



Regeneron Reports Third Quarter 2011 Financial and Operating Results

October 27, 2011

TARRYTOWN, N.Y., Oct. 27, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial results for the third quarter of 2011 and provided an update on development programs and upcoming milestones.

Clinical Programs Update

EYLEA™ (aflibercept injection) — Ophthalmologic Diseases

EYLEA™, also known as VEGF Trap-Eye, is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PIGF), proteins that are involved in the abnormal growth of new blood vessels. Regeneron maintains exclusive rights to EYLEA™ in the United States. Bayer HealthCare LLC has rights to market EYLEA™ outside the U.S., where the companies will share equally in profits from any future sales of the product candidate.

In August 2011, Regeneron announced that it received notification from the U.S. Food and Drug Administration (FDA) that the agency had extended its target date to November 18, 2011 to complete the priority review of our Biologics License Application (BLA) for marketing approval for EYLEA™ in the neovascular form of age-related macular degeneration (wet AMD). This represents a three month extension from the original Prescription Drug User Fee Act (PDUFA) action date. The extension is a result of the agency classifying the Company's responses to questions regarding the chemistry, manufacturing, and controls (CMC) section of the BLA as a major amendment to the BLA. The new action date provides the agency additional time to review information submitted.

EYLEA™ is also in two Phase 3 clinical studies for the treatment of central retinal vein occlusion (CRVO), another cause of visual impairment. As previously disclosed, based on positive six-month results in these two studies, Regeneron intends to submit an additional regulatory application for marketing approval for EYLEA™ in CRVO in the U.S. by the end of 2011, and Bayer HealthCare plans to submit a similar regulatory application in Europe in 2012.

Earlier this year, Regeneron and Bayer HealthCare also initiated Phase 3 trials of EYLEA™ in a third indication, diabetic macular edema (DME).

ZALTRAP® (aflibercept) — Oncology

ZALTRAP®, also known as VEGF Trap, is a fusion protein that is designed to bind VEGF-A, VEGF-B, and PIGF, proteins that are involved in the abnormal growth of new blood vessels in solid tumors. ZALTRAP® is being developed worldwide by Regeneron and its collaborator, Sanofi, for the potential treatment of patients with solid tumors.

Based upon positive results from the Phase 3 VELOUR trial in patients with previously treated metastatic colorectal cancer (mCRC), Regeneron and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP® to the FDA and the European Medicines Agency by the end of 2011.

In addition, a randomized Phase 2 study (AFFIRM) is evaluating ZALTRAP® as a first-line treatment for mCRC in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin). The AFFIRM study is fully enrolled, and initial data are anticipated by the end of 2011.

In July 2011, Regeneron announced that the Phase 3 VENICE clinical trial evaluating ZALTRAP® in the first-line treatment of patients with androgen-independent (hormone-refractory) metastatic prostate cancer would continue to completion as planned, with no modifications due to efficacy or to safety concerns. This decision was based on the recommendation of an Independent Data Monitoring Committee (IDMC) following a planned interim analysis. Final results are anticipated in the first half of 2012.

ARCALYST® (rilonacept) — Gout

ARCALYST® is a fusion protein that blocks the cytokine interleukin-1 (IL-1). ARCALYST® is currently available for prescription in the U.S. for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue.

In 2010 and 2011, Regeneron reported positive Phase 3 results for ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. Based on these results, Regeneron submitted a supplemental BLA filing to the FDA in this indication. Regeneron owns worldwide rights to ARCALYST®.

Monoclonal Antibodies

Since 2007, Regeneron and Sanofi have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune®* technology.

The following eight antibody candidates are currently in clinical development, seven under the collaboration with Sanofi:

Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), is in the Phase 3 stage of a Phase 2/3 study (MOBILITY) in rheumatoid arthritis (RA). As previously reported, in July 2011, Regeneron and Sanofi announced that in a Phase 2b study, sarilumab in combination with a standard RA treatment, methotrexate (MTX), achieved a significant and clinically meaningful improvement in signs and symptoms of moderate-to-severe RA

compared to patients treated with MTX alone. The most common adverse events (>5%) reported more frequently in active treatment arms included infections (non-serious), neutropenia, and liver function test abnormalities.

In July 2011, Regeneron and Sanofi also announced that in a Phase 2b trial in ankylosing spondylitis in patients who had inadequate response to NSAIDs, sarilumab did not meet the primary endpoint of the study.

REGN727, an antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, is in Phase 2 studies. In Phase 1 safety studies, using both intravenous (IV) and subcutaneous (SC) routes of administration as a single agent and in combination with statin therapy, single doses of REGN727 resulted in dose-dependent reductions in LDL cholesterol of approximately 40-60% from baseline. In these Phase 1 safety studies, injection site reactions were the most common adverse event. Three Phase 2 studies with subcutaneous regimens of REGN727 are underway: (1) a randomized, double-blind, multi-dose, placebo controlled, 75-patient trial in patients with heterozygous familial hypercholesterolemia (heFH), (2) a randomized, double-blind, multi-dose, placebo controlled, 90-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia, and (3) a randomized, double-blind, multi-dose, placebo controlled, 180-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia and on stable doses of atorvastatin. The primary endpoint of each Phase 2 study is the change in LDL cholesterol from baseline compared to placebo over the study period. Initial data from the Phase 2 studies are expected by the end of the year and in the first half of 2012. Regeneron and Sanofi are finalizing plans for initiating a Phase 3 program for REGN727.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, is in a Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma.

REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN910, an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN475, an antibody to nerve growth factor (NGF), has completed a Phase 2 trial in osteoarthritis of the knee. In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. An FDA Arthritis Advisory Committee, originally scheduled to meet on September 13, 2011 to discuss possible safety issues related to anti-NGF compounds, has been postponed. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

REGN728, whose target remains undisclosed, is in a Phase 1 study.

REGN846, whose target remains undisclosed, is being evaluated in a Phase 2a study in patients with atopic dermatitis. In July 2011, Sanofi elected not to continue co-development of REGN846, and Regeneron now has sole global rights to REGN846. Under the terms of the Company's agreement, Sanofi remains obligated to fund REGN846 clinical costs through conclusion of a planned proof-of-concept trial and is entitled to receive a mid-single digit royalty on any future sales of REGN846.

Financial Results

On October 17, 2011, the Company announced an offering of \$400 million aggregate principal amount of 1.875% convertible senior notes due October 1, 2016. The offering closed on October 21, 2011. The initial purchaser of the notes has a 13-day option to purchase up to an additional \$60 million aggregate principal amount of notes on the same terms and conditions. In connection with the offering of the notes, the Company entered into convertible note hedge and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser. The convertible note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of the Company's Common Stock that initially underlie the notes, and are intended to reduce the dilutive impact of the conversion feature of the notes. The Company estimates that the net proceeds from the convertible senior note offering were approximately \$391.3 million after deducting the initial purchaser's discount and estimated offering expenses (and will be approximately \$450.1 million if the initial purchaser exercises its full option to purchase additional notes). In addition, the cost of the initial convertible note hedge, after taking into account the proceeds received by the Company from the warrant transaction, was \$23.7 million. If the initial purchaser exercises its option to purchase additional notes, the Company may use net proceeds from the sale of the additional notes to enter into additional convertible note hedge and warrant transactions.

At September 30, 2011, cash and marketable securities totaled \$511.7 million (including \$8.2 million of restricted cash and marketable securities) compared with \$626.9 million (including \$7.5 million of restricted cash and marketable securities) at December 31, 2010. Including the net proceeds from the convertible senior notes offering and related transactions described above, the Company projects that cash and marketable securities at December 31, 2011 will be over \$800 million.

The Company's total revenues decreased to \$102.8 million in the third quarter of 2011 from \$106.0 million in the same quarter of 2010, primarily due to lower technology licensing revenue as the Company's *Veloclimmune*® license agreement with AstraZeneca ended in February 2011. The Company's total revenues decreased slightly to \$322.8 million in the first nine months of 2011 from \$325.4 million in the same period of 2010.

Net product sales of ARCALYST® (rilonacept) in the third quarter of 2011 were \$5.5 million, compared to \$4.9 million during the same quarter of 2010. ARCALYST® net product sales for the nine months ended September 30, 2011 and 2010, respectively, totaled \$14.9 million and \$20.0 million. ARCALYST® net product sales during the first nine months of 2010 included \$15.2 million of net product sales made during this period and \$4.8 million of previously deferred net product sales.

The Company's total operating expenses increased to \$161.3 million in the third quarter of 2011 from \$138.1 million in the same quarter of 2010, and to \$482.6 million for the first nine months of 2011 from \$410.1 million for the same period of 2010. Research and development (R&D) expenses in the third quarter of 2011 rose to \$127.9 million from \$122.0 million in the same quarter of 2010 and to \$400.5 million in the first nine months of 2011 from \$364.0 million for the same period of 2010. These increases in R&D expenses were primarily due to the Company's expanded R&D headcount and activities, principally in connection with the Sanofi antibody collaboration. In addition, selling, general, and administrative (SG&A) expenses in the third quarter of 2011 rose to \$32.9 million from \$15.7 million in the same quarter of 2010 and to \$80.9 million in the first nine months of 2011 from \$44.6 million for the same period of 2010. These increases in SG&A expenses in the third quarter of 2011, as well as in the first nine months of 2011, were primarily due to higher headcount, higher recruiting and compensation costs, and higher commercialization-related costs in connection with preparing to launch EYLEA™ for the treatment of wet AMD. The Company projects that full year 2011 SG&A expenses will be approximately \$120 million.

The Company had a net loss of \$62.4 million, or \$0.68 per share (basic and diluted), for the third quarter of 2011 compared with a net loss of \$33.9 million, or \$0.41 per share (basic and diluted), for the third quarter of 2010. The Company had a net loss of \$168.3 million, or \$1.87 per share (basic and diluted), for the first nine months of 2011 compared with a net loss of \$89.9 million, or \$1.10 per share (basic and diluted), for the same period of 2010.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is approved for the treatment of a rare inflammatory condition, Regeneron has completed Phase 3 clinical trials of rilonacept for a new indication and of product candidates EYLEA™ (aflibercept injection; VEGF Trap-Eye) in diseases of the eye, and ZALTRAP® (aflibercept; VEGF Trap) in colorectal cancer. EYLEA™ is currently under review with U.S. and European regulatory authorities. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on www.regeneron.com.

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 product candidates and research and clinical programs now underway or planned, 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 its product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any 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, 2010 and Form 10-Q for the quarter ended September 30, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2011	2010	2011	2010
Revenues				
Collaboration revenue	\$89,896	\$89,344	\$283,275	\$269,678
Technology licensing	5,893	10,037	18,966	30,112
Net product sales	5,468	4,936	14,934	19,985
Contract research and other	1,576	1,662	5,672	5,624
	<u>102,833</u>	<u>105,979</u>	<u>322,847</u>	<u>325,399</u>
Expenses				
Research and development	127,924	122,043	400,465	364,040
Selling, general, and administrative	32,916	15,658	80,912	44,560
Cost of goods sold	450	372	1,227	1,494
	<u>161,290</u>	<u>138,073</u>	<u>482,604</u>	<u>410,094</u>
Loss from operations	<u>(58,457)</u>	<u>(32,094)</u>	<u>(159,757)</u>	<u>(84,695)</u>
Other income (expense)				
Investment income	715	453	2,750	1,484
Interest expense	(4,061)	(2,234)	(11,827)	(6,660)
	<u>(3,346)</u>	<u>(1,781)</u>	<u>(9,077)</u>	<u>(5,176)</u>
Net loss before income tax expense (benefit)	(61,803)	(33,875)	(168,834)	(89,871)
Income tax expense (benefit)	<u>562</u>		<u>(517)</u>	
Net loss	<u>\$ (62,365)</u>	<u>\$ (33,875)</u>	<u>\$ (168,317)</u>	<u>\$ (89,871)</u>

Net loss per share amounts, basic and diluted	\$ (0.68)	\$ (0.41)	\$ (1.87)	\$ (1.10)
Weighted average shares outstanding, basic and diluted	91,046	81,638	90,215	81,433

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

	September 30, 2011	December 31, 2010
ASSETS		
Cash, restricted cash, and marketable securities	\$511,721	\$626,939
Receivables	78,447	93,112
Property, plant, and equipment, net	363,913	347,450
Other assets	28,950	21,931
Total assets	<u>\$983,031</u>	<u>\$1,089,432</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	\$86,295	\$61,008
Deferred revenue	308,081	340,579
Facility lease obligations	160,402	160,030
Stockholders' equity	428,253	527,815
Total liabilities and stockholders' equity	<u>\$983,031</u>	<u>\$1,089,432</u>

SOURCE Regeneron Pharmaceuticals, Inc.

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