PRESS RELEASE

Sanofi and Regeneron Present Results from Phase 3 MONARCH Study of Investigational Sarilumab at American College of Rheumatology Annual Meeting

- In the MONARCH Study, Sarilumab Monotherapy Demonstrated Superiority Over Adalimumab Monotherapy in Adults with Active Rheumatoid Arthritis –

Paris, France and Tarrytown, N.Y. - November 16, 2016 - Sanofi and Regeneron Pharmaceuticals, Inc. today will present results of SARIL-RA-MONARCH, a Phase 3 study, which demonstrated the superiority of investigational sarilumab monotherapy versus adalimumab (marketed by AbbVie as HUMIRA®) monotherapy in improving the clinical signs and symptoms in adults with active rheumatoid arthritis (RA). The results are being presented today at an oral session during the American College of Rheumatology (ACR) Annual Meeting in Washington, DC.

"Approximately 30 percent of people with RA are being treated with biologic monotherapy largely due to intolerance to methotrexate," said Dr. Gerd Burmester, Charité - University Medicine, Berlin, Germany and lead study author. *"In the MONARCH monotherapy study, sarilumab was more effective than adalimumab, which is one of the most commonly used biologics today."*

SARIL-RA-MONARCH Results

The SARIL-RA-MONARCH study enrolled 369 adults with active RA who were inadequate responders to, intolerant of, or inappropriate candidates for methotrexate (MTX). Patients were randomized to receive either subcutaneous sarilumab monotherapy (200 mg every 2 weeks) or adalimumab monotherapy (40 mg every 2 weeks); patients who did not respond adequately to adalimumab could increase to weekly dosing. Top-line results were previously announced in March 2016.[1]

The primary endpoint was change from baseline in DAS28-ESR at 24 weeks, which demonstrated a statistically significant difference in favor of sarilumab (-3.28 for sarilumab compared to -2.20 for adalimumab, p less than 0.0001).[1] DAS28-ESR is a measure of disease activity in RA, which includes the evaluation of 28 joints in the body for tenderness and swelling, a general health assessment by the patient, and ESR, a laboratory measure for inflammation.[2]

The study also met other important endpoints including improvement in American College of Rheumatology (ACR) criteria and the Health Assessment Questionnaire – Disability Index (HAQ-DI).[1] Results included:

- A greater improvement in signs and symptoms of RA with sarilumab as measured by the proportion of patients achieving a 20 percent improvement in the ACR criteria (72 percent for sarilumab vs. 58 percent for adalimumab, p less than 0.01). The proportion of patients achieving ACR50 was also higher with sarilumab (45 percent for sarilumab vs. 29 percent for adalimumab, p=0.0017) as well as for ACR70 (23 percent for sarilumab vs. 11 percent for adalimumab, p=0.0036).[1]
- Rates of DAS28-ESR remission (score<2.6) were higher for sarilumab vs. adalimumab (26 percent for sarilumab vs. 7 percent for adalimumab, p less than 0.0001).[1]

- Improvements in HAQ-DI were observed with sarilumab vs adalimumab. The change in baseline to week 24 in HAQ-DI for sarilumab was -0.61 vs. -0.43 for adalimumab (p=0.0037).[1]

The study also observed greater numerical response in Clinical Disease Activity Index (CDAI). The change in baseline to week 24 was -28.9 for sarilumab vs. -25.2 for adalimumab. Higher rates of CDAI remission were also observed for sarilumab (7 percent) vs. adalimumab (2 percent).[1] Adults treated with sarilumab also experienced greater improvement in functional disability, pain and fatigue over adults treated with adalimumab. These improvements included patient-reported outcomes, which were measured by Medical Outcomes Short Form 36 Health Survey; physician component summary score (PCS) and mental component summary score (MCS); and Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F).

The incidence of adverse events (64 percent for both groups), serious adverse events (5 percent for sarilumab vs. 7 percent for adalimumab), infections (29 percent for sarilumab vs. 28 percent for adalimumab), and serious infections (1 percent for both groups) were generally similar between groups. Neutropenia, which was not associated with infections, was more common with sarilumab (14 percent for sarilumab vs. 1 percent for adalimumab), as has been seen in previous studies with IL-6 inhibitors. Injection site erythema (8 percent sarilumab vs. 3 percent adalimumab) was also more common with sarilumab.[1]

The safety and efficacy of sarilumab have not been fully evaluated by any regulatory authority. If approved, sarilumab will be marketed by Regeneron and Sanofi Genzyme, the specialty care global business unit of Sanofi.

About RA

RA is a chronic inflammatory autoimmune disease, which carries substantial patient burden.[3,4] In RA, the immune system attacks the tissues of the joints, causing inflammation, pain, and eventually joint damage and disability.[3,4] RA affects approximately 1.3 million Americans, with nearly 75 percent being women.[3,5] It most often strikes people between 30 and 60 years old; however, it can occur in adults at any age.[6]

About Sarilumab

Sarilumab is a human monoclonal antibody directed against the IL-6 receptor that inhibits the inflammatory activity in RA mediated by the IL-6 signaling pathway. IL-6 is the most abundant cytokine in the serum and synovial fluid of patients with RA, and levels of IL-6 correlate with both disease activity and joint destruction. [7,8,9,10,11,12,13,14,15]

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families.

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.

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 regarding the clinical development of and potential marketing approvals for sarilumab. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans”, “would be” 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 of sarilumab, 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 sarilumab or biological application that may be filed for sarilumab as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of sarilumab, the absence of guarantee that sarilumab if approved will be commercially successful, risks associated with intellectual property, future litigation, the future approval and commercial success of therapeutic alternatives, and volatile economic conditions, as well as those risks 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, 2015. 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 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 impact of the previously disclosed manufacturing deficiencies raised by the U.S. Food and Drug Administration (the “FDA”) on the potential FDA approval of sarilumab; 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 sarilumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation sarilumab; 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 sarilumab; determinations by regulatory and administrative governmental authorities (such as the FDA) which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates, including without limitation sarilumab; 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, such as sarilumab; 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 (or their respective affiliated companies, as applicable), 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 and its Form 10-Q for the quarterly period ended September 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.

Contacts Sanofi:

Media Relations
Ashleigh Koss
Tel: 1 (908) 981-8745
ashleigh.koss@sanofi.com

Investor Relations
George Grofik
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com

Contacts Regeneron:

Media Relations
Arleen Goldenberg
Tel: 1 (914) 847-3456
Mobile: +1 (914) 260-8788
arleen.goldenberg@regeneron.com

Investor Relations
Manisha Narasimhan, Ph.D.
Tel: 1 (914) 847-5126
manisha.narasimhan@regeneron.com

---

[1] Burmester G. et al.#3321 Efficacy and Safety of Sarilumab Versus Adalimumab in a Phase 3, Randomized, Double-blind, Monotherapy Study in Patients With Active Rheumatoid Arthritis With Intolerance or Inadequate Response to Methotrexate. Arthritis Rheumatol. 2016; 68 (suppl 10).
[2] Arthritis Foundation. "Measuring Disease Activity in Rheumatoid Arthritis." http://www.arthritis.org/living-with-arthritis/life-stages/remission/measuring-disease-activity.php. Last accessed October 2016.
[3] American College of Rheumatology. "Rheumatoid Arthritis." Available at: http://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Rheumatoid-Arthritis. Last accessed: August 2016
[4] Mayo Clinic. "Rheumatoid Arthritis." Available at http://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/basics/definition/con-20014868. Last accessed July 2016.
[5] Centers for Disease Control. "Rheumatoid Arthritis." Available at http://www.cdc.gov/arthritis/basics/rheumatoid.htm. Last accessed October 2016.
[6] Arthritis Foundation. "What is Rheumatoid Arthritis?" Available at http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/what-is-rheumatoidarthritis.php. Last accessed October 2016.
[7] Wong PK, et al. Arthritis Rheum. 2006;54(1):158-168.
[8] de Hooge AS, et al. Am J Pathol. 2000;157(6):2081-2091.
[9] Nakamura I, et al. J Rheumatol. 2009;36(2):459-460.
[10] Van Leeuwen MA, et al. Ann Rheum Dis. 1995;54(1):33-38.
[11] Hashizume M, et al. Rheumatology (Oxford). 2008;47(11):1635-1640.
[12] Maggio M, et al. J Gerontol A Biol Sci Med Sci. 2006;61(6):575-584.
[13] Ducreux J, et al. Arthritis Rheumatol. 2014;66(1):15-23.
[14] Garnero P, et al. Arthritis Rheum. 2010;62(1):33-43.
[15] Ishimi Y, et al. J Immunol. 1990;145(10):3297-3303.