August 6, 2013

Regeneron Reports Second Quarter 2013 Financial and Operating Results

-- Second quarter EYLEA® (aflibercept) Injection global net sales of $426 million, including $330 million in the U.S. and $96 million in rest of world
-- Estimated full year 2013 EYLEA U.S. net sales forecast raised to $1.3 billion - $1.35 billion
-- Second quarter non-GAAP net income of $198 million or $1.73 per diluted share

TARRYTOWN, N.Y., Aug. 6, 2013 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ:REGN) today announced financial and operating results for the second quarter of 2013 and provided an update on development programs.

The Company reported total revenues of $458 million in the second quarter and $897 million in the first half of 2013, compared to $304 million in the second quarter and $536 million in the first half of 2012. EYLEA U.S. net product sales grew 70% to $330 million in the second quarter of 2013 from $194 million in the second quarter of 2012. First half of 2013 EYLEA U.S. net product sales grew 103% to $644 million from $318 million in the first half of 2012.

The Company reported non-GAAP net income of $198 million, or $1.73 per diluted share, in the second quarter and $398 million, or $3.50 per diluted share, in the first half of 2013, compared to $102 million, or $0.90 per diluted share, in the second quarter and $142 million, or $1.28 per diluted share, in the first half 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 $87 million, or $0.79 per diluted share, in the second quarter and $186 million, or $1.69 per diluted share, in the first half of 2013, compared to $77 million, or $0.70 per diluted share, in the second quarter and $88 million, or $0.81 per diluted share, in the first half of 2012. The Company's revenues and net income in both the second quarter and first half of 2013 were reduced by two $10 million up-front payments made to Sanofi to acquire full rights to antibodies to PDGF and antibodies to Ang2 in ophthalmology, as described below.

"We are pleased with the continued progress of EYLEA both in terms of commercialization and development in additional indications," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Today, we reported positive Phase 3 data for EYLEA from the VIVID-DME and VISTA-DME trials in diabetic macular edema (DME). Based upon discussions with the U.S. Food & Drug Administration, we now plan to submit a regulatory application for approval for EYLEA in the DME indication in the U.S. later this year, approximately one year ahead of our previous plan. Additional Phase 3 trials for EYLEA, alirocumab and sarilumab continue to advance and we expect to report data from the VIBRANT study with EYLEA in macular edema following branch retinal vein occlusion and the ODYSSEY MONO study with alirocumab for hypercholesterolemia later this year; the ODYSSEY MONO trial will be the first Phase 3 data from this class. We also moved two new antibodies into clinical development in this quarter."

Second Quarter (and Third Quarter To-Date) 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 second quarter of 2013, net sales were $330 million, compared to $194 million in the second 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 countries. In the second quarter of 2013, Bayer HealthCare recorded net sales of EYLEA outside of the United States of $96 million, compared to $65 million in the first quarter of 2013. Regeneron's share of profits (including royalties on sales in Japan) for EYLEA was $34 million in the second quarter of 2013, and after repaying $15 million in development expenses, the Company recognized $19 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. In May 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a positive recommendation for EYLEA for the treatment of wet AMD.
- Applications for marketing authorization for EYLEA for the treatment of macular edema following CRVO are also pending in Europe, Japan, and other countries. In July 2013, the European Committee for Medicinal Products for Human Use

(CHMP) recommended approval of EYLEA to the European Medicines Agency (EMA) for the treatment of macular edema secondary to CRVO and final approval is anticipated by the end of the year.
- In June 2013, the Company and Bayer HealthCare announced positive top-line results for EYLEA from the Phase 3 MYRROR study in myopic choroidal neovascularization (mCNV). Data from this study will be presented at an upcoming medical conference. The first application for regulatory approval is expected to be submitted for this indication in Asia by the end of 2013.
- Earlier today, the Company and Bayer HealthCare reported positive, top line, one-year results from the Phase 3 VIVID-DME and VISTA-DME trials in DME. Data from these studies will be presented at upcoming medical conferences. Applications for regulatory approvals in the United States and Europe are expected to be submitted for this indication by the end of 2013; the U.S. regulatory submission is approximately one year earlier than previously planned.

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.
- ZALTRAP is currently approved in over 30 countries, including the United States and European Union. Marketing authorization applications for ZALTRAP are currently under review by additional regulatory agencies worldwide.
- In the second quarter of 2013, Sanofi recorded worldwide net sales of ZALTRAP of $19 million, compared to $14 million in the first quarter of 2013.

Monoclonal Antibodies

- Regeneron has twelve fully human monoclonal antibodies based on the Company's *VelocImmune*® technology in clinical development, including seven 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 ODYSSEY program includes eleven clinical trials evaluating the effect of alirocumab dosed every two weeks. In addition, a trial of alirocumab dosed every four weeks (ODYSSEY CHOICE) will commence by the end of 2013. The Company expects to report initial results from the Phase 3 ODYSSEY MONO trial by the end of 2013. Alirocumab is being developed in collaboration with Sanofi.
- Data from a Phase 2a trial of dupilumab (REGN668) in allergic asthma were presented at the American Thoracic Society meeting in May 2013. These data were also published in the *New England Journal of Medicine* in June 2013. In the second quarter of 2013, Phase 2b trials of dupilumab in allergic asthma and atopic dermatitis were initiated and are currently enrolling patients. Dupilumab is being developed in collaboration with Sanofi.
- The Phase 3 program with sarilumab (REGN88) in rheumatoid arthritis includes multiple trials. SARIL-RA-MOBILITY has completed enrollment and data are expected in early 2014. SARIL-RA-TARGET continues to enroll patients. SARIL-RA-COMPARE and SARIL-RA-ASCERTAIN were initiated during the second quarter of 2013. Additionally, a Phase 2 study, SARIL-NIU-SATURN, in non-infectious uveitis will commence in the third quarter of 2013. Sarilumab is being developed in collaboration with Sanofi.
- Two novel antibodies against undisclosed targets, REGN1193 and REGN2009, entered clinical development. REGN2009 is being developed in collaboration with Sanofi. Development of REGN846, which completed a Phase 1 study against an undisclosed target, has been discontinued.
- In May 2013, the Company made two $10 million up-front payments to Sanofi in connection with the acquisition of full rights to antibodies targeting the PDGF (platelet derived growth factor) family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 receptor and ligand in ophthalmology. These antibodies were invested at Regeneron and previously included in the antibody collaboration with Sanofi.

Second Quarter 2013 Financial Results

Total Revenues: Total revenues were $458 million in the second quarter of 2013, compared to $304 million in the second quarter of 2012. Total revenues include collaboration revenues of $117 million in the second quarter of 2013, compared to $98 million in the second quarter of 2012. Collaboration revenues in the second quarter of 2013 were reduced by two $10 million up-front payments made to Sanofi to acquire full rights to antibodies to PDGF and antibodies to Ang2 in opthalmology.

Product Revenues: Net product sales were $334 million in the second quarter of 2013, compared to $200 million in the second quarter of 2012. EYLEA net product sales were $330 million in the second quarter of 2013, compared to $194 million in the second quarter of 2012. ARCALYST net product sales were $4 million in the second quarter of 2013, compared to $6 million in the second quarter of 2012.

Research and Development (R&D) Expenses: GAAP R&D expenses were $187 million in the second quarter of 2013, compared to $147 million in the second quarter of 2012. 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 2013, R&D related non-cash share-based compensation expense was $28 million, compared to $11 million in the second quarter of 2012.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were $72 million in the second quarter of 2013, compared to $48 million in the second 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 second quarter of 2013, SG&A related non-cash share-based compensation expense was $16 million, compared to $8 million in the second quarter of 2012.

Cost of Goods Sold (COGS): GAAP COGS was $27 million in the second quarter of 2013, compared to $22 million in the second quarter of 2012. The increase was due to higher EYLEA sales in 2013.

Cost of Collaboration Manufacturing: GAAP cost of collaboration manufacturing, which was $12 million in the second quarter of 2013, primarily consisted of third party royalties, as well as costs in connection with producing commercial supplies of EYLEA for Bayer HealthCare and ZALTRAP for Sanofi.

Interest Expense: GAAP interest expense was $11 million in both the second quarter of 2013 and 2012, which included $7 million related to the Company's convertible senior notes, which were issued in October 2011. Non-cash interest expense related to the convertible senior notes was $6 million in the second quarter of 2013 and $5 million in the second quarter of 2012.

Income Tax Expense: GAAP income tax expense was $60 million in the second quarter of 2013. The effective tax rate was 40.8% for the quarter.

In the second quarter of 2012, the Company did not recognize any income tax provision because it continued to recognize a full valuation allowance against its net operating loss carry-forward and other deferred tax assets. In the fourth quarter of 2012, the Company recorded an income tax benefit attributable to the release of substantially all of the valuation allowance against the Company's deferred tax assets. 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 $198 million, or $2.02 per basic share and $1.73 per diluted share, in the second quarter of 2013, compared to non-GAAP net income of $102 million, or $1.07 per basic share and $0.90 per diluted share, in the second 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 $87 million, or $0.89 per basic share and $0.79 per diluted share, in the second quarter of 2013, compared to GAAP net income of $77 million, or $0.81 per basic share and $0.70 per diluted share, in the second quarter of 2012.

Cash Position: At June 30, 2013, cash and marketable securities totaled $711 million, 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 $766 million at June 30, 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 second quarter 2013 financial and operating results on Tuesday, August 6, 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

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)

	June 30, 2013	December 31, 2012
Assets:		
Cash, restricted cash, and marketable securities	$ 710,834	$ 587,511
Accounts receivable - trade, net	767,865	593,207
Accounts receivable from Sanofi	108,151	99,913

Deferred tax assets	247,634	340,156
Property, plant, and equipment, net	419,651	379,940
Other assets	124,124	79,763
Total assets	$ 2,378,259	$ 2,080,490
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 164,026	$ 118,604
Deferred revenue	247,594	259,173
Facility lease obligations	165,186	160,810
Convertible senior notes	308,116	296,518
Stockholders' equity	1,493,337	1,245,385
Total liabilities and stockholders' equity	$ 2,378,259	$ 2,080,490

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,	
	2013	**2012**	**2013**	**2012**
Revenue:				
Net product sales	$ 333,893	$ 199,519	$ 652,633	$ 327,450
Sanofi collaboration revenue	85,529	88,988	184,802	173,993
Bayer HealthCare collaboration revenue	31,104	9,124	46,011	21,607
Technology licensing	5,893	5,893	11,786	11,786
Other revenue	1,223	875	2,074	1,352
	457,642	304,399	897,306	536,188
Expenses:				
Research and development	187,463	147,373	367,762	286,235
Selling, general, and administrative	72,463	47,705	149,723	106,133
Cost of goods sold	27,283	21,843	55,304	34,141
Cost of collaboration manufacturing	12,330		13,364	
	299,539	216,921	586,153	426,509
Income from operations	158,103	87,478	311,153	109,679
Other income (expenses):				
Investment income	954	501	1,410	1,111
Interest expense	(11,365)	(11,236)	(23,040)	(22,396)
	(10,411)	(10,735)	(21,630)	(21,285)
Income before income taxes	147,692	76,743	289,523	88,394
Income tax expense	(60,316)		(103,273)	
Net income	$ 87,376	$ 76,743	$ 186,250	$ 88,394
Net income per share - basic	$ 0.89	$ 0.81	$ 1.91	$ 0.94
Net income per share - diluted	$ 0.79	$ 0.70	$ 1.69	$ 0.81
Weighted average shares outstanding - basic	97,700	94,589	97,289	94,017
Weighted average shares outstanding - diluted	111,060	110,167	110,305	108,998

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,	
	2013	**2012**	**2013**	**2012**
GAAP net income	$ 87,376	$ 76,743	$ 186,250	$ 88,394
Adjustments:				
R&D: Non-cash share-based compensation expense	27,722	11,442	54,484	21,998
SG&A: Non-cash share-based compensation expenses	16,344	7,790	42,130	20,368
COGS: Non-cash share-based compensation expense	376	391	859	502
Interest expense: Non-cash interest related to convertible senior notes	5,535	5,316	11,316	10,534
Income taxes: Non-cash income tax expense	60,316		103,273	
Non-GAAP net income	$ 197,669	$ 101,682	$ 398,312	$ 141,796
Non-GAAP net income per share - basic	$ 2.02	$ 1.07	$ 4.09	$ 1.51
Non-GAAP net income per share - diluted (1)	$ 1.73	$ 0.90	$ 3.50	$ 1.28
Shares used in calculating:				
Non-GAAP net income per share - basic	97,700	94,589	97,289	94,017
Non-GAAP net income per share - diluted (2)	115,261	114,928	114,711	113,760

(1) For diluted non-GAAP per share calculations, excludes $1.8 million of interest expense for both the three month periods ended June 30, 2013 and 2012, and $3.7 million of interest expense for both the six month periods ended June 30, 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.