

# REGENERON

## Regeneron Reports Second Quarter 2011 Financial and Operating Results

July 28, 2011

TARRYTOWN, N.Y., July 28, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the second 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 (PlGF), 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 April 2011, the U.S. Food and Drug Administration (FDA) granted the Company's request for Priority Review of its Biologics License Application (BLA) for EYLEA™ for the treatment of the neovascular form of age-related macular degeneration (wet AMD) and set August 20, 2011 as the target date for an FDA decision. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA unanimously recommended that the FDA approve EYLEA™.

Also in June 2011, Bayer Healthcare submitted regulatory applications for marketing approval for EYLEA™ for the treatment of wet AMD in the European Union and in Japan. As previously disclosed, Regeneron intends to submit an additional regulatory application for marketing approval for EYLEA™ in a second indication, central retinal vein occlusion (CRVO), in the U.S. in the second half of 2011, and Bayer HealthCare plans to submit a similar regulatory application in Europe in 2012.

During the second quarter of 2011, Regeneron and Bayer Healthcare each initiated a Phase 3 study of EYLEA™ in a third indication, diabetic macular edema (DME). The Bayer Healthcare-led study (called VIVID-DME), will be conducted in Europe, Japan, and Australia. The study led by Regeneron (called VISTA-DME) will be conducted 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, Sanofi, for the potential treatment of patients with solid tumors.

In June 2011, results from the Phase 3 study (called VELOUR) of ZALTRAP™ in previously treated metastatic colorectal cancer (mCRC) patients were presented at the European Society of Medical Oncology World Congress on Gastrointestinal Cancer. In this study, the addition of ZALTRAP™ to the FOLFIRI chemotherapy regimen (folinic acid [leucovorin], 5-fluorouracil, and irinotecan) significantly improved both overall survival (HR=0.817; p=0.0032) and progression-free survival (HR=0.758; p=0.00007) compared to FOLFIRI plus placebo. A similar effect was seen with ZALTRAP™ therapy whether or not patients had received prior bevacizumab therapy.

In the VELOUR study, grade 3 or 4 adverse events (AEs) that occurred with a more than two percent greater incidence in the ZALTRAP™ arm than in the placebo arm included diarrhea, asthenia/fatigue, stomatitis/ulceration, infections, hypertension, GI/abdominal pains, neutropenia, neutropenic complications, and proteinuria. Deaths on study treatment due to AEs occurred in 2.4 percent of patients in the ZALTRAP™ arm and in 1.0 percent of patients in the placebo arm.

Based upon these positive findings, Regeneron and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP™ for the treatment of patients with previously treated mCRC to the FDA and the European Medicines Agency in the second half of 2011.

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. In July 2011, the study's Independent Data Monitoring Committee met for a scheduled interim analysis and recommended that the trial continue to completion. 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.

As previously reported, based upon positive Phase 3 results Regeneron plans to submit in the second half of 2011 a supplemental BLA for U.S. regulatory approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. 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. During the fourth quarter of 2009, Regeneron and Sanofi 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, seven under the collaboration with Sanofi:

*Sarilumab (REGN88)*, an antibody to the interleukin-6 receptor (IL-6R), is in a Phase 2/3 study in rheumatoid arthritis (RA). In July 2011, Regeneron and Sanofi announced that 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 primary endpoint of the Phase 2b study was the proportion of patients achieving at least a 20% improvement in RA symptoms (ACR20) after 12 weeks. In the trial, there was a dose response observed in patients receiving sarilumab in combination with MTX. An ACR20 response after 12 weeks was seen in 49.0% of patients receiving the lowest sarilumab dose regimen and 72.0% of patients receiving the highest dose regimen compared to 46.2% of patients receiving placebo and MTX ( $p=0.02$ , corrected for multiplicity, for the highest sarilumab dose regimen). The most common adverse events (>5%) reported more frequently in active treatment arms included infections (non-serious), neutropenia, and liver function test abnormalities. The types and frequencies of adverse events were consistent with those previously reported with IL-6 inhibition. The incidence of serious adverse events among the five sarilumab treatment groups and the placebo group was comparable.

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, has been evaluated in Phase 1 studies using both intravenous (IV) and subcutaneous (SC) routes of administration as a single agent and in combination with statin therapy. In these Phase 1 studies, single doses of REGN727, when given by either the IV or SC route of administration, resulted in reductions in LDL cholesterol of approximately 40-60% from baseline and lasting more than two to four weeks. Three Phase 2 studies with subcutaneous regimens of REGN727 have been initiated: (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.

*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 (Dl14), 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 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 placed REGN475 on clinical hold. On September 13, 2011, the FDA's Arthritis Advisory Committee will meet to discuss possible safety issues related to anti-NGF compounds. The FDA will ask the Committee to determine whether reports of joint destruction represent a safety signal for the class and whether the risk-benefit balance for these compounds favors continued development as analgesics. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

*REGN728*, whose target remains undisclosed, has entered clinical development.

*REGN846*, whose target remains undisclosed, has entered clinical development. 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 our 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**

The Company's total revenues decreased to \$107.8 million in the second quarter of 2011 from \$115.9 million in the same quarter of 2010, primarily due to lower technology licensing revenue as the Company's *VelocImmune*® license agreement with AstraZeneca ended in February 2011. The Company's total revenues increased slightly to \$220.0 million in the first half of 2011 from \$219.4 million in the same period of 2010.

Net product sales of ARCALYST® (rilonacept) in the second quarter of 2011 were \$5.0 million, compared to \$5.2 million during the same quarter of 2010. ARCALYST® net product sales for the six months ended June 30, 2011 and 2010, respectively, totaled \$9.5 million and \$15.0 million.

ARCALYST® net product sales during the first six months of 2010 included \$10.2 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 \$168.1 million in the second quarter of 2011 from \$139.6 million in the same quarter of 2010, and to \$321.3 million for the first six months of 2011 from \$272.0 million for the same period of 2010. Research and development (R&D) expenses in the second quarter of 2011 rose to \$143.1 million from \$124.5 million in the same quarter of 2010 and to \$272.5 million in the first six months of 2011 from \$242.0 million for the same period of 2010. These increases in R&D expenses were primarily due to the Company's expanding R&D headcount and activities, principally in connection with the Sanofi antibody collaboration. In addition, selling, general, and administrative (SG&A) expenses in the second quarter of 2011 rose to \$24.6 million from \$14.7 million in the same quarter of 2010 and to \$48.0 million in the first six months of 2011 from \$28.9 million for the same period of 2010. These increases in SG&A expenses in the first half 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 had a net loss of \$62.5 million, or \$0.69 per share (basic and diluted), for the second quarter of 2011 compared with a net loss of \$25.5

million, or \$0.31 per share (basic and diluted), for the second quarter of 2010. The Company had a net loss of \$106.0 million, or \$1.18 per share (basic and diluted), for the first six months of 2011 compared with a net loss of \$56.0 million, or \$0.69 per share (basic and diluted), for the same period of 2010.

At June 30, 2011, cash and marketable securities totaled \$569.1 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.

#### 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](http://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 June 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.*

#### Contact Information:

Michael Aberman, M.D.	Peter Dworkin
Investor Relations	Corporate Communications
914.345.7799	914.345.7640
<a href="mailto:michael.aberman@regeneron.com">michael.aberman@regeneron.com</a>	<a href="mailto:peter.dworkin@regeneron.com">peter.dworkin@regeneron.com</a>

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

	June 30, 2011	December 31, 2010
<b>ASSETS</b>		
Cash, restricted cash, and marketable securities	\$569,104	\$626,939
Receivables	84,564	93,112
Property, plant, and equipment, net	361,883	347,450
Other assets	31,313	21,931
	<u>\$1,046,864</u>	<u>\$1,089,432</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable, accrued expenses, and other liabilities	\$88,471	\$61,008
Deferred revenue	320,025	340,579
Facility lease obligations	160,334	160,030
Stockholders' equity	478,034	527,815
	<u>\$1,046,864</u>	<u>\$1,089,432</u>
Total liabilities and stockholders' equity	<u>\$1,046,864</u>	<u>\$1,089,432</u>

**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS (Unaudited)**

(In thousands, except per share data)

	For the three months ended June 30,		For the six months ended June 30,	
	2011	2010	2011	2010
Revenues				
Collaboration revenue	\$95,569	\$98,576	\$193,379	\$180,334
Technology licensing	5,228	10,037	13,073	20,075
Net product sales	5,039	5,197	9,466	15,049
Contract research and other	1,974	2,076	4,096	3,962
	<u>107,810</u>	<u>115,886</u>	<u>220,014</u>	<u>219,420</u>
Expenses				
Research and development	143,149	124,526	272,541	241,997
Selling, general, and administrative	24,585	14,679	47,996	28,902
Cost of goods sold	395	405	777	1,122
	<u>168,129</u>	<u>139,610</u>	<u>321,314</u>	<u>272,021</u>
Loss from operations	<u>(60,319)</u>	<u>(23,724)</u>	<u>(101,300)</u>	<u>(52,601)</u>
Other income (expense)				
Investment income	998	592	2,035	1,031
Interest expense	(4,047)	(2,342)	(7,766)	(4,426)
	<u>(3,049)</u>	<u>(1,750)</u>	<u>(5,731)</u>	<u>(3,395)</u>
Net loss before income tax benefit	(63,368)	(25,474)	(107,031)	(55,996)
Income tax benefit	<u>(863)</u>		<u>(1,079)</u>	
Net loss	<u>\$ (62,505)</u>	<u>\$ (25,474)</u>	<u>\$ (105,952)</u>	<u>\$ (55,996)</u>
Net loss per share amounts, basic and diluted	\$ (0.69)	\$ (0.31)	\$ (1.18)	\$ (0.69)
Weighted average shares outstanding, basic and diluted	90,436	81,492	89,799	81,330

SOURCE Regeneron Pharmaceuticals, Inc.

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