

# Regeneron Announces Data Publication and Presentations with Potential First-in-Class Lipid-Lowering PCSK9 Antibody

# March 21, 2012

TARRYTOWN, N.Y., March 21, 2012 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that results of the Phase 1 clinical program with their investigational product REGN727/SAR236553, a novel, high-affinity, subcutaneously administered, fully-human antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9 serine protease) were published in the March 22, 2012 issue of the *New England Journal of Medicine*. The primary author of the article, entitled "Effect of a Monoclonal Antibody to PCSK9 on LDL Cholesterol," was Evan A. Stein, M.D., Ph.D., Director of the Metabolic and Atherosclerosis Research Center in Cincinnati, Ohio, and Principal Investigator of one of the REGN727/SAR236553 Phase 1 clinical trials.

Additionally, results of two of three completed Phase 2 studies of REGN727/SAR236553 will be presented at oral sessions at the American College of Cardiology (ACC) annual meeting. The presentations are:

- "A Randomized, Double-Blind, Placebo-Controlled Trial Of The Safety And Efficacy of a Monoclonal Antibody To Proprotein Convertase Subtilisin/Kexin Type 9 Serine Protease, REGN727/SAR236553, in Patients With Primary Hypercholesterolemia" will be presented by James M. McKenney, Pharm.D, Professor Emeritus, Virginia Commonwealth University School of Medicine, during a Late-Breaking Clinical Trial session on Monday, March 26 at 11:14 AM.
- "The Effects of Co-administering a Monoclonal Antibody to Proprotein Convertase Subtilisin/Kexin Type 9 Serine Protease, REGN727/SAR236553, with 10 and 80 mg Atorvastatin Compared to 80 mg Atorvastatin Alone in Patients With Primary Hypercholesterolemia" will be presented by Eli M. Roth, M.D., Professor of Clinical Medicine and Director of Preventive Cardiology for the Division of Cardiology, University of Cincinnati College of Medicine, on Sunday, March 25 at 8:25 AM.

## About PCSK9

PCSK9 is known to be a determinant of circulating LDL levels, as it binds to LDL receptors resulting in their degradation so that fewer are available on liver cells to remove excess LDL-cholesterol from the blood. Moreover, traditional LDL-lowering therapies such as statins actually stimulate the production of PCSK9, which may limit their ability to lower LDL-cholesterol. Blocking the PCSK9 pathway is therefore a potentially novel mechanism for lowering LDL-cholesterol.

#### About REGN727

REGN727/SAR236553 is a fully-human monoclonal antibody directed against PCSK9, administered via subcutaneous injection. By inhibiting PCSK9, a determinant of circulating LDL-cholesterol levels in the blood, REGN727 increases the number of free LDL receptors which can bind to circulating LDL and clear it from the bloodstream. REGN727 was created using Regeneron's pioneering VelocImmune® technology and is being developed by Regeneron in collaboration with Sanofi.

# **About Regeneron Pharmaceuticals**

Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products in the United States, one for the treatment of neovascular (wet) age-related macular degeneration and another for the treatment of a rare inflammatory condition. Additionally, Regeneron has three regulatory applications pending before the U.S. Food and Drug Administration (FDA) and 10 drug candidates in clinical development. More information and recent news releases are available on the Regeneron web site at <a href="https://www.regeneron.com">www.regeneron.com</a>

## Regeneron Forward-Looking Statement

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future 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, including without limitation REGN727/SAR236553, 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 products and drug candidates, uncertainty of market acceptance of Regeneron's products and drug candidates, unanticipated expenses, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with the Sanofi 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, 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:**

Media Relations Peter Dworkin 914.847.7640 Investor Relations Manisha Narasimhan, Ph.D. 914.847.5126 manisha.narasimhan@regeneron.com

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