SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Libtayo® (cemiplimab) approved by the European Commission as the first immunotherapy indicated for patients with advanced basal cell carcinoma

- Approval based on data from the largest trial to date in patients with advanced basal cell carcinoma previously treated with a hedgehog pathway inhibitor
- Libtayo now approved by the European Commission for three advanced cancers

PARIS and TARRYTOWN, NY – June 25, 2021 – The European Commission (EC) has approved Sanofi and Regeneron's PD-1 inhibitor Libtayo® (cemiplimab) to treat adults with locally advanced or metastatic basal cell carcinoma (BCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HHI).

BCC is the most common type of skin cancer worldwide, representing up to 80% of non-melanoma skin cancers, and incidence is increasing across many European countries. While the large majority of BCCs are caught early and easily cured with surgery and/or radiation, a small proportion of cases can develop into advanced BCC and penetrate deeper into surrounding tissues (locally advanced) or spread to other parts of the body (metastatic), becoming more difficult to treat.

> *"Since its launch in Europe just two years ago, Libtayo has redefined the standard of care for advanced CSCC and has the potential to do the same in advanced BCC,"* said Peter C. Adamson, M.D., Global Development Head, Oncology at Sanofi. *"Together with Regeneron, we're committed to addressing gaps in the treatment of advanced forms of non-melanoma skin cancer."*

Libtayo is now approved for three advanced cancers in the European Union, following the EC's concurrent approval of Libtayo for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) whose tumor cells have ≥50% PD-L1 expression and no EGFR, ALK or ROS1 aberrations. In 2019, Libtayo was approved by the EC as the first treatment for adults with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation. Across all of its approved indications, Libtayo had a generally consistent safety profile. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue during or after treatment with Libtayo.

The EC approval in BCC is based on data from the largest prospective clinical trial (n=119) in patients with advanced BCC previously treated with an HHI to date. Libtayo-treated

patients with locally advanced BCC experienced an objective response rate (ORR) of 32% (95% confidence interval [CI]: 22-43) (25% partial response, 7% complete response) by independent central review. Libtayo-treated patients with metastatic BCC demonstrated an ORR of 29% (95% CI: 15-46) (26% partial response, 3% complete response) by investigator assessment. In addition, approximately 90% of patients across both groups had a duration of response (DOR) of 6 months or longer per Kaplan Meier estimates, and the median DOR has not been reached for either group. Median duration of follow-up was 16 months for locally advanced BCC and 9 months for metastatic BCC.

Safety was assessed in 816 patients across all four Libtayo monotherapy pivotal trials in its approved indications. Adverse events were serious in 30% of patients and led to permanent discontinuation in 8% of patients. Immune-related adverse reactions occurred in 22% of patients and led to permanent discontinuation in 4% of patients. The most common immune-related adverse reactions were hypothyroidism (8%), hyperthyroidism (3%), pneumonitis (3%), hepatitis (2%), colitis (2%) and immune-related skin adverse reactions (2%).

> *"Libtayo is the first immunotherapy to show a clinical benefit in patients with advanced BCC after HHI therapy in a pivotal trial, and with this first-in-class approval has the potential to transform treatment for patients in Europe whose cancer has progressed despite HHI treatment,"* said Israel Lowy, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Oncology at Regeneron. *"We look forward to continuing to investigate this medicine in additional settings, with the goal of helping more patients with difficult-to-treat cancers around the world."*

About the Phase 2 Trial in Advanced BCC

The EC approval was based on data from an ongoing open-label, multi-center, non-randomized Phase 2 trial of patients with unresectable locally advanced BCC or metastatic BCC (nodal or distant). Patients in both cohorts had either progressed on HHI therapy, had not had an objective response after 9 months on HHI therapy, or were intolerant of prior HHI therapy. The primary efficacy endpoint was confirmed ORR, and a key secondary endpoint was DOR, assessed by independent central review.

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.

The recommended dose of Libtayo is 350 mg administered as an intravenous infusion over 30 minutes every three weeks, until disease progression or unacceptable toxicity. Libtayo is available as a single-dose 350 mg vial. No PD-L1 or tumor mutational burden (TMB) testing is required before starting treatment with Libtayo for advanced BCC.

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. Current clinical development programs include Libtayo in combination with chemotherapy for advanced NSCLC irrespective of PD-L1 expression and Libtayo monotherapy for advanced cervical cancer. Libtayo is also being investigated in combination with either conventional or novel therapeutic approaches for other solid tumors and blood cancers. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

The generic name for Libtayo in its approved U.S. indications 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 (FDA). Libtayo is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

About Regeneron

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 nine FDA-approved treatments and numerous product candidates in development, almost 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, hematologic conditions, 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.

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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, 2020. 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, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized 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 product candidates being developed by

Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Libtayo® (cemiplimab) for the treatment of locally advanced or metastatic basal cell carcinoma; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as Libtayo) and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the study discussed in this press release, on any of the foregoing; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, such as possible regulatory approval of Libtayo in combination with chemotherapy for advanced non-small cell lung cancer irrespective of PD-L1 expression and as monotherapy for advanced cervical cancer (as well as in combination with either conventional or novel therapeutic approaches for both solid tumors and blood cancers); 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 Regeneron's Product Candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products (such as Libtayo) and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; 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 Regeneron's Product Candidates, including without limitation Libtayo; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products 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, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; 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/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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, collaboration, or supply 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; 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 EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), Praluent® (alirocumab), and REGEN-COV™ (casirivimab and imdevimab)), 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, 2020 and its Form 10-Q for the quarterly period ended March 31, 2021. 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 or otherwise) 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).