



Regeneron Presentations at ASCO 2020 Showcase Diverse Clinical Oncology Portfolio

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Regeneron will host investor webcast on Monday, June 1 to discuss oncology program strategy and progress

[Regeneron Pharmaceuticals, Inc.](#) (NASDAQ: **REGN**) today announced the company will share updates from its diverse clinical oncology portfolio at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting from May 29-31 taking place virtually.

Among the accepted abstracts are new, longer-term data for PD-1 inhibitor Libtayo[®] (cemiplimab-rwlc) in advanced cutaneous squamous cell carcinoma (CSCC). The data published today, which will be updated during ASCO, add to the most mature dataset for any therapy in advanced CSCC and show that median overall survival and median duration of response have yet to be reached for Libtayo-treated patients with no new safety signals observed. Additional abstracts outline the clinical trial designs for Regeneron's first costimulatory bispecific REGN5678 (PSMAxCD28) in metastatic castration-resistant prostate cancer and the company's first tumor-targeted bispecific REGN5093 (METxMET) in MET-altered advanced non-small cell lung cancer (NSCLC).

"Regeneron is committed to advancing an oncology program to potentially transform treatment paradigms across multiple solid tumors and blood cancers where there are significant unmet needs," said Israel Lowy, M.D., Senior Vice President, Translational and Clinical Sciences, Oncology at Regeneron. "We've already made significant progress. Libtayo is the standard of care for advanced cutaneous squamous cell carcinoma, and we recently announced clinically meaningful outcomes from our pivotal Libtayo trials in advanced non-small cell lung cancer and advanced basal cell carcinoma. At ASCO, we will build on these milestones with three-year data from Libtayo in advanced cutaneous squamous cell carcinoma and updates from our expanding bispecific antibody platform."

Investor Webcast Information

Regeneron will host a conference call and simultaneous webcast to share updates on Regeneron's oncology portfolio on Monday, June 1 at 4:30 pm ET. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International). A link to the webcast may be accessed from the "Investors and Media" page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for at least 30 days.

Regeneron presentations and publications at ASCO

Libtayo (PD-1 inhibitor) & Skin Cancer (jointly presented and published with Sanofi)

- Phase 2 study of cemiplimab in patients (pts) with advanced cutaneous squamous cell carcinoma (CSCC): Longer follow-up (Abstract 10018, Poster 367; Danny Rischin, M.D.; Poster Discussion)
- Health-related quality of life (HRQL) in patients with advanced cutaneous squamous cell carcinoma (CSCC) treated with cemiplimab: Post hoc exploratory analysis of a Phase 2 clinical trial (Abstract 10033, Poster 382; Michael Migden, M.D.; Poster)
- Assessing the value of cemiplimab for adults with advanced cutaneous squamous cell carcinoma (CSCC): A cost-effectiveness analysis (Abstract e19397; Eleanor Paul; Online Publication)
- A Phase 3, randomized, double-blind study of adjuvant cemiplimab versus placebo post-surgery and radiation therapy (RT) in patients (pts) with high-risk cutaneous squamous cell carcinoma (CSCC) (Abstract TPS10084, Poster 433; Danny Rischin, M.D.; Trial in Progress Poster)
- Patterns of hedgehog inhibitor (HHI) treatment interruptions and re-initiations among patients with basal cell carcinoma (BCC) in real-world clinical practice (Abstract e19349; Jessica Jalbert, Ph.D.; Online Publication)

REGN5678 (PSMAxCD28 Costimulatory Bispecific)

- A Phase 1/2 study of REGN5678 (Anti-PSMAxCD28, a costimulatory bispecific antibody) with cemiplimab (anti-PD-1) in patients with metastatic castration-resistant prostate cancer (Abstract TPS5592, Poster 173; Charles Drake, M.D., Ph.D.; Trial in Progress Poster)

REGN5093 (METxMET Tumor-targeted Bispecific)

- A Phase 1/2 study of REGN5093, a METxMET bispecific antibody, in patients with MET-altered advanced non-small cell lung cancer (NSCLC) (Abstract TPS9628, Poster 394; Tracey Rowlands, Ph.D.; Trial in Progress Poster)

Diffuse Large B-Cell Lymphoma

- Real-world treatment patterns among patients with diffuse large B-cell lymphoma (DLBCL) treated with CD19-directed chimeric antigen receptor T-cell therapy (CAR T) (Abstract e19351; Jessica Jalbert, Ph.D.; Online Publication)

About the Regeneron Bispecific Antibody Platform

All of Regeneron's bispecifics are designed to closely resemble natural human antibodies and bind to two different targets. They are derived from a next-generation version of Regeneron's proprietary *VelocImmune*[®] technology and created using the company's *Veloci-Bi*[®] platform. These allow for the creation of bispecifics with no linkers or artificial sequences. Additionally, Regeneron bispecifics are manufactured using similar approaches used for human antibody medicines, with similar pharmacokinetics.

There are six Regeneron investigational bispecific antibodies currently in ongoing clinical trials for multiple blood cancers and solid tumors. These bispecifics fall into three categories:

- **CD3 bispecifics** are designed to bridge T-cells and tumor cells. At the tumor site, they activate T-cells via their CD3 receptors and promote T-cell killing of the cancer cells. Investigational candidates include:
 - CD20xCD3 (odronextamab) for B-cell non-Hodgkin lymphoma;
 - Two distinct BCMAxCD3s (REGN5458 and REGN5459) for multiple myeloma;
 - MUC16xCD3 (REGN4018) for ovarian cancer.
- **CD28 costimulatory bispecifics** are also designed to bridge T-cells and tumor cells. At the tumor site, they costimulate T-cells via their CD28 receptors and may synergize with PD-1 inhibitors and/or CD3 bispecifics. Investigational candidates include:
 - PSMAxCD28 (REGN5678) in combination with Libtayo for prostate cancer.
- **Tumor-targeted bispecifics** are designed to target proteins only on the cancer cell. In this way, they may affect various signaling pathways to hamper the cancer cells' ability to survive and proliferate. Investigational candidates include:
 - METxMET (REGN5093) for NSCLC that is driven by MET mutations and/or amplifications. REGN5093 targets two different parts of the MET receptor on cancer cells to degrade the receptor and block its ability to trigger cell proliferation.

The bispecifics mentioned in this release are currently under clinical development, and their safety and efficacy have not been evaluated by any regulatory authority. Libtayo in combination with REGN5678 is currently under clinical development for metastatic castration-resistant prostate cancer, and its safety and efficacy have not been evaluated by any regulatory authority for this use.

As part of a global collaboration agreement, Regeneron and Sanofi are jointly developing the BCMAxCD3 and MUC16xCD3 bispecific programs.

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., European Union, and other countries for adults with metastatic 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 a potentially registrational Phase 2 trial in basal cell carcinoma and additional trials in adjuvant and neoadjuvant CSCC. Libtayo is also being investigated in potentially registrational Phase 3 trials in NSCLC 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.

Libtayo was invented using Regeneron's proprietary *VelocImmune* technology that utilizes a proprietary genetically-engineered mouse platform endowed with a genetically-humanized immune system to produce optimized fully-human antibodies. *VelocImmune* technology has been used to create multiple antibodies including Dupixent[®] (dupilumab), Praluent[®] (alirocumab) and Kevzara[®] (sarilumab), which are approved in multiple countries around the world. Regeneron previously used these technologies to rapidly develop a treatment for Ebola virus infection, which is currently under review by the FDA, and is now being used in efforts to create preventative and therapeutic medicines for COVID-19.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR U.S. PATIENTS

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.

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.

For more information, please see [full Prescribing Information](#), including Medication Guide.

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.

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, 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-rwlc), REGN5678 (a PSMAxCD28 costimulatory bispecific antibody being studied in combination with Libtayo), REGN5093 (a METxMET bispecific antibody), and Regeneron's other investigational bispecific antibodies discussed in this press release; 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 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 for the treatment of non-small cell lung cancer, basal cell carcinoma, and cervical cancer (as well as in combination with novel therapeutic approaches for both solid tumors and blood cancers, as applicable); unforeseen safety issues resulting from the administration of Regeneron's Products (such as Libtayo) and product candidates (such as Regeneron's investigational bispecific antibodies discussed in this press release) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to develop or commercialize Regeneron's Products and 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 (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 extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may lead to advancement of product candidates to clinical trials or therapeutic applications; 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 and its Form 10-Q for the quarterly period ended March 31, 2020. 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>).

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