



## Regeneron and Sanofi Announce Plan to Use Priority Review Voucher For Alirocumab U.S. FDA Submission

July 30, 2014

TARRYTOWN, N.Y. and PARIS, July 30, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi (EURONEXT: **SAN** and NYSE: **SNY**) today announced that the Companies intend to use a U.S. Food and Drug Administration (FDA) rare pediatric disease priority review voucher in connection with the Biologics License Application (BLA) submission for alirocumab. The priority review voucher entitles the holder to designate a BLA for priority review, which provides for an expedited 6-month review from the filing date instead of the standard 10-month review.

Regeneron Ireland, an indirect, wholly-owned subsidiary of Regeneron Pharmaceuticals, Inc., purchased the voucher from BioMarin GALNS Ltd., a direct, wholly-owned subsidiary of BioMarin Pharmaceutical, Inc., which had received it through the FDA's Rare Pediatric Disease Priority Review Voucher Program. Sanofi and Regeneron will equally share the purchase price of \$67.5 million.

"The priority review voucher program was established to provide incentives that would enhance innovation in key areas of unmet patient need," said Ned Braunstein, M.D., Vice President, Regulatory Affairs at Regeneron. "Our decision to acquire and leverage the voucher is clear evidence that this program is a valuable incentive for biopharmaceutical companies."

Sanofi and Regeneron expect to submit U.S. and EU regulatory submissions for alirocumab before year end. Alirocumab is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) that is being evaluated for its potential to lower low-density lipoprotein cholesterol (LDL-C) in patients who are not at their current LDL-C target with standard lipid-modifying therapies.

The Pediatric PRV was created by the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) and is intended to encourage the development of treatments for rare pediatric diseases. Companies that receive a voucher may use it or transfer the voucher, including by sale, to other organizations.

### About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### About Regeneron Pharmaceuticals, Inc.

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York, that discovers, invents, develops, manufactures, and commercializes biologic medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit [www.regeneron.com](http://www.regeneron.com).

### Sanofi Forward-Looking Statements

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements.*

*These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

### Regeneron Forward-Looking Statements

*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. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation alirocumab; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product*

*candidates in clinical trials, such as the ODYSSEY global trial program evaluating alirocumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, such as alirocumab, including the impact (if any) of the planned use of the U.S. Food and Drug Administration's Rare Pediatric Disease Priority Review Voucher in connection with the contemplated Biologics License Application submission for alirocumab; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties 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, 2013 and its Form 10-Q for the quarter ended March 31, 2014. The reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.*

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