Regeneron Reports Second Quarter 2014 Financial and Operating Results

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TARRYTOWN, N.Y., Aug. 5, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial results for the second quarter of 2014 and provided an update on development programs.

Financial Highlights

($ in millions, except per share data)	Three months ended June 30,		
	2014	2013	% Change
EYLEA U.S. net product sales	$ 415	$ 330	26%
Total revenues	$ 666	$ 458	45%
Non-GAAP net income	$ 289	$ 198	46%
Non-GAAP net income per share - diluted	$2.47	$1.73	43%
GAAP net income	$ 93	$ 87	7%
GAAP net income per share - diluted	$0.82	$0.79	4%

"Regeneron continued to make progress across all aspects of our business, delivering continued growth and another strong quarter," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In the last two months alone, we received approval for an additional indication for EYLEA in diabetic macular edema and reported positive clinical results from our late-stage portfolio with alirocumab in hypercholesterolemia, dupilumab in atopic dermatitis and sarilumab in rheumatoid arthritis."

Business Highlights

EYLEA® (aflibercept) Injection for Intravitreal Injection

- In the second quarter of 2014, net sales of EYLEA in the United States increased 26% to $415 million from $330 million in the second quarter of 2013. Net sales in the second quarter of 2013 were impacted by a modest decrease in distributor inventory. Excluding these changes in inventory, underlying demand for EYLEA in the second quarter of 2014 in the United States increased by approximately 22% year over year.
- Bayer HealthCare LLC commercializes EYLEA outside the United States. In the second quarter of 2014, net sales of EYLEA outside of the United States(1) were $247 million, compared to $102 million in the second quarter of 2013. In the second quarter of 2014, Regeneron recognized $67 million from its share of net profit from EYLEA sales outside the United States, compared to $19 million in the second quarter of 2013 (each after repayment of $15 million in development expenses).
- In July 2014, the FDA approved EYLEA for the treatment of diabetic macular edema (DME).
- Applications for marketing approval in the European Union (EU) and Japan for EYLEA in DME have also been submitted. In June 2014, EYLEA was recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) for the treatment of DME. The decision of the European Commission is expected in the second half of 2014.
- In July 2014, the Company reported that two-year results from the Phase 3 VIVID-DME trial of EYLEA for the treatment of DME demonstrated sustained improvement in vision. The 52-week results (primary analyses) from this study have been previously reported.
- The target date for an FDA decision on the supplemental BLA for U.S. regulatory approval of EYLEA for the treatment of macular edema following branch retinal vein occlusion (BRVO) is October 23, 2014. In June 2014, Bayer HealthCare submitted an application to the European Medicines Agency (EMA) seeking marketing authorization in the EU for EYLEA for the treatment of macular edema following BRVO.
- In the Phase 3 SIGHT trial of EYLEA in wet age-related macular degeneration (AMD) patients in China, EYLEA 2 milligrams (mg) dosed every two months achieved the primary endpoint of a significantly greater improvement in best-corrected visual acuity (BCVA) from baseline compared to photodynamic therapy (PDT) at 28 weeks (14 letters for EYLEA vs. 3.9 letters for PDT, *p less than 0.0001*). The safety results were consistent with results from prior studies in wet AMD.

Pipeline Progress

Regeneron has fourteen fully human monoclonal antibodies generated using the Company's *VelocImmune*® technology in clinical development, including six in collaboration with Sanofi. Highlights from the late-stage antibody pipeline include:

Alirocumab, the Company's antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) to lower LDL-cholesterol (LDL-C), is currently being evaluated in the global Phase 3 ODYSSEY program. In July 2014, the Company and Sanofi reported positive, top-line results from nine Phase 3 ODYSSEY studies. All nine studies (ODYSSEY LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II and ALTERNATIVE) met their primary efficacy endpoint of a greater percent reduction from baseline in LDL-C at week 24, compared to placebo or active comparator. Alirocumab was generally well tolerated in the nine ODYSSEY trials. The most common adverse events were nasopharyngitis and upper respiratory tract infections, which were generally balanced between treatment groups. Injection site reactions occurred more often in the alirocumab group compared to placebo. Serious adverse events and deaths were generally balanced between treatment groups as were other key adverse events including musculoskeletal, neurocognitive, and liver-related events. Data from these nine studies, along with the previously announced positive data from the ODYSSEY MONO study, will form the basis for the Company's initial global regulatory filings. The ODYSSEY program is expected to enroll more than 23,500 patients across 14 clinical trials of alirocumab both in combination with other lipid-lowering agents and as monotherapy. All of the trials in the ODYSSEY program are studying every two-week dosing of alirocumab, except for CHOICE I and CHOICE II, which are studying every four-week dosing. The Phase 3 ODYSSEY program remains ongoing. This includes three additional studies, CHOICE I, CHOICE II and OUTCOMES, which are expected to report primary endpoints in 2015 and beyond.

In July 2014, the Company and Sanofi also announced that the companies intend to use an FDA rare pediatric disease priority review voucher in connection with the planned BLA submission for alirocumab. The priority review voucher entitles the holder to designate a human drug application for priority review, which provides for an expedited 6-month review from the filing date instead of the standard 10-month review.

Sarilumab, the Company's antibody targeting IL-6R for rheumatoid arthritis, is currently continuing enrollment in the global Phase 3 SARIL-RA program. In June 2014, data from the first positive Phase 3 trial in the SARIL-RA program, MOBILITY, were presented at the annual meeting of The European League Against Rheumatism (EULAR) in Paris, France.

Dupilumab, the Company's antibody that blocks signaling of IL-4 and IL-13 for allergic diseases, is currently in Phase 2b testing. In July 2014, positive results from four Phase 1 and Phase 2 studies of dupilumab in adults with moderate-to-severe atopic dermatitis were published in the *New England Journal of Medicine*. In addition, positive results from the Phase 2b trial of dupilumab in atopic dermatitis were reported in July 2014. A Phase 2b trial of dupilumab in asthma and a Phase 2a trial in nasal polyposis are both fully enrolled.

Second Quarter 2014 Financial Results

Product Revenues: Net product sales were $418 million in the second quarter of 2014, compared to $334 million in the second quarter of 2013. EYLEA net product sales in the United States were $415 million in the second quarter of 2014, compared to $330 million in the second quarter of 2013.

Total Revenues: Total revenues increased by 45% to $666 million in the second quarter of 2014, compared to $458 million in the second quarter of 2013. Total revenues include collaboration revenues of $240 million in the second quarter of 2014, compared to $117 million in the second quarter of 2013. Collaboration revenues increased primarily due to an increase in the Company's net profit from commercialization of EYLEA outside the United States and higher reimbursement of antibody development costs by Sanofi. Collaboration revenues in the second quarter of 2014 also included a $15 million sales milestone earned from Bayer HealthCare. Collaboration revenues in the second quarter of 2013 were reduced by two $10 million upfront payments made to Sanofi to acquire full rights to antibodies to PDGF and antibodies to Ang2 in ophthalmology.

Refer to Table 4 for a summary of collaboration revenue.

Research and Development (R&D) Expenses: GAAP R&D expenses were $295 million in the second quarter of 2014, compared to $187 million in the second quarter of 2013. The increase was principally due to increased R&D activities, primarily related to the Company's antibody collaboration with Sanofi, higher R&D headcount, and higher non-cash share-based compensation expense. In the second quarter of 2014, R&D-related non-cash share-based compensation expense was $44 million, compared to $28 million in the second quarter of 2013.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were $102 million in the second quarter of 2014, compared to $72 million in the second quarter of 2013. The increase was primarily due to higher non-cash compensation expense, higher legal costs resulting primarily from patent enforcement, and higher commercialization-related expenses. In the second quarter of 2014, SG&A-related non-cash share-based compensation expense was $26 million, compared to $16 million in the second quarter of 2013.

Income Tax Expense: GAAP income tax expense was $110 million in the second quarter of 2014, compared to $60 million in the second quarter of 2013. The effective tax rate was 54.3% for second quarter of 2014, compared to 40.8% for the second quarter of 2013. The effective tax rate for the second quarter of 2014 was negatively impacted by losses incurred in foreign jurisdictions with rates lower than the federal statutory rate and expiration at the end of 2013 of the federal tax credit for increased research activities. Due to the amounts of the Company's net operating loss and tax credit carry-forwards available for tax purposes, the Company does not currently pay significant cash income taxes.

Other Income (Expense): GAAP other expense includes an $11 million loss on extinguishment of debt in the second quarter of 2014 related to the conversion of $61 million principal amount of the $400 million aggregate principal amount of the Company's

1.875% convertible senior notes.

Non-GAAP and GAAP Net Income: The Company reported non-GAAP net income of $289 million, or $2.88 per basic share and $2.47 per diluted share, in the second quarter of 2014, compared to non-GAAP net income of $198 million, or $2.02 per basic share and $1.73 per diluted share, in the second quarter of 2013.

The Company reported GAAP net income of $93 million, or $0.92 per basic share and $0.82 per diluted share, in the second quarter of 2014, compared to GAAP net income of $87 million, or $0.89 per basic share and $0.79 per diluted share, in the second quarter of 2013.

Cash Position: At June 30, 2014, cash and marketable securities totaled $1.37 billion, compared to $1.08 billion at December 31, 2013.

2014 Financial Guidance

The Company's updated full year 2014 financial guidance consists of the following components:

EYLEA U.S. net product sales	$1.7 billion - $1.8 billion (*reaffirmed*)
Non-GAAP unreimbursed R&D[(2)]	$470 million - $510 million *(previously $425 million - $475 million)*
Non-GAAP SG&A[(2)]	$310 million - $350 million *(previously $330 million - $380 million)*
Capital expenditures	$350 million - $425 million *(reaffirmed)*

(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 LLC in countries other than Japan and sales by Santen Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with a Japanese subsidiary of Bayer HealthCare LLC. 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, and non-GAAP SG&A, 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, (iii) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control, and (iv) income tax expense, since the Company does not currently pay significant cash income taxes due primarily to the utilization of net operating loss and tax credit carry-forwards; therefore, 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 GAAP to non-GAAP results is included in Table 3 of this press release.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its second quarter 2014 financial and operating results on Tuesday, August 5, 2014, 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

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 eye diseases, colorectal cancer, and a rare inflammatory condition, and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

Forward-Looking Statement

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron, 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 EYLEA for the treatment of macular edema following branch retinal vein occlusion, alirocumab (including the impact (if any) of the planned use of the U.S. Food and Drug Administration's Rare Pediatric Disease Priority Review Voucher in connection with the anticipated Biologics License Application submission for alirocumab), sarilumab, and dupilumab; ongoing regulatory obligations and oversight impacting Regeneron's 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; 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, 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, 2013 and its Form 10-Q for the quarterly period ended June 30, 2014. 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.

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 these measures.

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TABLE 1

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

	June 30, 2014	December 31, 2013
Assets:		
Cash and marketable securities	$1,367,727	$ 1,083,875
Accounts receivable - trade, net	664,075	787,071
Accounts receivable from Sanofi and Bayer HealthCare	229,849	167,896
Inventories	109,897	70,354
Deferred tax assets	307,658	276,555
Property, plant, and equipment, net	707,321	526,983
Other assets	69,551	38,279
Total assets	$3,456,078	$ 2,951,013
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 298,353	$ 262,226
Deferred revenue	271,037	231,199
Facility lease obligations	235,585	185,197
Convertible senior notes	282,261	320,315
Stockholders' equity	2,368,842	1,952,076

Total liabilities and stockholders' equity	$3,456,078	$ 2,951,013

TABLE 2

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

	Three months ended June 30,		Six months ended June 30,	
	2014	**2013**	**2014**	**2013**
Revenues:				
Net product sales	$ 418,022	$ 333,893	$ 780,400	$ 652,633
Sanofi collaboration revenue	142,595	85,529	273,103	184,802
Bayer HealthCare collaboration revenue	97,295	31,104	222,607	46,011
Technology licensing and other revenue	7,788	7,116	15,330	13,860
	665,700	457,642	1,291,440	897,306
Expenses:				
Research and development	294,501	187,463	581,880	367,762
Selling, general, and administrative	102,414	72,463	211,264	149,723
Cost of goods sold	29,945	27,283	57,418	55,304
Cost of collaboration manufacturing	16,434	12,330	32,533	13,364
	443,294	299,539	883,095	586,153
Income from operations	222,406	158,103	408,345	311,153
Other income (expense):				
Investment income	1,677	954	2,614	1,410
Interest expense	(10,177)	(11,365)	(21,790)	(23,040)
Loss on extinguishment of debt	(10,787)	—	(10,787)	—
	(19,287)	(10,411)	(29,963)	(21,630)
Income before income taxes	203,119	147,692	378,382	289,523
Income tax expense	(110,384)	(60,316)	(220,204)	(103,273)
Net income	$ 92,735	$ 87,376	$ 158,178	$ 186,250
Net income per share - basic	$ 0.92	$ 0.89	$ 1.58	$ 1.91
Net income per share - diluted	$ 0.82	$ 0.79	$ 1.40	$ 1.69
Weighted average shares outstanding - basic	100,391	97,700	100,085	97,289
Weighted average shares outstanding - diluted	113,032	111,060	113,121	110,305

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 June 30,		Six months ended June 30,	
	2014	**2013**	**2014**	**2013**
GAAP net income	$ 92,735	$ 87,376	$ 158,178	$ 186,250
Adjustments:				
R&D: Non-cash share-based compensation expense	43,814	27,722	87,118	54,484
SG&A: Non-cash share-based compensation expense	26,167	16,344	63,754	42,130
COGS: Non-cash share-based compensation expense	531	376	1,048	859

Interest expense: Non-cash interest related to convertible senior notes	4,947	5,535	10,871	11,316
Other expense: Loss on extinguishment of debt	10,787	—	10,787	—
Income tax expense	110,384	60,316	220,204	103,273
Non-GAAP net income	$ 289,365	$ 197,669	$ 551,960	$ 398,312
Non-GAAP net income per share - basic	$ 2.88	$ 2.02	$ 5.51	$ 4.09
Non-GAAP net income per share - diluted [a]	$ 2.47	$ 1.73	$ 4.70	$ 3.50
Shares used in calculating:				
Non-GAAP net income per share - basic	100,391	97,700	100,085	97,289
Non-GAAP net income per share - diluted [b]	117,805	115,261	118,027	114,711

[a] For diluted non-GAAP net income per share calculations, excludes $1.4 million and $1.8 million, respectively, of interest expense for the three-month periods ended June 30, 2014 and 2013, and $3.2 million and $3.7 million, respectively, of interest expense for the six-month periods ended June 30, 2014 and 2013, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive.

[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 June 30,		Six months ended June 30,	
	2014	**2013**	**2014**	**2013**
Sanofi collaboration revenue:				
Regeneron's share of losses in connection with commercialization of ZALTRAP®	$ (692)	$ (8,216)	$ (3,904)	$ (16,005)
Regeneron's share of antibody commercialization expenses	(4,295)	—	(4,295)	—
Reimbursement of Regeneron research and development expenses	139,231	107,266	267,145	208,979
Up-front payments to Sanofi for acquisition of rights related to two antibodies	—	(20,000)	—	(20,000)
Other	8,351	6,479	14,157	11,828
Total Sanofi collaboration revenue	142,595	85,529	273,103	184,802
Bayer HealthCare collaboration revenue:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	66,781	19,055	127,940	25,417
Sales milestones	15,000	—	45,000	—
Cost-sharing of Regeneron development expenses	2,120	3,629	22,980	9,466
Other	13,394	8,420	26,687	11,128
Total Bayer HealthCare collaboration revenue	97,295	31,104	222,607	46,011
Total collaboration revenue	$ 239,890	$ 116,633	$ 495,710	$ 230,813

SOURCE Regeneron Pharmaceuticals, Inc.