Regeneron Reports First Quarter 2014 Financial and Operating Results

May 8, 2014

TARRYTOWN, N.Y., May 8, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ:REGN) today announced financial results for the first quarter of 2014 and provided an update on development programs.

Financial Highlights

($ in millions, except per share data)	Three months ended March 31,		
	2014	**2013**	**% Change**
EYLEA U.S. net product sales	$ 359	$ 314	14%
Total revenues	$ 626	$ 440	42%
Non-GAAP net income	$ 263	$ 201	31%
Non-GAAP net income per share - diluted	$ 2.26	$ 1.78	27%
GAAP net income	$ 65	$ 99	(34%)
GAAP net income per share - diluted	$ 0.58	$ 0.90	(36%)

Business Highlights

EYLEA® (aflibercept) Injection for Intravitreal Injection

- In the first quarter of 2014, net sales of EYLEA in the United States increased 14% to $359 million from $314 million in the first quarter of 2013. Net sales in the first quarter of 2014 were negatively impacted by a decrease in distributor inventory, while net sales in the first quarter of 2013 benefited from an increase in distributor inventory. Excluding these changes in inventory, underlying demand for EYLEA in the United States increased by over 25% year over year.
- Bayer HealthCare LLC commercializes EYLEA outside the United States. In the first quarter of 2014, net sales of EYLEA outside of the United States(1) were $218 million, compared to $62 million in the first quarter 2013. In the first quarter of 2014, Regeneron recognized $61 million from its share of net profit from EYLEA sales outside the United States, after repayment of $14 million in development expenses.
- The target date for an FDA decision on the supplemental BLA for U.S. regulatory approval of EYLEA for the treatment of diabetic macular edema (DME) is August 18, 2014. Applications for marketing approval in the European Union and Japan for EYLEA in DME have also been submitted.
- In February 2014, the Company reported positive two year results from the Phase 3 VISTA-DME trial for the treatment of DME.
- During the first quarter of 2014, the Company's supplemental BLA for U.S. regulatory approval of EYLEA for the treatment of macular edema following branch retinal vein occlusion (BRVO) was accepted by the FDA; the target date for an FDA decision on this supplemental BLA is October 23, 2014.
- In February 2014, the Company initiated a Phase 1 trial of EYLEA in combination with REGN2176, an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), in a co-formulated intravitreal injection, for the treatment of neovascular age-related macular degeneration (wet AMD). In January 2014, the Company entered into a license and collaboration agreement with Bayer HealthCare for the joint development and commercialization outside the United States of REGN2176, including in combination with EYLEA, for the treatment of ocular diseases and disorders.
- In May 2014, the Company entered into a research collaboration and license agreement with Avalanche Biotechnologies, Inc. to discover, develop, and commercialize novel gene therapy products for the treatment of ophthalmologic diseases.

Monoclonal Antibodies

Regeneron has fifteen fully human monoclonal antibodies generated using the Company's *VelocImmune*® technology in clinical development, including eight 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. The ODYSSEY program is expected to enroll more than 23,000 patients and currently includes 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. All of the trials in the ODYSSEY program, including CHOICE I and CHOICE II, are fully enrolled with the exception of the 18,000 patient ODYSSEY OUTCOMES study. Data from nine of these Phase 3 trials

are expected to be available in mid-2014 and, along with the data from the previously announced ODYSSEY MONO trial, will form the basis for the Company's initial global regulatory filings. Five abstracts for alirocumab were presented at the American College of Cardiology meeting in March 2014. These included the first presentation of data from the positive Phase 3 ODYSSEY MONO trial, data from the one-year open-label treatment of heterozygous familial hypercholesterolemia patients, and data from testing alirocumab with 150 milligrams (mg) dosed every four weeks in patients who are not on statins. In addition, in April 2014, the Company and Sanofi reported positive results from the first Phase 2 study of alirocumab in Japanese patients.

Sarilumab, the Company's antibody targeting IL-6R for rheumatoid arthritis, is currently continuing enrollment in the global Phase 3 SARIL-RA program. The SARIL-RA Phase 3 program consists of 5 studies and is expected to enroll approximately 2,600 adults with moderate-to-severe rheumatoid arthritis who have not achieved adequate results with other treatment agents. Data from the first positive Phase 3 trial in the SARIL-RA program, MOBILITY, will be presented at an upcoming medical conference.

Dupilumab, the Company's antibody targeting IL-4R alpha for allergic diseases, is currently in Phase 2b testing. During the first quarter of 2014, positive Phase 2a data of dupilumab for the treatment of moderate-to-severe atopic dermatitis were presented at the annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI). The Company expects Phase 2b data for dupilumab for the treatment of atopic dermatitis to become available during the second quarter of 2014. A phase 2b trial of dupilumab in asthma is ongoing, as is a Phase 2 trial in nasal polyposis. Additional indications for dupilumab clinical development are being evaluated.

Human Genetics Initiative

- In January 2014, the Company announced the launch of a new human genetics initiative via a newly created wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC will leverage de-identified clinical and molecular data from human volunteers for medically relevant associations in a blinded fashion designed to preserve patients' privacy. RGC will perform sequencing and genotyping to generate de-identified genomic data. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process.
- In January 2014, the Company also announced that RGC and Geisinger Health System, one of the largest integrated health systems in the United States serving approximately 3 million residents, entered into a research collaboration focused on studying the genetic determinants of human disease. The aim of the collaboration is to build a high-throughput platform for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs.

First Quarter 2014 Financial Results

Product Revenues: Net product sales were $362 million in the first quarter of 2014, compared to $319 million in the first quarter of 2013. EYLEA net product sales in the United States were $359 million in the first quarter of 2014, compared to $314 million in the first quarter of 2013. ARCALYST® net product sales were $3 million in the first quarter of 2014, compared to $5 million in the first quarter of 2013.

Total Revenues: Total revenues increased by 42% to $626 million in the first quarter of 2014, compared to $440 million in the first quarter of 2013. Total revenues include collaboration revenues of $256 million in the first quarter of 2014, compared to $114 million in the first 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 first quarter of 2014 also included $30 million of sales milestones earned from Bayer HealthCare.

Refer to Table 4 for a summary of collaboration revenue.

Research and Development (R&D) Expenses: GAAP R&D expenses were $287 million in the first quarter of 2014, compared to $180 million in the first quarter of 2013. The higher R&D expenses in the first quarter of 2014 were 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 first quarter of 2014, R&D-related non-cash share-based compensation expense was $43 million, compared to $27 million in the first quarter of 2013.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were $109 million in the first quarter of 2014, compared to $77 million in the first quarter of 2013. The increase was primarily due to higher expenses in connection with contributions to a not-for-profit organization that assists patients with chronic disease conditions and higher non-cash compensation expense. In the first quarter of 2014, SG&A-related non-cash share-based compensation expense was $38 million, compared to $26 million in the first quarter of 2013.

Cost of Collaboration Manufacturing: GAAP cost of collaboration manufacturing was $16 million in the first quarter of 2014, compared to $1 million in the first quarter of 2013. Cost of collaboration manufacturing increased primarily due to royalties payable to a third party, which commenced in May 2013 pursuant to a license and settlement agreement, in connection with sales of EYLEA outside the United States. Cost of collaboration manufacturing also includes costs of producing commercial supplies of EYLEA for Bayer HealthCare and ZALTRAP for Sanofi.

Income Tax Expense: The Company does not currently pay, or expect to pay in the near future, significant cash income taxes. GAAP income tax expense was $110 million in the first quarter of 2014, compared to $43 million in the first quarter of 2013. The effective tax rate was 62.7% for first quarter of 2014, compared to 30.3% for the first quarter of 2013. The effective tax rate for the first quarter of 2014 was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, and (iii) recently enacted New York State tax legislation. This tax legislation reduced the Company's New York State income tax rate to zero percent effective in 2014; however, it also resulted in a one-time charge related to the Company reducing its related deferred tax assets in the first quarter of 2014. The effective tax rate for the first quarter of 2013 included the impact of The American Taxpayer Relief Act, which was enacted in January 2013, and retroactively extended various expiring tax provisions, including the credit for increased research activities. As a result, during the first quarter of 2013, the Company recognized the benefit of its full year 2012 federal research tax credit. Non-GAAP net income excludes income tax expense.

Non-GAAP and GAAP Net Income: The Company reported non-GAAP net income of $263 million, or $2.66 per basic share and $2.26 per diluted share, in the first quarter of 2014, compared to non-GAAP net income of $201 million, or $2.07 per basic share and $1.78 per diluted share, in the first quarter of 2013.

The Company reported GAAP net income of $65 million, or $0.66 per basic share and $0.58 per diluted share, in the first quarter of 2014, compared to GAAP net income of $99 million, or $1.02 per basic share and $0.90 per diluted share, in the first quarter of 2013. The decrease in GAAP net income resulted primarily from the Company's higher effective tax rate in the first quarter of 2014, as described above.

Cash Position: At March 31, 2014, cash and marketable securities totaled $1.183 billion, compared to $1.084 billion at December 31, 2013.

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(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 Pharmaceuticals in Japan under a co-promotion agreement with a Japanese subsidiary 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 and non-GAAP net income per share, 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) income tax expense, since the Company does not currently pay, or expect to pay in the near future, 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. 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 first quarter 2014 financial and operating results on Thursday, May 8, 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, including without limitation Regeneron's human genetics initiative; 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 diabetic macular edema and macular edema following branch retinal vein occlusion, 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 and income tax obligations; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property 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 March 31, 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.

Contact Information:

Manisha Narasimhan, Ph.D.	Peter Dworkin
Investor Relations	Corporate Communications
914-847-5126	914-847-7640
manisha.narasimhan@regeneron.com	peter.dworkin@regeneron.com

TABLE 1

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

	March 31, 2014	December 31, 2013
Assets:		
Cash and marketable securities	$ 1,182,822	$ 1,083,875
Accounts receivable - trade, net	801,773	787,071
Accounts receivable from Sanofi and Bayer HealthCare	245,723	167,896
Deferred tax assets	285,077	276,555
Property, plant, and equipment, net	600,864	526,983
Other assets	144,137	108,633
Total assets	$ 3,260,396	$ 2,951,013
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 249,729	$ 262,226
Deferred revenue	268,306	231,199
Facility lease obligations	204,440	185,197
Convertible senior notes	326,673	320,315
Stockholders' equity	2,211,248	1,952,076
Total liabilities and stockholders' equity	$ 3,260,396	$ 2,951,013

TABLE 2

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

	Three months ended March 31,	
	2014	2013
Revenues:		
Net product sales	$ 362,378	$ 318,740
Sanofi collaboration revenue	130,508	99,273
Bayer HealthCare collaboration revenue	125,312	14,907
Technology licensing and other revenue	7,542	6,744
	625,740	439,664
Expenses:		
Research and development	287,379	180,299
Selling, general, and administrative	108,850	77,260
Cost of goods sold	27,473	28,021
Cost of collaboration manufacturing	16,099	1,034
	439,801	286,614
Income from operations	185,939	153,050
Other income (expense):		
Investment income	937	456
Interest expense	(11,613)	(11,675)

	(10,676)	(11,219)
Income before income taxes	175,263	141,831
Income tax expense	(109,820)	(42,957)
Net income	$ 65,443	$ 98,874
Net income per share - basic	$ 0.66	$ 1.02
Net income per share - diluted	$ 0.58	$ 0.90
Weighted average shares outstanding - basic	98,709	96,878
Weighted average shares outstanding - diluted	112,151	109,369

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,	
	2014	**2013**
GAAP net income	$ 65,443	$ 98,874
Adjustments:		
R&D: Non-cash share-based compensation expense	43,304	26,761
SG&A: Non-cash share-based compensation expense	37,587	25,787
COGS: Non-cash share-based compensation expense	517	483
Interest expense: Non-cash interest related to convertible senior notes	5,924	5,781
Income tax expense	109,820	42,957
Non-GAAP net income	$ 262,595	$ 200,643
Non-GAAP net income per share - basic	$ 2.66	$ 2.07
Non-GAAP net income per share - diluted [(a)]	$ 2.26	$ 1.78
Shares used in calculating:		
Non-GAAP net income per share - basic	98,709	96,878
Non-GAAP net income per share - diluted [(b)]	117,186	113,730

(a) For diluted non-GAAP net income per share calculations, excludes $1.7 million and $1.9 million, respectively, of interest expense for the three month periods ended March 31, 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 March 31,	
	2014	**2013**
Sanofi collaboration revenue:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	$ (3,212)	$ (7,789)
Reimbursement of Regeneron research and development expenses	127,914	101,712
Other	5,806	5,350
Total Sanofi collaboration revenue	130,508	99,273
Bayer HealthCare collaboration revenue:		

Regeneron's net profit in connection with commercialization of EYLEA outside the United States	61,159	6,362
Sales milestones	30,000	—
Cost-sharing of Regeneron development expenses	20,860	5,888
Other	13,293	2,657
Total Bayer HealthCare collaboration revenue	125,312	14,907
Total collaboration revenue	$ 255,820	$ 114,180

SOURCE Regeneron Pharmaceuticals, Inc.