Regeneron and Teva Provide Update on Fasinumab Clinical Development Programs

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TARRYTOWN, N.Y. and JERUSALEM, Oct. 17, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Teva Pharmaceutical Industries Ltd. (NYSE and TASE: **TEVA**) today provided an update on fasinumab, triggered by a recent development in a Phase 2b fasinumab study in patients with chronic low back pain. Fasinumab is an investigational Nerve Growth Factor (NGF) antibody in clinical development for osteoarthritis pain and chronic low back pain.

Chronic Low Back Pain Program Update
The U.S. Food and Drug Administration (FDA) has placed the Phase 2b study in chronic low back pain on clinical hold and requested an amendment of the study protocol after observing a case of adjudicated arthropathy in a patient receiving high dose fasinumab who had advanced osteoarthritis at study entry. As a result of the FDA decision, Regeneron completed an unplanned interim review of results and has stopped dosing in the study. The unplanned analysis showed clear evidence of efficacy with improvement in pain scores in all fasinumab groups compared to placebo at the 8- and 12-week time points (nominal p less than 0.01). Preliminary safety results are generally consistent with what has been previously reported with the class. The Phase 2b chronic low back pain study enrolled approximately 70 percent of the targeted 800 patients in four dose groups: placebo, 6mg subcutaneously monthly, 9mg subcutaneously monthly and 9mg intravenously every two months. Regeneron has notified health authorities and study investigators about the decision. Patients will continue to be followed for up to 36 weeks.

Based on these results, Regeneron and Teva plan to design a pivotal Phase 3 study in chronic low back pain that excludes patients with advanced osteoarthritis. The companies plan to submit a pivotal program plan for review with the FDA and other health authorities.

Osteoarthritis Pain Program Update
Sixteen week positive results from the fasinumab Phase 2/3 osteoarthritis pain study in 421 patients were previously reported. Patients received their last dose at 12 weeks and a follow-up analysis occurred at 36 weeks. The study incorporated extensive imaging and analyses at baseline and during the study of index and non-index joints, with particular focus on arthropathies including subchondral insufficiency fractures (SIF), osteonecrosis (ON) and rapidly progressive osteoarthritis (RPOA). At the 36-week analysis, the incidence of adjudicated arthropathies was found to be potentially dose-dependent, with a higher rate of patients experiencing arthropathies in the higher dose groups [12 percent (9mg), 7 percent (6mg), 5 percent (3mg), 2 percent (1mg) and 1 percent (placebo)]. Based on these data, the companies are planning to advance only lower doses in the ongoing fasinumab osteoarthritis pivotal Phase 3 program, subject to discussion with the FDA and other health authorities.

Updated data from the osteoarthritis pain Phase 2/3 study and the chronic low back pain Phase 2b study will be presented at upcoming medical congresses.

"We are making data-driven decisions on Phase 3 fasinumab dosing that we believe will maximize potential benefit for patients in need, while minimizing the likelihood of side effects," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer, Regeneron and President, Regeneron Laboratories. "We look forward to working with global health authorities to advance this important investigational therapy for patients with often difficult-to-treat osteoarthritis pain and chronic low back pain."

"We believe fasinumab represents an important potential innovation for patients with osteoarthritis pain and chronic low back pain who currently have clear unmet need and limited treatment options," said Michael Hayden, M.D., Ph.D., President of Global R&D and Chief Scientific Officer at Teva. "We look forward to advancing clinical development for this promising novel therapy."

Regeneron and Teva are collaborating on the global development and commercialization of fasinumab. Under a separate agreement with Regeneron, Mitsubishi Tanabe Pharma has exclusive development and commercial rights to fasinumab in Japan, Korea and nine other Asian countries.

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

About Teva
Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,800 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has a world-leading position in innovative treatments for disorders of the central nervous system, including pain, as well as a strong portfolio of respiratory products. Teva integrates its generics and specialty capabilities in its global research and development division to create new ways of addressing unmet patient needs by combining drug development capabilities with devices, services and technologies. Teva's net revenues in 2015 amounted to $19.7 billion. For more information, visit www.tevapharm.com.

Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:
This release contains forward-looking statements, which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize additional pharmaceutical products; competition for our specialty

products, especially Copaxone® (which faces competition from orally-administered alternatives and a generic version); our ability to integrate Allergan plc's worldwide generic pharmaceuticals business ("Actavis Generics") and to realize the anticipated benefits of the acquisition (and the timing of realizing such benefits); the fact that following the consummation of the Actavis Generics acquisition, we are dependent to a much larger extent than previously on our generic pharmaceutical business; potential restrictions on our ability to engage in additional transactions or incur additional indebtedness as a result of the substantial amount of debt incurred to finance the Actavis Generics acquisition; the fact that for a period of time following the Actavis Generics acquisition, we will have significantly less cash on hand than previously, which could adversely affect our ability to grow; the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from investments in our pipeline of specialty and other products; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2015 and in our other filings with the U.S. Securities and Exchange Commission (the "SEC"). Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise any forward-looking statements or other information, whether as a result of new information, future events or otherwise.

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) for osteoarthritis pain, chronic low back pain, or other potential indications; 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 for osteoarthritis pain and other potential indications pursuant to the collaboration agreement with Teva Pharmaceutical Industries Ltd.) 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, including without limitation fasinumab for osteoarthritis pain, chronic low back pain, or other potential indications, as well as the potential fasinumab pivotal Phase 3 study in patients with chronic low back pain and the fasinumab pivotal Phase 3 program in patients with osteoarthritis pain; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including fasinumab; serious complications or side effects in connection with the use of Regeneron's products and product candidates in clinical trials, such as the current and contemplated global clinical development programs evaluating fasinumab for osteoarthritis pain, chronic low back pain, or other potential indications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates (such as fasinumab) and new indications for marketed products; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; 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; 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 (or their respective affiliated companies, as applicable) and the respective collaboration agreements with Teva Pharmaceutical Industries Ltd. and Mitsubishi Tanabe Pharma Corporation relating to the development of fasinumab, to be cancelled or terminated without any 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 and its Form 10-Q for the quarterly period ended June 30, 2016. 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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