Regeneron and Sanofi Launch Major New Immuno-Oncology Collaboration

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TARRYTOWN, N.Y. and PARIS, July 28, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi have entered into a new global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology. As part of the agreement, the two companies will jointly develop a programmed cell death protein 1 (PD-1) inhibitor currently in Phase 1 testing and plan to initiate clinical trials in 2016 with new therapeutic candidates based on ongoing, innovative preclinical programs.

"The field of immuno-oncology has shown the potential to dramatically improve outcomes for patients with certain types of cancer. However, the field is still in its very early days," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer, Regeneron and President, Regeneron Laboratories. "We believe the approaches most likely to deliver the best results to patients will combine multiple innovative therapies acting on different pathways and targets both in the tumor and the body's immune response - and will precisely target these medicines to the right patient. The efficiency and power of our suite of technologies, such as VelocImmune® and VelociGene®, combined with our human genetics capabilities, uniquely positions the Sanofi-Regeneron Alliance to accelerate the development of potential new immuno-oncology treatment options for cancer patients."

Sanofi will make an upfront payment to Regeneron of $640 million, and the companies will invest $1 billion for discovery through proof of concept (POC) development (usually a Phase 2a study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25 percent by Regeneron ($250 million) and 75 percent by Sanofi ($750 million). The companies have also committed to equally fund an additional $650 million (or $325 million per company) for development of REGN2810, a PD-1 inhibitor. In addition, Sanofi will pay Regeneron a one-time milestone of $375 million in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product exceed, in the aggregate, $2 billion in any consecutive 12-month period. Finally, the two companies have agreed to re-allocate $75 million (over three years) for immuno-oncology antibodies from Sanofi's $160 million annual contribution to their existing antibody collaboration, which otherwise continues as announced in November 2009. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

"The Sanofi-Regeneron Alliance has demonstrated its ability to translate cutting-edge science into groundbreaking medicines for patients with serious needs," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. "With more than eight years of successful collaboration between us, I am confident in our ability to advance these novel programs. In addition to PD-1, the collaboration brings together a range of validated, innovative preclinical programs that have unique potential to help patients either as monotherapy or in combination approaches."

The new agreement covers both monoclonal antibodies and new bi-specific antibodies, a variation of standard antibody therapeutics in which two distinct targets within the body can be bound by the same molecule, usually the cancer cell and an immune cell. Regeneron has developed a novel and flexible manufacturing platform that enables efficient production of bi-specific antibodies that are otherwise similar to natural antibodies. Beyond PD-1, other programs in preclinical development include antibodies to lymphocyte-activation gene 3 (LAG3), glucocorticoid-induced tumor-necrosis-factor-receptor-related protein (GITR) and a programmed death ligand (PD-L1) inhibitor. Finally, the collaboration is advancing bi-specific antibodies that target hematologic and solid cancers, either as monotherapies or in combination regimens with other immune modulating treatments.

"Despite many advances over the last decades, cancer remains a leading cause of death and suffering around the world," said Israel Lowy, M.D., Ph.D., Vice President Clinical Sciences, Head of Translational Science and Oncology, Regeneron. "Although initial advances with immuno-oncology have helped certain patients, there is a tremendous opportunity to further unlock the potential of this new approach to help even greater numbers of people living with cancer."

The framework of the new immuno-oncology collaboration is as follows:

- Regeneron will be responsible for discovery, antibody generation and development through POC, at which time Sanofi will have the ability to opt-in to further development and commercialization. In the existing antibody collaboration, Sanofi has the opportunity to opt-in at the time of an Investigational New Drug application (IND).
- The companies will alternate serving as the lead development and commercialization organization after Sanofi opts-in to an antibody program.
- For programs where Regeneron is the lead, including REGN2810, Regeneron will serve as the U.S. commercial lead, including recording U.S. sales, and the companies will equally fund post-POC development. Sanofi will record sales and serve as the commercial lead for all countries outside the U.S. Sanofi will retain the right to co-promote in the U.S. and Regeneron will retain the right to co-promote outside the U.S.
- For programs where Sanofi is the lead, Sanofi will serve as the U.S. commercial lead and fund 100 percent of post-POC development, with Regeneron reimbursing up to 50 percent of such costs through the IO collaboration development balance, which represents the amount of development funding that Regeneron is obligated to repay out of its share of profits as described below. Sanofi will record sales and serve as the commercial lead for all countries outside the U.S. Regeneron will retain the right to co-promote in the U.S. and outside the U.S.
- Sanofi and Regeneron will share equally in worldwide profits from sale of collaboration immuno-oncology antibodies.
- As in the existing antibody agreement, Regeneron will repay the immuno-oncology collaboration development balance from its share of overall profits of the immuno-oncology antibodies, in an annual amount equal to 10 percent of the Regeneron

share of profits.

The exclusive collaboration to discover and develop potential monotherapy or novel combination immuno-oncology antibody candidates through POC will last five years with an ability to extend the collaboration for selected ongoing programs for an additional three years. The agreement does not include Chimeric Antigen Receptors. Additional terms, including potential therapeutic targets or mechanisms, were not disclosed.

About Sanofi
Sanofi, a 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 (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 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 oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit 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, 2014. 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 Pharmaceuticals, Inc. ("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 REGN2810 and antibodies targeting programmed death-ligand 1 (PD-1), lymphocyte-activation gene 3 (LAG3), and glucocorticoid-induced tumour-necrosis-factor-receptor-related protein (GITR), as well as other monoclonal antibodies and bi-specific antibodies that may be subject to the immuno-oncology collaboration with Sanofi described in this news release; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi (such as the immuno-oncology collaboration described in this news release) and Bayer HealthCare LLC, to be cancelled, not extended, or otherwise terminated without any further product success; 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; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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; 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 quarter ended March 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.

Contacts Sanofi:

Media Relations
Jack Cox
Tel: +33 (0) 1 53 77 94 74
Mobile: +33 (0) 6 78 52 05 36
Jack.Cox@sanofi.com

Investor Relations
Sébastien Martel
Tel: +33 (0)1 53 77 45 45
IR@sanofi.com

Contacts Regeneron

Media Relations	Investor Relations
Hala Mirza	**Manisha Narasimhan**
Tel: +1 (914) 847-3422	Tel: +1 (914) 847-5126
Mobile: +1 (917) 929-1734	manisha.narasimhan@regeneron.com
hala.mirza@regeneron.com	