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Regeneron Reports First Quarter 2011 Financial and Operating Results

TARRYTOWN, N.Y., May 3, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial results for the first quarter of 2011 and provided an update on development programs and upcoming milestones.

Clinical Programs Update

VEGF Trap-Eye (aflibercept ophthalmic solution) — Ophthalmologic Diseases

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 (PlGF), proteins that are involved in the abnormal growth of new blood vessels. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare LLC has rights to market VEGF Trap-Eye outside the U.S., where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

In February 2011, Regeneron submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for VEGF Trap-Eye for the treatment of the neovascular form of age-related macular degeneration (wet AMD). In April 2011, the FDA accepted the BLA for filing and granted the Company's request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011.

Also in February 2011, data from the Phase 3 VIEW 1 and VIEW 2 trials of VEGF Trap-Eye in patients with wet AMD and the Phase 3 COPERNICUS trial in macular edema due to central retinal vein occlusion (CRVO) were presented at the Bascom Palmer Eye Institute's Angiogenesis, Exudation and Degeneration 2011 meeting. Results of the Phase 2 DA VINCI trial of VEGF Trap-Eye in diabetic macular edema (DME) were also presented.

In April 2011, Regeneron and Bayer HealthCare announced positive top-line results for VEGF Trap-Eye in the Phase 3 GALILEO study in patients with macular edema due to CRVO. The positive results from the GALILEO study confirmed the results of the similarly designed COPERNICUS study that were announced in December 2010. In GALILEO, the primary endpoint at week 24 was achieved: 60.2% of patients receiving 2 milligrams (mg) of VEGF Trap-Eye monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections ($p<0.0001$). The key secondary endpoint of the study was also met: patients receiving 2 mg of VEGF Trap-Eye monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$). As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. Detailed results of the GALILEO study will be presented at the EURETINA Congress in London in May 2011.

Based on these positive results, Regeneron intends to submit a regulatory application for marketing approval for VEGF Trap-Eye in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in Europe in 2012.

In April 2011, Regeneron and Bayer Healthcare announced that Bayer HealthCare has initiated the Phase 3 VIVID-DME study of VEGF Trap-Eye in DME in Australia. The trial will also be conducted in Europe and Japan. Regeneron intends to commence a second Phase 3 study (VISTA-DME) in DME later in 2011 in the U.S., Canada, and other countries.

ZALTRAP™ (aflibercept) - Oncology

ZALTRAP™, also known as VEGF Trap, is a fusion protein that is designed to bind VEGF-A, VEGF-B, and PlGF, 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, the sanofi-aventis Group, for the potential treatment of solid tumors.

In April 2011, Regeneron and sanofi-aventis announced that the Phase 3 VELOUR trial evaluating ZALTRAP™ in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in the second-line treatment of metastatic colorectal cancer (mCRC). Full results will be presented at an upcoming medical meeting. The most frequent adverse events reported with ZALTRAP™ in combination with FOLFIRI were diarrhea, asthenia/fatigue, stomatitis and ulceration, nausea, infection,

hypertension, gastrointestinal and abdominal pains, vomiting, decreased appetite, decreased weight, epistaxis, alopecia, and dysphonia.

Based upon these positive findings, Regeneron and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the European Medicines Agency in the second half of 2011.

In February 2011, Regeneron and sanofi-aventis announced results from the Phase 3 VITAL trial evaluating ZALTRAP™ for the second-line treatment of non-small cell lung cancer (NSCLC). The data showed that adding ZALTRAP™ to the chemotherapy drug docetaxel did not meet the pre-specified criteria for the primary endpoint of improvement in overall survival compared with a regimen of docetaxel plus placebo (HR=1.01, CI: 0.868 to 1.174). The addition of ZALTRAP™ to docetaxel demonstrated activity as measured by key secondary endpoints of the study: progression free survival (PFS) (HR=0.82, CI: 0.716 to 0.937) and an overall objective response rate (ORR) of 23.3% in the ZALTRAP™ arm compared to 8.9% in the placebo arm. The types and frequencies of adverse events reported in the ZALTRAP™ treatment arm were generally consistent with those reported in previous studies with anti-VEGF agents. The most frequent Grade 3/4 adverse events included fatigue, stomatitis, disease progression, and hypertension.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAP™ as a first-line treatment for metastatic, castration-resistant prostate cancer in combination with docetaxel/prednisone. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an Independent Data Monitoring Committee in mid-2011, and final results are anticipated in 2012.

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

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 February 2011, Regeneron reported the results of its second and third Phase 3 studies of ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy and announced that, based on these studies and a previously reported Phase 3 study, the Company plans to submit a supplemental BLA for U.S. regulatory approval of ARCALYST® in this setting in mid-2011. The Company reported that in the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group ($p<0.0001$). These results were consistent with those in the identical Phase 3 efficacy study (PRE-SURGE 1) reported in June 2010. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most frequently reported adverse event was upper respiratory tract infection (15.5% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 12.2% with placebo).

Regeneron also announced that in the third Phase 3 study (RE-SURGE), which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. RE-SURGE evaluated 1,315 patients who were at risk for gout flares while initiating or taking uric acid-lowering drug treatment. Other than injection site reactions, the incidence of treatment-emergent adverse events was generally well-balanced among the 985 patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg and the 330 patients who received placebo. Injection site reactions, usually considered mild, were reported more commonly with ARCALYST® (15.2%) than with placebo (3.3%). Overall, the cumulative rate of infections was 20.1% in patients treated with ARCALYST® and 19.1% in placebo patients. Serious infections were reported in 0.5% of patients treated with ARCALYST® and 0.9% of placebo patients. Deaths were reported for 0.3% of patients treated with ARCALYST® and 0.9% of placebo patients.

In the RE-SURGE study, ARCALYST® also met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period ($p<0.0001$). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Regeneron owns worldwide rights to ARCALYST®.

Monoclonal Antibodies

Since 2007, Regeneron and sanofi-aventis have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. During the fourth quarter of 2009, Regeneron and sanofi-aventis expanded and extended their collaboration with the objective to advance an average of four to five antibodies into clinical development each year between 2010 and 2017. The following eight antibody candidates are currently in clinical development under the collaboration:

REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, has been evaluated in Phase 1 studies using both intravenous and subcutaneous routes of administration. REGN727 is being studied as a single agent and in combination with statin therapy. Phase 2 studies have been initiated in combination with statins in patients with hypercholesterolemia.

REGN88, an antibody to the interleukin-6 receptor (IL-6R), is in a Phase 2/3 study in rheumatoid arthritis and a Phase 2 study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in mid-2011.

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

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, has completed Phase 1 testing in healthy volunteers. A Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma are underway.

REGN910, an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target, is in a Phase 1 study in an oncology setting.

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 has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

REGN728 and *REGN846*, whose targets remain undisclosed, have entered clinical development.

Financial Results

The Company's total revenues increased to $112.2 million in the first quarter of 2011 from $103.5 million in the same quarter of 2010. The increases were primarily due to higher collaboration revenue in the first quarter of 2011 in connection with the Company's antibody collaboration with sanofi-aventis.

Net product sales of ARCALYST® in the first quarter of 2011 were $4.4 million. Net product sales of ARCALYST® in the first quarter of 2010 were $9.9 million, which included $5.1 million of net product sales made during the quarter and $4.8 million of previously deferred net product sales.

The Company's total operating expenses increased to $153.2 million in the first quarter of 2011 from $132.4 million in the same quarter of 2010. The increases were primarily due to higher research and development expenses arising from the Company's expanding research and development activities in 2011 and related higher employee headcount, principally in connection with the sanofi-aventis antibody collaboration. Research and development expenses in the first quarter of 2011 rose to $129.4 million from $117.5 million in the same quarter of 2010.

The Company had a net loss of $43.4 million, or $0.49 per share (basic and diluted), for the first quarter of 2011 compared with a net loss of $30.5 million, or $0.38 per share (basic and diluted), for the first quarter of 2010.

At March 31, 2011, cash and marketable securities totaled $607.6 million (including $7.5 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.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and

certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at 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 the sanofi-aventis Group 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 March 31, 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.

Contacts Information:

Michael Aberman, M.D.	Peter Dworkin
Investor Relations	Corporate Communications
914.345.7799	914.345.7640
michael.aberman@regeneron.com	peter.dworkin@regeneron.com

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

	March 31, 2011	December 31, 2010
ASSETS		
Cash, restricted cash, and marketable securities	$607,582	$626,939
Receivables	88,156	93,112
Property, plant, and equipment, net	357,423	347,450
Other assets	21,132	21,931
Total assets	$1,074,293	$1,089,432
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	$65,782	$61,008
Deferred revenue	330,269	340,579
Facility lease obligations	160,151	160,030
Stockholders' equity	518,091	527,815
Total liabilities and stockholders' equity	$1,074,293	$1,089,432

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

	For the three months ended March 31,	
	2011	**2010**
Revenues		
Collaboration revenue	$97,810	$81,758
Technology licensing	7,845	10,038
Net product sales	4,427	9,852
Contract research and other	2,122	1,886
	112,204	103,534
Expenses		
Research and development	129,392	117,471
Selling, general, and administrative	23,411	14,223
Cost of goods sold	382	717
	153,185	132,411
Loss from operations	(40,981)	(28,877)
Other income (expense)		
Investment income	1,037	439
Interest expense	(3,719)	(2,084)
	(2,682)	(1,645)
Net loss before income tax benefit	(43,663)	(30,522)
Income tax benefit	(216)	
Net loss	$ (43,447)	$ (30,522)
Net loss per share amounts, basic and diluted	$ (0.49)	$ (0.38)
Weighted average shares outstanding, basic and diluted	89,162	81,169

SOURCE Regeneron Pharmaceuticals, Inc.