Regeneron Announces Positive Topline Results from Phase 2/3 Fasinumab Study in Patients with Osteoarthritis Pain

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TARRYTOWN, N.Y., May 2, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced positive topline results from a placebo-controlled Phase 2/3 study evaluating fasinumab in patients with moderate-to-severe osteoarthritis pain of the hip or knee who have a history of inadequate pain relief or intolerance to current analgesic therapies. At 16 weeks, patients treated with all four doses of fasinumab, an investigational Nerve Growth Factor (NGF) antibody, demonstrated a statistically significant improvement in pain relief, the primary endpoint of the study, as well as improvements in the secondary measure evaluating physical function.

"Chronic osteoarthritis is a common cause of pain, disability, and productivity loss for older adults," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "There is a real need for new, non-opioid pain therapies that can provide relief to patients without the toxicity and potential for abuse of currently available opioid treatments. We had previously evaluated an intravenous formulation of fasinumab in osteoarthritis patients, and this is our first trial of a convenient subcutaneous monthly regimen. We look forward to continuing to study the safety and efficacy of fasinumab in our Phase 3 program."

The U.S. study enrolled 421 adult patients with moderate-to-severe osteoarthritis of the hip or knee who had a history of inadequate pain relief or intolerance to acetaminophen, and at least one oral nonsteroidal anti-inflammatory drug (NSAID) and an opioid. Patients in the study were experiencing significant pain at baseline with an average pain score of 6.3 on a 10-point scale. Patients were evaluated for pain, stiffness, and physical function using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in addition to other measures. Patients were randomized to one of five treatment groups in a 1:1:1:1:1 fashion: fasinumab 1mg, 3mg, 6mg, 9mg, or placebo, all delivered subcutaneously every 4 weeks through week 12, with the primary efficacy measured at week 16. Following week 16, patients are being studied for an additional 20 weeks off treatment.

On the primary endpoint, fasinumab-treated patients reported less pain at 16 weeks when compared to placebo on the 10-point WOMAC subscale for pain. Results for each of the dose groups are noted below.

	Placebo n= 83	**1 mg fasinumab** n=85	**3 mg fasinumab** n=84	**6 mg fasinumab** n=85	**9 mg fasinumab** n=84
Baseline pain score (mean)	6.43	6.33	6.35	6.10	6.53
Week 16 change from baseline (LS mean)	-2.25	-3.35	-3.33	-3.03	-3.65
p-value		0.0025	0.0029	0.0304	0.0001

The safety analysis includes all results at the time of the primary efficacy analysis; complete data will be reported when all patients complete the full 36 weeks. Overall incidence of adverse events, including serious and severe events, was similar across the fasinumab groups and placebo. As expected with antibodies to NGF, there was an increase in certain neuro-musculoskeletal adverse events in the fasinumab treatment groups (17 percent combined fasinumab; 6 percent placebo) including arthralgia, paraesthesia, hypoaesthesia, and peripheral edema.

Because of prior concerns with other anti-NGF therapies regarding the possible risk of joint damage, the study incorporated extensive imaging and analyses at baseline and during the study, of index and non-index joints, with particular focus on subchondral insufficiency fractures (SIF), osteonecrosis (ON) and rapidly progressive osteoarthritis (RPOA). Approximately 2 percent of screened subjects were excluded from participation based on findings of SIF or ON on baseline imaging exams. During the study period there were no cases of ON, there was 1 case of SIF in placebo, 0, 2, 0 and 4 cases of SIF in the 1mg, 3mg, 6mg, and 9mg fasinumab dose groups respectively, and 1 case of RPOA in each of the 3mg, 6mg, and 9mg fasinumab dose groups. A modest increase in the lab value for bone-specific alkaline phosphatase, a marker of osteoblast activity, was noted in fasinumab-treated patients; there was no increase in liver ALT and AST enzymes.

The company plans to present detailed results at an upcoming medical congress.

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.

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; 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 clinical development programs evaluating fasinumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, such as fasinumab for patients with osteoarthritis pain or other indications; 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 fasinumab; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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 relating to fasinumab, 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, 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).

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