,818	312,291
Convertible senior notes	30,723	146,773
Stockholders' equity	3,296,867	2,550,251
Total liabilities and stockholders' equity	$ 5,182,915	$ 3,837,672

** Certain revisions have been made to the previously reported December 31, 2014 amounts. See note (4) above.*

TABLE 2

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014*	2015	2014*
Revenues:				
Net product sales	$ 737,562	$ 448,844	$ 1,939,954	$ 1,229,244
Sanofi collaboration revenue	224,735	132,925	593,201	406,028
Bayer HealthCare collaboration revenue	157,596	135,853	415,679	358,460
Technology licensing and other revenue	17,529	8,166	56,817	23,496
	1,137,422	725,788	3,005,651	2,017,228
Expenses:				
Research and development	425,924	337,728	1,159,367	919,608
Selling, general, and administrative	209,993	144,003	543,572	343,960
Cost of goods sold	67,199	33,655	170,624	91,073
Cost of collaboration and contract manufacturing (COCM)	41,884	21,938	111,254	54,471
	745,000	537,324	1,984,817	1,409,112
Income from operations	392,422	188,464	1,020,834	608,116
Other income (expense):				
Investment and other income	2,603	2,591	4,533	5,205
Interest expense	(1,715)	(9,232)	(10,632)	(31,022)
Loss on extinguishment of debt	(21)	—	(16,927)	(10,787)
	867	(6,641)	(23,026)	(36,604)
Income before income taxes	393,289	181,823	997,808	571,512
Income tax expense	(182,891)	(98,448)	(516,746)	(323,481)
Net income	$ 210,398	$ 83,375	$ 481,062	$ 248,031
Net income per share - basic	$ 2.04	$ 0.83	$ 4.68	$ 2.47
Net income per share - diluted	$ 1.82	$ 0.73	$ 4.18	$ 2.19
Weighted average shares outstanding - basic	103,348	100,796	102,825	100,325
Weighted average shares outstanding - diluted	115,944	117,423	115,144	113,203

** Certain revisions have been made to the previously reported amounts for the three and nine months ended September 30, 2014. See note (4) above.*

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 September 30,		Nine Months Ended September 30,	
	2015	2014*	2015	2014*
GAAP net income	$ 210,398	$ 83,375	$ 481,062	$ 248,031
Adjustments:				
R&D: Non-cash share-based compensation expense	63,590	46,049	183,137	133,167
SG&A: Non-cash share-based compensation expense	36,481	21,173	110,814	73,620
SG&A: Branded Prescription Drug Fee incremental charge	—	40,600	—	40,600
COGS and COCM: Non-cash share-based compensation expense	2,571	897	6,706	1,945
Interest expense: Non-cash interest related to convertible senior notes	194	4,575	2,777	15,446
Other expense: Loss on extinguishment of debt	21	—	16,927	10,787
Non-cash income taxes	89,616	98,448	275,521	323,481
Non-GAAP net income	$ 402,871	$ 295,117	$ 1,076,944	$ 847,077

Non-GAAP net income per share - basic	$ 3.90	$ 2.93	$ 10.47	$ 8.44
Non-GAAP net income per share - diluted [(a)]	$ 3.47	$ 2.52	$ 9.24	$ 7.22
Shares used in calculating:				
Non-GAAP net income per share - basic	103,348	100,796	102,825	100,325
Non-GAAP net income per share - diluted [(b)]	116,014	117,642	116,559	117,919

** Certain revisions have been made to the amounts previously reported for the three and nine months ended September 30, 2014. See note (4) above.*

(a) For diluted non-GAAP net income per share calculations, excludes $1.3 million and $4.4 million of interest expense for the three and nine-month periods ended September 30, 2014, respectively, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive. Such amounts were not material for the three and nine-month periods ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Sanofi collaboration revenue:				
Regeneron's share of losses in connection with commercialization of antibodies	$ (74,865)	$ (12,830)	$ (143,583)	$ (17,125)
Reimbursement of Regeneron research and development expenses	223,698	141,758	604,720	408,903
Reimbursement of Regeneron commercialization-related expenses	53,341	1,688	89,145	7,062
Other	22,561	2,309	42,919	7,188
Total Sanofi collaboration revenue	224,735	132,925	593,201	406,028
Bayer HealthCare collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	130,510	85,351	326,567	213,291
Sales milestones	—	30,000	15,000	75,000
Cost-sharing of Regeneron development expenses	3,335	4,912	15,636	27,892
Other	23,751	15,590	58,476	42,277
Total Bayer HealthCare collaboration revenue	157,596	135,853	415,679	358,460
Total collaboration revenue	$ 382,331	$ 268,778	$ 1,008,880	$ 764,488

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