Regeneron Reports First Quarter 2013 Financial and Operating Results

May 3, 2013

TARRYTOWN, N.Y., May 3, 2013 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial and operating results for the first quarter of 2013 and provided an update on development programs.

The Company reported total revenues of $440 million in the first quarter of 2013, compared to $232 million in the first quarter of 2012. Total revenues include EYLEA U.S. net product sales of $314 million in the first quarter of 2013, compared to $124 million in the first quarter of 2012. The Company reported non-GAAP net income of $201 million, or $1.78 per diluted share, in the first quarter of 2013, compared to $40 million, or $0.37 per diluted share, in the first quarter of 2012. Non-GAAP net income excludes non-cash share-based compensation expense, non-cash interest expense related to the Company's convertible senior notes, and non-cash income taxes. The Company reported GAAP net income of $99 million, or $0.90 per diluted share, in the first quarter of 2013, compared to $12 million, or $0.11 per diluted share, in the first quarter of 2012.

"The first quarter of 2013 was a productive quarter where we delivered sustained revenue and earnings growth," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "EYLEA sales in the U.S. continue to enjoy strong growth and we are raising our estimate of full year U.S. EYLEA net sales to $1.25 to $1.325 billion in 2013. The ex-U.S. launch of EYLEA by our partner, Bayer HealthCare, is also going very well and resulted in a positive contribution to our earnings this quarter. Our broad, late-stage pipeline is making progress. We expect our first data from the alirocumab Phase 3 program for reducing LDL cholesterol in the second half of 2013. We reported positive data with our IL-4R inhibitor, dupilumab, in atopic dermatitis and additional data for dupilumab are expected in allergic asthma later this month."

2013 Business Highlights

EYLEA® (aflibercept) Injection for Intravitreal Injection

- EYLEA is currently approved in the United States for the treatment of neovascular age-related macular degeneration (wet AMD) and macular edema following central retinal vein occlusion (CRVO). In the first quarter of 2013, net sales were $314 million, compared to $124 million in the first quarter of 2012, and $276 million in the fourth quarter of 2012.
- The Company and Bayer HealthCare collaborate on the global development and commercialization of EYLEA outside the United States, and share profits and losses from commercialization of EYLEA outside the United States except for Japan, where the Company receives a royalty on sales. Regeneron maintains exclusive rights to EYLEA in the United States and is entitled to all profits from any such sales.
- Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals in the European Union, Japan, Australia, and other regions. In the first quarter of 2013, Bayer HealthCare recorded net sales of EYLEA outside of the United States of $65 million, compared to $19 million in the fourth quarter of 2012. Our share of profits (including royalties on sales in Japan) for EYLEA was $19 million, and after repaying $13 million in development expenses, we recognized $6 million in net profit from EYLEA sales outside the United States in the quarter.
- Launches in additional countries are anticipated to continue throughout 2013 as regulatory and pricing approvals for EYLEA for the treatment of wet AMD are achieved.
- Applications for marketing authorization for EYLEA for the treatment of macular edema following CRVO are also pending in Europe, Japan, and other regions.
- Regeneron and Bayer HealthCare are conducting Phase 3 trials, VISTA-DME and VIVID-DME, to evaluate the efficacy and safety of EYLEA in the treatment of diabetic macular edema (DME). Both studies are fully enrolled. In February 2013, Bayer HealthCare initiated another Phase 3 DME trial, VIVID EAST-DME, in Russia, China, and other Asian countries.
- The VIBRANT study of EYLEA in macular edema following branch retinal vein occlusion (BRVO) is now fully enrolled.

ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion

- The Company and Sanofi collaborate on the global development and commercialization of ZALTRAP, and share profits and losses from commercialization of ZALTRAP except for Japan, where the Company will receive a royalty on sales.
- In February 2013, the European Commission (EC) granted marketing authorization in the European Union for ZALTRAP concentrate for solution for infusion in combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen. Marketing authorization applications for ZALTRAP are also currently under review by other regulatory agencies worldwide.
- In the first quarter of 2013, Sanofi recorded worldwide net sales of ZALTRAP of $14 million.

Monoclonal Antibodies

- Regeneron has eleven fully human monoclonal antibodies based on the Company's *VelocImmune*® technology in clinical development, including six in collaboration with Sanofi.
- ODYSSEY, a large, global Phase 3 program with alirocumab (REGN727), an antibody targeting PCSK9 to reduce LDL cholesterol, was initiated in June 2012 and is currently enrolling patients. The Company expects to report initial results from a Phase 3 ODYSSEY trial in the second half of 2013. Alirocumab is being developed in collaboration with Sanofi.
- Positive proof of concept data from two Phase 1b trials with dupilumab (REGN668), an antibody targeting IL-4R, in atopic dermatitis were presented at the 71st Annual Meeting of the American Academy of Dermatology in March 2013. Data from a Phase 2a trial of dupilumab in allergic asthma will be presented at the American Thoracic Society meeting in May 2013. Dupilumab is being developed in collaboration with Sanofi.

First Quarter 2013 Financial Results

Total Revenues: Total revenues were $440 million in the first quarter of 2013, compared to $232 million in the first quarter of 2012. Total revenues include collaboration revenues of $114 million in the first quarter of 2013, compared to $97 million in the first quarter of 2012.

Product Revenues: Net product sales were $319 million in the first quarter of 2013, compared to $128 million in the first quarter of 2012. EYLEA net product sales were $314 million in the first quarter of 2013, compared to $124 million in the first quarter of 2012. ARCALYST net product sales were $5 million in the first quarter of 2013, compared to $4 million in the first quarter of 2012.

Research and Development (R&D) Expenses: GAAP R&D expenses were $180 million in the first quarter of 2013, compared to $139 million in the first quarter of 2012. The higher R&D expenses in 2013 were principally due to increased R&D headcount and activities, primarily related to the Company's antibody collaboration with Sanofi, and higher non-cash share-based compensation expense. In the first quarter of 2013, R&D related non-cash share-based compensation expense was $27 million, compared to $11 million in the first quarter of 2012.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were $77 million in the first quarter of 2013, compared to $58 million in the first quarter of 2012. The increase was primarily due to higher expenses in connection with commercialization of EYLEA and higher non-cash share-based compensation expense. In the first quarter of 2013, SG&A related non-cash share-based compensation expense was $26 million, compared to $13 million in the first quarter of 2012.

Cost of Goods Sold (COGS): GAAP COGS was $29 million in the first quarter of 2013, compared to $12 million in the first quarter of 2012. The increase was due to higher EYLEA sales in 2013.

Interest Expense: GAAP interest expense was $12 million in the first quarter of 2013, compared to $11 million in the first quarter of 2012. In connection with the Company's convertible senior notes, which were issued in October 2011, the Company incurred interest expense of $8 million in the first quarter of 2013, which included $6 million of non-cash interest expense. In the first quarter of 2012, the Company incurred interest expense of $7 million related to the Company's convertible senior notes, which included $5 million of non-cash interest expense.

Income Tax Expense: GAAP income tax expense was $43 million in the first quarter of 2013. The effective tax rate of 30.3% for the quarter includes 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.

In the first quarter of 2012, the Company continued to recognize a full valuation allowance against its net operating loss carry-forward and other deferred tax assets since the Company had an extended history of losses. In the fourth quarter of 2012, the Company recorded an income tax benefit attributable to the release of substantially all of the remaining valuation allowance against the Company's deferred tax assets. The decision to reverse the valuation allowance was made after the Company determined that it was more likely than not that these deferred tax assets would be realized. Due to the release of the valuation allowance in 2012, starting in 2013, the Company has recorded income taxes on GAAP income using an estimated effective tax rate. Non-GAAP net income excludes non-cash income tax expense. The Company does not currently pay, or expect to pay in the near future, significant cash income taxes.

Non-GAAP and GAAP Net Income: The Company reported 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, compared to non-GAAP net income of $40 million, or $0.43 per basic share and $0.37 per diluted share, in the first quarter of 2012. Non-GAAP net income excludes non-cash share-based compensation expense, non-cash interest expense related to the convertible senior notes, and non-cash income tax expense.

The Company reported GAAP net income of $99 million, or $1.02 per basic share and $0.90 per diluted share, in the first quarter of 2013, compared to GAAP net income of $12 million, or $0.12 per basic share and $0.11 per diluted share, in the first quarter of 2012.

Cash Position: At March 31, 2013, cash and marketable securities totaled $663 million (including $8 million of restricted cash and marketable securities), compared to $588 million (including $8 million of restricted cash and marketable securities) at December 31, 2012. In addition, accounts receivable related to sales of EYLEA totaled $702 million at March 31, 2013, compared to $592 million at December 31, 2012.

Use of Non-GAAP Financial Measures: The Company believes that the presentation of non-GAAP measures is useful to investors because it excludes (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) non-cash 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, non-cash income tax expense is not deemed useful in evaluating the Company's operating performance. Furthermore, 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 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. The non-GAAP financial measures 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 2013 financial and operating results on Friday, May 3, 2013, 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 markets 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, allergic asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

Regeneron Forward-Looking Statement

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept); unforeseen safety issues resulting from the administration of products and product candidates in patients; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates; 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 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; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled 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 United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2012. 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, unless required by law.

This news release and/or the financial results attached to this news 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)

	March 31, 2013	December 31, 2012
ASSETS		
Cash, restricted cash, and marketable securities	$ 662,811	$ 587,511
Accounts receivable - trade, net	703,857	593,207
Accounts receivable from Sanofi	98,781	99,913
Deferred tax assets	300,951	340,156
Property, plant, and equipment, net	392,378	379,940
Other assets	117,220	79,763
Total assets	$ 2,275,998	$ 2,080,490
LIABILITIES AND STOCKHOLDERS' EQUITY		

Accounts payable, accrued expenses, and other liabilities	$ 154,199	$ 118,604
Deferred revenue	252,703	259,173
Facility lease obligations	160,480	160,810
Convertible senior notes	302,268	296,518
Stockholders' equity	1,406,348	1,245,385
Total liabilities and stockholders' equity	$ 2,275,998	$ 2,080,490

TABLE 2

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

	Three months ended March 31,	
	2013	**2012**
Revenues:		
Net product sales	$ 318,740	$ 127,931
Sanofi collaboration revenue	99,273	85,005
Bayer HealthCare collaboration revenue	14,907	12,483
Technology licensing	5,893	5,893
Other revenue	851	477
	439,664	231,789
Expenses:		
Research and development	180,299	138,862
Selling, general, and administrative	77,260	58,428
Cost of goods sold	29,055	12,298
	286,614	209,588
Income from operations	153,050	22,201
Other income (expense):		
Investment income	456	610
Interest expense	(11,675)	(11,160)
	(11,219)	(10,550)
Income before income taxes	141,831	11,651
Income tax expense	(42,957)	
Net income	$ 98,874	$ 11,651
Net income per share - basic	$ 1.02	$ 0.12
Net income per share - diluted	$ 0.90	$ 0.11
Weighted average shares outstanding - basic	96,878	93,446
Weighted average shares outstanding - diluted	109,369	107,734

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,	
	2013	**2012**
GAAP net income	$ 98,874	$ 11,651
Adjustments:		
R&D: Non-cash share-based compensation expense	26,761	10,556

SG&A: Non-cash share-based compensation expense	25,787	12,578
COGS: Non-cash share-based compensation expense	483	111
Interest expense: Non-cash interest related to convertible senior notes	5,781	5,218
Income taxes: Non-cash income tax expense	42,957	
Non-GAAP net income	$ 200,643	$ 40,114
Non-GAAP net income per share - basic	$ 2.07	$ 0.43
Non-GAAP net income per share - diluted (1)	$ 1.78	$ 0.37
Shares used in calculating:		
Non-GAAP net income per share - basic	96,878	93,446
Non-GAAP net income per share - diluted (2)	113,730	112,495

(1) For diluted non-GAAP per share calculations, excludes $1.9 million of interest expense for both the three month periods ended March 31, 2013 and 2012, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive

(2) Weighted average shares outstanding includes the dilutive effect, if any, of employee stock options, restricted stock awards, convertible senior notes, and warrants

SOURCE Regeneron Pharmaceuticals, Inc.