

Libtayo® (cemiplimab) shows clinically meaningful and durable responses in second-line advanced basal cell carcinoma

- * Objective responses seen in 29% of patients with locally advanced basal cell carcinoma (BCC)
- * In a preliminary analysis, objective responses seen in 21% of patients with metastatic BCC
- * Approximately 85% of patients who responded to Libtayo maintained their response for at least one year
- * Sanofi and Regeneron plan regulatory submissions in 2020

Paris and Tarrytown, NY – May 5, 2020 - Topline data for a pivotal, single-arm, open-label trial for Sanofi and Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab) in patients with advanced basal cell carcinoma (BCC) who had progressed on or were intolerant to prior hedgehog pathway inhibitor (HPI) therapy were announced today. Libtayo demonstrated clinically meaningful and durable responses in this group of patients for whom there are no approved treatments. Sanofi and Regeneron plan regulatory submissions in 2020.

BCC is a skin cancer and is the most common cancer worldwide, with approximately two million new cases diagnosed every year in the U.S. alone. While the vast majority of BCCs are caught early and cured with surgery or radiation, a small proportion of tumors can become advanced and penetrate deeper into surrounding tissues (locally advanced), which is more difficult to treat. Approximately 20,000 U.S. patients have advanced BCC and it is estimated that about 3,000 die each year. BCC marks the second non-melanoma skin cancer for which Libtayo has demonstrated first-in-class data and follows its initial U.S. approval in advanced cutaneous squamous cell carcinoma (CSCC) in 2018.

In the trial, the objective response rate (ORR) for patients (n=84) with locally advanced disease was 29% (95% CI: 19%-40%), with an estimated duration of response (DOR) exceeding one year in 85% of responders. The durable disease control rate (DCR — response or stable disease lasting at least 6 months) was 60% (95% CI: 48%-70%). In a preliminary analysis of patients (n=28) with metastatic disease, the ORR was 21% (95% CI: 8%-41%), with an estimated DOR exceeding one year in 83% of responders. The durable DCR was 46% (95% CI: 28%-66%). All data were assessed by an independent central review. Data are expected to continue to evolve with further follow-up across both patient groups.

“While PD-1 inhibitors have transformed the outlook for many patients with melanoma, progress for patients with non-melanoma skin cancers has not been as rapid,” said Peter C. Adamson, M.D, Global Head of Oncology Development at

Sanofi. *“We are continuing to address this unmet need by first bringing Libtayo to patients with advanced cutaneous squamous cell carcinoma, and now, with this second trial, as a potential therapy for patients with advanced basal cell carcinoma. These important new results further demonstrate Libtayo’s potential in patients with difficult-to-treat, non-melanoma skin cancers.”*

There were no new safety signals in this trial. Among the 132 patients assessed for safety (84 locally advanced and 48 metastatic), 95% of patients experienced an adverse event (AE), 32% had a serious AE and 13% discontinued due to an AE. There were 10 deaths in the locally advanced group and nine deaths in the metastatic group; none of the deaths were considered treatment-related. Sanofi and Regeneron will present additional trial findings at an upcoming medical meeting.

“Libtayo is being investigated as a monotherapy treatment and as a foundation therapy for combinations with novel therapeutic approaches being developed by Regeneron and our collaborators,” Israel Lowy, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Oncology at Regeneron. *“These data in advanced BCC provide the third instance where Libtayo monotherapy has demonstrated robust and clinically meaningful outcomes in advanced cancer, and follows last week’s announcement in advanced non-small cell lung cancer where the pivotal trial was stopped early for positive overall survival.”*

In this ongoing global Phase 2 trial, patients received Libtayo 350 mg intravenously every three weeks for up to 93 weeks or until disease progression, unacceptable toxicity, withdrawal of consent or confirmed complete response. ORR is the primary endpoint and key secondary endpoints include overall survival, progression-free survival, duration of response, safety and quality of life.

Libtayo is being jointly developed and commercialized by Sanofi and Regeneron under a global collaboration agreement.

The use of Libtayo to treat advanced BCC is investigational and the safety and efficacy have not been evaluated by any regulatory authority.

About Libtayo

Libtayo is a fully-human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T-cells. By binding to PD-1, Libtayo has been shown to block cancer cells from using the PD-1 pathway to suppress T-cell activation.

Libtayo is the first and only immunotherapy approved in the U.S., EU, and other countries for adults with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. In the U.S., the generic name for Libtayo in its approved indication is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the U.S. Food and Drug Administration.

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. In skin cancer, this includes trials in adjuvant and neoadjuvant CSCC. Libtayo is also being investigated in potentially registrational Phase 3 trials in non-small lung cancer and cervical cancer, as well as in trials combining Libtayo with novel therapeutic approaches for both solid tumors and blood cancers. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary VelociSuite® technologies, such as VelocImmune which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Sanofi Media Relations Contact

Sally Bain
Tel.: +1 617 834 6026
sally.bain@sanofi.com

Sanofi Investor Relations Contact

Felix Lauscher
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com

Regeneron Media Relations Contact

Daren Kwok
Tel: +1 (914) 847-1328
daren.kwok@regeneron.com

Regeneron Investor Relations Contact

Vesna Tosic
Tel: +1 (914) 847-5443
Vesna.Tosic@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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product.

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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties 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, 2019. 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 press 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 SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron’s business and its employees, collaborators, suppliers, and other third parties on which Regeneron relies, Regeneron’s and its collaborators’ ability to continue to conduct research and clinical programs (including those discussed in this press release), Regeneron’s ability to manage its supply chain, net product sales of products marketed by Regeneron and/or its collaborators (collectively, “Regeneron’s Products”), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron’s Products and Regeneron’s product candidates and research and clinical programs now underway or planned, including without limitation Libtayo® (cemiplimab) in patients with advanced basal cell carcinoma (“BCC”), as a monotherapy and combination therapy in patients with first-line locally advanced or metastatic non-small cell lung cancer (“NSCLC”), and as a monotherapy or in combination with conventional treatments or other investigational agents (as applicable) for the treatment of adjuvant and neoadjuvant cutaneous squamous cell carcinomas, cervical cancer, blood cancers, and other potential indications; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and lead to therapeutic applications; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron’s product candidates and new indications for Regeneron’s Products, including without limitation any possible regulatory approval of Libtayo (as a monotherapy or in combination with conventional treatments or other investigational agents, as applicable) for the treatment of BCC, NSCLC, adjuvant and neoadjuvant cutaneous squamous cell carcinomas, cervical cancer, blood cancers, and other potential indications; unforeseen safety issues resulting from the administration of Regeneron’s Products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron’s Products and product candidates (such as Libtayo) in clinical trials (including those referenced in this press release); 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; ongoing regulatory obligations and oversight impacting Regeneron’s Products (such as Libtayo), research and clinical programs, and business, including those relating to patient privacy; 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 availability and extent of reimbursement of Regeneron’s Products (such as Libtayo) from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to Regeneron’s Products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron’s collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron’s Products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its 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, Bayer, and Teva Pharmaceutical Industries Ltd. (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 (including without limitation the patent litigation and other related proceedings relating to Dupixent® (dupilumab) and Praluent® (alirocumab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron’s business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron’s filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2019. 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>).