Updated Libtayo® (cemiplimab-rwlc) Results Reinforce Durable and Substantial Response Rates in Advanced Cutaneous Squamous Cell Carcinoma

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New data at ASCO include more than double the patients previously reported; median overall survival still not reached with a median follow-up of up to 17 months

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that positive updated data for Libtayo® (cemiplimab-rwlc) in locally advanced and metastatic cutaneous squamous cell carcinoma (CSCC) will be shared at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting from May 31 to June 4 in Chicago. Libtayo is a fully-human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1) and is the only treatment approved for patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation in the U.S.

These data from the pivotal Phase 2 EMPOWER-CSCC-1 trial include the primary analysis for the locally advanced CSCC group and longer-term data from the metastatic CSCC group. Together, they provide updated Libtayo efficacy and safety outcomes following its approval by the U.S. Food and Drug Administration (FDA) in September 2018 and will be shared alongside two additional joint Regeneron-Sanofi abstracts on CSCC.

"The data presented at this meeting offer longer-term results in more than twice as many patients as initially reported for the Phase 2 trial at ASCO last year, confirming how Libtayo can lead to beneficial and significant treatment outcomes for patients with advanced CSCC," said Israel Lowy, M.D., Ph.D., Head of Clinical and Translational Sciences, Oncology at Regeneron. "The medical community's rapid adoption of Libtayo since its approval last September is a testament to its strong body of evidence and the great unmet need in advanced CSCC."

Key data from EMPOWER-CSCC-1 include:

	Locally Advanced CSCC (n=78[a])	**Metastatic CSCC (n=59[b])**
Median follow-up[c]	9 months (Range: 1 to 28 months)	17 months (Range: 1 to 27 months)
Overall response rate[d] (n; 95% confidence interval [CI])	44% (34; 32%, 55%)	49% (29; 36%, 63%)
Complete response rate[d]	13% (10)	17% (10)
Partial response rate[d]	31% (24)	32% (19)
Median duration of response (DOR)	Not yet reached	Not yet reached
Median observed time to response	2 months (Range: 2 to 9 months)	2 months (Range: 2 to 9 months)
Durable disease control rate (DCR) of ≥16 weeks[e]	63% (95% CI: 51% to 74%)	63% (95% CI: 49% to 75%)
Median progression free survival	Not yet reached	18 months (95% CI: 7 months to not evaluable)
Median overall survival	Not yet reached	Not yet reached

[a] October 10, 2018 data cutoff

[b] September 20, 2018 data cutoff

[c] Excluding survival follow-up

[d] As assessed by central review

[e] Durable DCR includes stable disease or response

Among patients with locally advanced CSCC, the most common adverse events (AEs) were fatigue (42%), diarrhea and pruritus (both 27%) and nausea (22%). Grade 3 or higher immune-related AEs occurred in 10% of patients; one patient died due to an unknown cause assessed as treatment-related. Among patients with metastatic CSCC, the most common AEs were diarrhea (29%), fatigue (25%) and nausea (24%). Investigator-assessed Grade 3 or higher immune-related AEs occurred in 14% of patients.

In addition to the EMPOWER-CSCC-1 data, Regeneron and Sanofi are also sharing results from the largest retrospective data set of patients with metastatic or locally advanced CSCC who were treated with chemotherapy or an EGFR (epidermal growth factor receptor) inhibitor but who did not receive anti-PD-1 or anti-PD-L1 therapy.

Regeneron and Sanofi joint presentations at ASCO include:

Poster Discussion and Poster Sessions

- **Primary analysis of Phase 2 results of cemiplimab, a human monoclonal anti-PD-1, in patients with locally advanced cutaneous squamous cell carcinoma** (Dr. Michael Migden; Saturday, June 1; Poster Display: 1:15-4:15 PM; Poster Discussion: 4:30-6:00 PM)
- **Phase 2 study of cemiplimab, a human monoclonal anti-PD-1, in patients with metastatic cutaneous squamous cell carcinoma (mCSCC; Group 1): 12 month follow-up** (Dr. Alexander Guminski; Monday, June 3; Poster Display: 1:15-4:15 PM)

Publication-Only Abstracts

- **Treatment patterns and outcomes among patients with advanced cutaneous squamous cell carcinoma in a U.S. community oncology setting** (Dr. C. Lance Cowey; Publication Only)
- **Patterns of major surgeries among patients diagnosed with cutaneous squamous cell carcinoma** (Chieh-I Chen; Publication Only)

Libtayo is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. Libtayo was invented by Regeneron using the company's proprietary *VelocImmune*® technology that yields optimized fully-human antibodies.

About CSCC
CSCC is the second most common type of skin cancer in the world, accounting for approximately 20% of all skin cancers, and the number of newly diagnosed cases is expected to rise substantially in many countries. Although CSCC has a good prognosis when caught early, the cancer can prove especially difficult to treat effectively when it is advanced, and patients can experience reduced quality of life due to the impact of the disease as it progresses. Advanced CSCC is the deadliest non-melanoma skin cancer. While estimates vary, sources suggest that 7,000 people in the U.S. die annually of advanced CSCC.

About Libtayo
Libtayo is approved in the U.S., Canada and Brazil, and under review by the European Commission following a positive opinion for conditional approval by the Committee for Medicinal Products for Human Use (CHMP). In the U.S., Libtayo is approved for the treatment of patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The generic name for Libtayo in the U.S. is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the FDA.

Libtayo is also being investigated in potential registrational trials in non-small cell lung cancer, basal cell carcinoma and cervical cancer, along with additional trials in squamous cell carcinoma of the head and neck, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin's lymphoma and non-Hodgkin's lymphoma. These trials are designed to investigate Libtayo as monotherapy; in combination with conventional treatments like chemotherapy; or in combination with other investigational agents, including vaccines, oncolytic viruses and bispecific antibodies, among others. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR U.S. PATIENTS

What is the most important information I should know about Libtayo?
Libtayo is a medicine that may treat a type of skin cancer by working with your immune system. Libtayo can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse:

- **Lung problems (pneumonitis).** Signs and symptoms of pneumonitis may include new or worsening cough, shortness of breath, and chest pain.
- **Intestinal problems (colitis) that can lead to tears or holes in your intestine.** Signs and symptoms of colitis may include diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky or that have blood or mucus; and severe stomach-area (abdomen) pain or tenderness.
- **Liver problems (hepatitis).** Signs and symptoms of hepatitis may include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea colored), bleeding or bruising more easily than normal, and feeling less hungry than usual.
- **Hormone gland problems** (especially the adrenal glands, pituitary, thyroid and pancreas). Signs and symptoms that your hormone glands are not working properly may include headaches that will not go away or unusual headaches, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, dizziness or fainting, feeling more hungry or

thirsty than usual, hair loss, feeling cold, constipation, deeper voice, very low blood pressure, urinating more often than usual, nausea or vomiting, stomach-area (abdomen) pain, and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.
- **Kidney problems,** including nephritis and kidney failure. Signs of these problems may include decrease in your amount of urine, blood in your urine, swelling in your ankles, and loss of appetite.
- **Skin problems.** Signs of these problems may include rash, itching, skin blistering, and painful sores or ulcers in the mouth, nose, throat, or genital area.
- **Problems in other organs.** Signs of these problems may include headache, tiredness or weakness, sleepiness, changes in heartbeat (such as beating fast, seeming to skip a beat, or a pounding sensation), confusion, fever, muscle weakness, balance problems, nausea, vomiting, stiff neck, memory problems, seizures (encephalitis), swollen lymph nodes, rash or tender lumps on skin, cough, shortness of breath, vision changes, or eye pain (sarcoidosis), seeing or hearing things that are not there (hallucinations), severe muscle weakness, low red blood cells (anemia), bruises on the skin or bleeding, and changes in eyesight.
- **Rejection of a transplanted organ.** Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.
- **Infusion (IV) reactions that can sometimes be severe and life-threatening.** Signs of these problems may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling of passing out, back or neck pain, and facial swelling.

Getting medical treatment right away may help keep these problems from becoming more serious.

Your healthcare provider will check you for these problems during your treatment with Libtayo. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may delay or completely stop treatment if you have severe side effects.

Before you receive Libtayo, tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus;
- have had an organ transplant;
- have lung or breathing problems;
- have liver or kidney problems;
- have diabetes;
- are pregnant or plan to become pregnant; Libtayo can harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider will give you a pregnancy test before you start treatment.
  - You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of Libtayo. Talk with your healthcare provider about birth control methods that you can use during this time.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Libtayo.
- are breastfeeding or plan to breastfeed. It is not known if Libtayo passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of Libtayo.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of Libtayo include tiredness, rash, and diarrhea. These are not all the possible side effects of Libtayo. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Regeneron Pharmaceuticals and Sanofi at 1-877-542-8296.

Please see accompanying full Prescribing Information, including Medication Guide.

What is Libtayo?

Libtayo is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.

It is not known if Libtayo is safe and effective in children.

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 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, neuromuscular diseases, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*® which produces optimized fully-human antibodies, and 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

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 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 Libtayo® (cemiplimab) Injection; uncertainty of market acceptance and commercial success of Regeneron's products (such as Libtayo) and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the EMPOWER-CSCC-1 trial discussed in this press release, on the commercial success of Regeneron's products and product candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, including any possible regulatory approval of Libtayo for non-small cell lung cancer, basal cell carcinoma, cervical cancer, squamous cell carcinoma of the head and neck, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin's lymphoma, and non-Hodgkin's lymphoma (as monotherapy or in combination with other conventional treatments or other investigational agents); 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 (such as Libtayo) in clinical trials; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as Libtayo), 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, including without limitation Libtayo; 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; the availability and extent of reimbursement of the Company'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; 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; 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) Injection, and Praluent® (alirocumab) Injection, the ultimate outcome of any such proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; and 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. 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, 2018 and its Form 10-Q for the quarterly period ended March 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).

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, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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