



Regeneron Announces Collaboration with Mitsubishi Tanabe Pharma for Investigational Pain Therapy Fasinumab in Asia

October 1, 2015

Tarrytown, N.Y., Oct. 1, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced a collaboration with Mitsubishi Tanabe Pharma Corporation (TSE: **4508**) (MTPC) providing MTPC with exclusive development and commercial rights to fasinumab (REGN475), Regeneron's NGF antibody in late-stage development for musculoskeletal pain. Under the terms of the agreement, MTPC will obtain exclusive development and commercial rights to fasinumab in Japan, Korea and nine other Asian countries, excluding China.

"Pain is one of the most common causes of disability, suffering and productivity loss across the world, and yet current treatments have limited efficacy, hold the risk of abuse or have other serious side effects," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "MTPC has proven experience marketing biologics for rheumatology and pain management and thus is an ideal partner in Asia. We look forward to advancing our NGF program in the coming months with the goal of bringing this investigational therapy to patients in serious need."

Under the agreement, Regeneron will receive up to \$55 million in upfront and other near-term payments. The agreement provides for additional payments to Regeneron of up to \$170 million in R&D reimbursement payments and development milestones. Upon commercialization, Regeneron will supply the product at a range of purchase prices depending on net sales, such that Regeneron shares in a significant portion of any potential profits. Regeneron is also eligible for additional one-time purchase price adjustment payments of up to \$100 million total upon achievement of specified annual net sales.

About the Fasinumab Program

Fasinumab is a fully human monoclonal antibody that is highly selective for Nerve Growth Factor (NGF). In a prior clinical study in osteoarthritis, fasinumab demonstrated reductions in pain compared to placebo and a safety profile that was comparable to placebo. Fasinumab is currently on partial clinical hold by the U.S. Food and Drug Administration (FDA), limiting duration of trials in osteoarthritis to 16 weeks. The FDA placed fasinumab and other investigational agents against NGF on partial clinical hold in December 2012 due to reports of sympathetic nervous system toxicity in mature animals being treated with other NGF antibodies. A Phase 2b/3 study of fasinumab for pain due to osteoarthritis was initiated in mid-2015.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: **REGN**) is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for high LDL cholesterol, eye diseases and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation is a research-driven pharmaceutical company based in Osaka, Japan. MTPC is taking on the challenge of drug discovery in the fields of autoimmune disorders, central nervous system diseases, diabetes and kidney diseases, and vaccines. To those ends, MTPC is strengthening its R&D pipeline. MTPC contributes to the healthier lives of people around the world through the creation of pharmaceuticals. www.mt-pharma.co.jp/e

Regeneron Forward-Looking Statements and Use of Digital Media

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), 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 fasinumab (REGN475) and the collaboration agreement with Mitsubishi Tanabe Pharma Corporation discussed in this news release; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators (including without limitation the development of fasinumab conducted pursuant to the collaboration agreement discussed in this news release) may lead to therapeutic applications; 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, such as the U.S. Food and Drug Administration's decision whether to lift the partial clinical hold relating to fasinumab; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, including without limitation fasinumab; unforeseen safety issues and possible liability resulting from the administration of products and product candidates (such as fasinumab) in patients; serious complications or side effects in connection with the use of Regeneron's products and product candidates (such as fasinumab) in clinical trials; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business; 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 and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the 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 and the collaboration agreement with Mitsubishi Tanabe Pharma Corporation discussed in this news release, 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, 2014 and its Form 10-Q for the quarterly period ended June 30, 2015. Any forward-looking statements are made based on management's current beliefs and judgment, and 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

Your IR Contact at Regeneron:

Manisha Narasimhan, Ph.D., Tel. 914.847.5126

E-Mail: manisha.narasimhan@regeneron.com

Your Media Contact at Regeneron:

Alexandra Bowie, Tel. 914.847.3407

E-Mail: alexandra.bowie@regeneron.com

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/regeneron-announces-collaboration-with-mitsubishi-tanabe-pharma-for-investigational-pain-therapy-fasinumab-in-asia-300152786.html>

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media