

# Positive Phase 2b Results with Sarilumab in Rheumatoid Arthritis to be Presented as a Late-Breaking Poster at the 2011 American College of Rheumatology Annual Meeting

# October 27, 2011

TARRYTOWN, N.Y., Oct. 27, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that detailed clinical data from the positive Phase 2b portion of the seamless Phase 2/3 MOBILITY trial of sarilumab (REGN88/SAR153191) in rheumatoid arthritis (RA) will be presented at a late-breaking poster session at the upcoming American College of Rheumatology (ACR) Annual Scientific Meeting, which will take place from November 5-9 in Chicago. Sarilumab is a novel, high-affinity, subcutaneously administered, fully-human antibody targeting the interleukin-6 receptor (IL-6R)

The poster will be presented on Tuesday, November 8 from 9 AM to 6 PM EST. The abstract, titled "Sarilumab for the Treatment of Moderateto-Severe Rheumatoid Arthritis: Results of a Phase 2, Randomized, Double-Blind, Placebo-Controlled, International Study," is available on the ACR website at: <u>http://acr.confex.com/acr/2011/webprogram/Paper24502.html</u>.

## About Sarilumab

Sarilumab (REGN88/ SAR153191) is the first fully human monoclonal antibody directed against the alpha subunit of the IL-6 receptor complex (IL-6R Alpha). Sarilumab is a high affinity, subcutaneously delivered, specific inhibitor of IL-6 signaling. It blocks the binding of IL-6 to its receptor and interrupts the resultant cytokine-mediated inflammatory signaling cascade. Sarilumab was developed using Regeneron's VelocImmune® antibody technology.

## About the MOBILITY trial

The MOBILITY trial is a randomized, double-blind, placebo-controlled, multicenter, two-part, dose ranging Phase 2b and confirmatory Phase 3 study with an operationally seamless design, evaluating efficacy and safety of sarilumab in combination with methotrexate (MTX) in patients with active RA who are inadequate responders to MTX therapy.

The primary objective of the dose ranging portion of the trial was to demonstrate that sarilumab in combination with MTX is effective in reducing the signs and symptoms of RA at 12 weeks. The five doses tested were 100 milligrams (mg) and 150 mg every week and 100 mg, 150 mg, and 200 mg every other week.

The primary objective of the Phase 3 portion of the trial, which is currently enrolling patients, is to demonstrate that sarilumab in combination with MTX is effective in reducing the signs and symptoms of RA at 24 weeks. The Phase 3 portion of the MOBILITY trial is evaluating two active doses of sarilumab, 150 mg and 200 mg administered every other week, compared to placebo. Further details about the MOBILITY trial are available at <a href="http://clinicaltrials.gov/ct2/results?term=SAR+153191+mobility">http://clinicaltrials.gov/ct2/results?term=SAR+153191+mobility</a>.

#### About Rheumatoid arthritis

Rheumatoid arthritis (RA) is a chronic systemic autoimmune disease affecting approximately 0.5%—1% of the global adult population. Abnormal immune response causes an inflamed, thickened synovium, the membrane that lines the joint. As synovitis expands, the inflammatory process can damage the bone and cartilage of the joint and the surrounding tissues. RA-related inflammation can involve the heart and the lung. In 10% of patients with RA, the liver is affected. Complications of RA include anemia and leucopenia. At times, RA can be very painful and affect a person's ability to carry out everyday tasks. Most people with RA experience periods when their symptoms worsen (flares or active disease), separated by periods in which the symptoms improve. Studies suggest that blockade of IL-6 signaling, one of several key cytokines involved in the inflammatory processes related to RA, may reduce inflammation of the joints, prevent long-term damage, and relieve certain systemic effects of RA, such as decreased hemoglobin, fatigue, and osteoporosis.

#### **About Regeneron Pharmaceuticals**

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, manufacturers, 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<sup>™</sup> (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

### Forward Looking Statements

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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