Regeneron Strengthens Commitment to Oncology through Purchase of Sanofi's Stake in the Regeneron and Sanofi Collaboration on Libtayo® (cemiplimab), a PD-1 Inhibitor Approved for Multiple Forms of Cancer

June 2, 2022

Regeneron will secure global rights to Libtayo from Sanofi in exchange for upfront payment of $900 million, plus royalties and potential future milestone payments

18 different investigational treatment combinations with Libtayo currently being evaluated in 22 clinical trials

Regeneron will host an investor conference call today at 8:30 am ET; dial-in details are available below

TARRYTOWN, N.Y., June 2, 2022 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced its intent to purchase Sanofi's stake in the Regeneron and Sanofi collaboration on Libtayo® (cemiplimab), providing Regeneron with exclusive worldwide development, commercialization and manufacturing rights to the medicine. The transaction is subject to merger control clearance outside the United States and is expected to close in the third quarter of 2022. Once the transaction has closed, Regeneron will record 100% of global net sales and expenses for the Libtayo program.

Libtayo, which was invented using Regeneron's proprietary *VelocImmune*® technology, is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T cells. It is currently approved by regulatory authorities in more than two dozen countries, including by the U.S. Food and Drug Administration (FDA) as cemiplimab-rwlc monotherapy treatment for certain patients with advanced basal cell carcinoma (BCC), advanced cutaneous squamous cell carcinoma (CSCC) and advanced non-small cell lung cancer (NSCLC). Libtayo is a leading and first-in-class PD-1 inhibitor for the treatment of approved non-melanoma skin cancers and is considered a standard of care.

Regulatory reviews are also underway for Libtayo in combination with chemotherapy as a first-line treatment in advanced NSCLC in multiple markets, including the U.S. and European Union, where approvals would provide promising opportunities to extend the medicine's reach. It is also currently being studied with 18 investigational agents in 22 clinical trials for a variety of difficult-to-treat cancers. These combinations include numerous assets from Regeneron, including its antibody targeting the LAG-3 checkpoint receptor, and several assets from its collaborators.

"This strategic acquisition is a major step towards Regeneron's goal of becoming a global oncology leader, centered on Libtayo as an important choice in settings where PD-1 inhibitors can be used as monotherapy and, excitingly, in potential new combinations with our differentiated and diverse pipeline of oncology assets," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In 2021, Libtayo was approved for two new monotherapy indications in the U.S. and EU and global net product sales increased 32% year-over-year, providing a strong foundation for our multi-faceted oncology strategy and helping to maximize the potential value of our pipeline."

Regeneron and Sanofi entered into the Immuno-oncology License and Collaboration Agreement in 2015. Pursuant to this agreement, the companies currently split Libtayo's worldwide operating profits equally and co-commercialize Libtayo in the U.S., with Sanofi solely responsible for commercialization outside the U.S.

Under the terms announced today, Sanofi will transfer the rights to develop, commercialize and manufacture Libtayo entirely to Regeneron, on a worldwide basis, over the course of a defined transition period. Upon closing of the transaction, Regeneron will make an upfront payment of $900 million to Sanofi, which will be entitled to receive an 11% royalty on worldwide net sales of Libtayo. Sanofi will also be entitled to a $100 million regulatory milestone payment upon the first approval by either the FDA or European Commission of Libtayo in combination with chemotherapy for first-line treatment of certain patients with NSCLC, as well as sales-related milestone payments of up to $100 million in total over the next two years.

Pursuant to the agreement, Regeneron will accelerate reimbursement of the development balance associated with Regeneron and Sanofi's separate Antibody Collaboration. Regeneron will increase from 10% to 20% the share of its profits that are paid to Sanofi to reimburse Sanofi-funded development expenses, until Regeneron's share of the total cumulative development costs incurred under the collaboration has been reached.

Updates to 2022 GAAP and non-GAAP financial guidance as a result of this transaction will be provided following its successful completion. Assuming a third quarter 2022 close, there will be no financial or accounting impact to second quarter 2022 results.

Regeneron Investor Call Information
Participants may access today's conference call live via webcast on the 'Investors and Media' page of Regeneron's website at https://investor.regeneron.com/events-and-presentations. To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the Company's website for at least 30 days.

About Libtayo

Libtayo, which was invented using Regeneron's proprietary *VelocImmune*® technology, 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. In the U.S. and other countries Libtayo is indicated in certain patients with advanced basal cell carcinoma (BCC), advanced cutaneous squamous cell carcinoma (CSCC) and advanced non-small cell lung cancer (NSCLC), as well as in advanced cervical cancer in Canada. In the U.S., the generic name for Libtayo in its approved indications is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary

Naming of Biological Products Guidance for Industry issued by the FDA. Outside of the U.S., the generic name for Libtayo in its approved indication is cemiplimab.

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. Libtayo is currently being investigated in trials as a monotherapy, as well as 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.

Select Approved Indications

In the U.S., Libtayo is an FDA-approved prescription medicine used to treat people with:

-- A type of skin cancer called advanced CSCC that has spread or cannot be cured by surgery or radiation.

-- A type of skin cancer called BCC:

- That cannot be removed by surgery (locally advanced BCC) and have received treatment with a hedgehog inhibitor (HHI), or cannot receive treatment with an HHI.
- That has spread (metastatic BCC) and have received treatment with an HHI, or cannot receive treatment with an HHI. This use is approved based on how many patients responded to treatment and how long they responded. Studies are ongoing to provide additional information about clinical benefit.

-- A type of lung cancer called NSCLC. Libtayo may be used as your first treatment when your lung cancer has not spread outside your chest (locally advanced lung cancer) and you cannot have surgery or chemotherapy with radiation, or your lung cancer has spread to other areas of your body (metastatic lung cancer), and your tumor tests positive for high "PD-L1" and your tumor does not have an abnormal "EGFR", "ALK" or "ROS1" gene.

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

In Canada, Libtayo has received full or conditional approval for similar indications to the U.S., with the exception of metastatic BCC. Libtayo is also approved in Canada for the treatment of adult patients with cervical cancer who have progressed on or after prior platinum-based chemotherapy and who require additional systemic therapy to treat recurrent or metastatic disease.

About Regeneron's *VelocImmune* Technology

Regeneron's *VelocImmune* technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's President and Chief Scientific Officer George D. Yancopoulos was a graduate student with his mentor Frederick W. Alt in 1985, they were the first to envision making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing *VelocImmune* and related *VelociSuite* technologies. Dr. Yancopoulos and his team have used *VelocImmune* technology to create approximately one fifth of all original, FDA-approved or authorized fully human monoclonal antibodies currently available. This includes REGEN-COV® (casirivimab and imdevimab), Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb) and Inmazeb™ (atoltivimab, maftivimab, and odesivimab-ebgn).

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 certain cancers 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. You can have more than one of these problems at the same time. 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 new or worsening signs or symptoms, including:

- **Lung problems:** cough, shortness of breath, or chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual, stools that are black, tarry, sticky or have blood or mucus, or severe stomach area (abdomen) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), or bleeding or bruising more easily than normal
- **Hormone gland problems:** headache that will not go away or unusual headaches, eye sensitivity to light, eye problems, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, feeling more hungry or thirsty than usual, urinating more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, or changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, or loss of appetite
- **Skin problems:** rash, itching, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat, or genital area, fever or flu-like symptoms, or swollen lymph nodes
- Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with Libtayo. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include: chest pain, irregular heartbeat, shortness of breath or swelling of ankles, confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs, double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight, persistent or severe muscle pain or weakness, muscle cramps, low red blood cells, or bruising

- **Infusion reactions that can sometimes be severe.** Signs and symptoms of infusion reactions may include: nausea, chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain, or facial swelling.
- **Rejection of a transplanted organ.** Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.
- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with Libtayo. Your healthcare provider will monitor you for these complications.

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 also need to delay or completely stop treatment with Libtayo 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 received an organ transplant

-- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)

-- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome 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 muscle or bone pain, 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 full Prescribing Information, including Medication Guide.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for nearly 35 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.

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. Risks that may cause these forward-looking statements to be inaccurate include, among others: risks related to the satisfaction or waiver of the conditions to closing the proposed restructuring (the "Proposed Restructuring") of the Company's Immuno-oncology Collaboration with Sanofi related to Libtayo® (cemiplimab-rwlc) (including the failure to obtain necessary regulatory approvals) in the anticipated timeframe or at all; risks related to the Company's ability to realize the anticipated benefits of the Proposed Restructuring, including the possibility that the expected benefits from the Proposed Restructuring will not be realized or will not be realized within the expected time period; the impact of the Proposed Restructuring on

Regeneron's business, operating results, and financial condition, as well as effects of this announcement or the consummation of the Proposed Restructuring on the market price of the Company's common stock; significant transaction costs; 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 or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products, product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Libtayo as a monotherapy treatment or in combination with chemotherapy or certain of the Company's investigational assets as referenced in this press release; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; 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 Libtayo in combination with chemotherapy as a first-line treatment in advanced non-small cell lung cancer; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the ability of Regeneron's collaborators, licensees, 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 and/or its collaborators to manufacture and manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products 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; 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; 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, 2021 and its Form 10-Q for the quarterly period ended March 31, 2022. 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).

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