Regeneron to Showcase Progress in Advancing Novel Investigational Treatment Approaches for a Broad Range of Solid Tumors and Blood Cancers at ASCO

April 24, 2024 at 10:05 AM EDT

Oral presentation will feature new data for investigational REGN7075, an EGFRxCD28 costimulatory bispecific with the potential to enhance the treatment of certain advanced solid tumors in combination with Libtayo® (cemiplimab-rwlc)

17 presentations to highlight Regeneron's investigational pipeline including checkpoint inhibitors, CD3 bispecifics and CD28 costimulatory bispecifics

TARRYTOWN, N.Y., April 24, 2024 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced new and updated data from its oncology and hematology pipeline will be shared across 17 presentations at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting, taking place from May 31 to June 5 in Chicago, IL. Notably, new safety and efficacy results from a Phase 1/2 trial investigating the costimulatory bispecific antibody REGN7075 (EGFRxCD28) in combination with Libtayo in patients with certain advanced solid tumors will be featured in an oral presentation.

“The breadth of our presentations at ASCO showcase our progress in advancing multiple promising and distinct investigational treatment approaches for a diverse array of difficult-to-treat cancers,” said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer at Regeneron. “These latest clinical results build on our ongoing commitment to cancer research and reflect our focus on advancing a pipeline of internally-developed candidates that have the potential to offer novel and differentiated therapies. Poised to tackle more than 30 types of cancer, our oncology pipeline is a testament to Regeneron’s relentless commitment to transforming cancer care for those who need it most.”

Beyond the REGN7075 data, additional presentations will feature results from Regeneron’s diverse pipeline of checkpoint inhibitors and bispecific antibodies. Among them are presentations on updated data and new analyses for linvoseltamab (BCMAxCD3) in multiple myeloma; odronextamab (CD20xCD3) in several lymphoma subtypes; REGN6569 (GITR) in combination with Libtayo across solid tumors; and fianlimab (LAG-3 inhibitor) in combination with Libtayo in non-small cell lung cancer, melanoma and head and neck cancer.

Regeneron presentations at ASCO:

Medicine	Abstract title	Abstract	Lead author	Presentation date/time (all CDT)
Solid Tumor Malignancies				
REGN7075, Libtayo	A Phase 1/2 study of REGN7075 in combination with cemiplimab in patients with advanced solid tumors: Updated dose escalation results	#2503 Oral Presentation Session— Developmental Therapeutics —Immunotherapy	Segal, N.H.	Monday, June 3 11:30 a.m. – 2:30 p.m.
REGN6569, Libtayo	A Phase 1 study of REGN6569, a GITR mAb, in combination with cemiplimab in patients (pts) with advanced solid tumor malignancies: Initial dose-escalation results	#2650 Poster Presentation Session— Developmental Therapeutics —Immunotherapy	Lakhani, N.J.	Saturday, June 1 9:00 a.m. – 12:00 p.m.
Blood Cancer				
Linvoseltamab	Indirect comparison of linvoseltamab (linvo) versus teclistamab (tec) for treatment of triple-class exposed (TCE) relapsed/refractory multiple myeloma (RRMM)	#7560 Poster Presentation Session— Hematologic Malignancies—Plasma Cell Dyscrasia	Jagannath, S.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Linvoseltamab	Comparative effectiveness of linvoseltamab (Linvo) vs. standard of care (SOC) in real-world patients (pts) with triple class exposed (TCE) relapsed/refractory multiple myeloma (RRMM)	#7561 Poster Presentation Session— Hematologic Malignancies—Plasma Cell Dyscrasia	Kumar, S.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Odronextamab	Phase 3 trial evaluating the efficacy and safety of odronextamab versus investigator’s choice in previously untreated follicular lymphoma (OLYMPIA-1)	#7096 Poster Presentation Session— Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia	Birhiray, R.	Monday, June 3 9:00 a.m. – 12:00 p.m.

Odronextamab	Phase 3 trial evaluating the efficacy and safety of odronextamab plus chemotherapy versus rituximab plus chemotherapy in previously untreated follicular lymphoma (OLYMPIA-2)	#7099 Poster Presentation Session— Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia	Hardin, C.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Odronextamab	Phase 3 trial evaluating efficacy and safety of odronextamab plus CHOP vs rituximab plus CHOP in previously untreated diffuse large B-cell lymphoma (DLBCL; OLYMPIA-3)	#7086 Poster Presentation Session— Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia	Matasar, M.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Odronextamab	Phase 3 trial evaluating the efficacy and safety of odronextamab versus standard-of-care (SOC) therapy in relapsed/refractory (R/R) aggressive B-cell non-Hodgkin lymphoma (B-NHL;OLYMPIA-4)	#7093 Poster Presentation Session— Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia	Hawkes, E.A.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Odronextamab	Phase 3 trial of odronextamab plus lenalidomide versus rituximab plus lenalidomide in relapsed/refractory (R/R) follicular lymphoma (FL) and marginal one lymphoma (MZL; (OLYMPIA-5)	#7094 Poster Presentation Session— Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia	Vitolo, U.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Odronextamab	Results from the follicular lymphoma (FL) outcomes in relapsed/refractory (R/R) patients treated with systemic therapy in a real-world assessment (FLORA) study	#7076 Poster Presentation Session— Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia	Luminari, S.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Skin Cancer				
Fianlimab, Libtayo	A Phase 3 trial of fixed dose combinations of fianlimab (anti-LAG-3) + cemiplimab (anti-PD-1) versus relatlimab + nivolumab in patients with unresectable or metastatic melanoma	#TPS9611 Poster Presentation Session— Melanoma/Skin Cancers	Khushalani, N.I.	Saturday, June 1 1:30 p.m. – 4:30 p.m.
Lung Cancer				
Fianlimab, Libtayo	A Phase 2/3 study of fianlimab, cemiplimab, plus chemotherapy versus cemiplimab plus chemotherapy in first-line advanced non-small cell lung cancer	#TPS8660 Poster Presentation Session— Lung Cancer —Non-Small Cell Metastatic	Gabrail, N.	Monday, June 3 1:30 p.m. – 4:30 p.m
Fianlimab, Libtayo	A Phase 2/3 study of fianlimab plus cemiplimab versus cemiplimab in patients with advanced non-small cell lung cancer with tumors expressing PD-L ≥50%	#TPS8663 Poster Presentation Session— Lung Cancer —Non-Small Cell Metastatic	Faulkner, N.	Monday, June 3 1:30 p.m. – 4:30 p.m.
Gynecologic Cancer				
Libtayo	Combination of cemiplimab and ISA101b vaccine for the treatment of recurrent/metastatic HPV16 cervical cancer*	#5522 Poster Presentation Session— Gynecologic Cancer	Lorusso, D.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Ubamatamab, Libtayo	A Phase 1/2 study of ubamatamab (REGN4018), a MUC16×CD3 bispecific antibody, administered alone or in combination with cemiplimab (anti–PD-1) in patients with recurrent ovarian cancer or MUC16+ endometrial cancer: Trial in progress update	#TPS5632 Poster Presentation Session— Gynecologic Cancer	Nieuwenhuysen, E.	Monday, June 3 9:00 a.m. – 12:00 p.m.
Head and Neck Cancer				
Fianlimab, Libtayo	A Phase 1 study of fianlimab (anti-LAG-3) in combination with cemiplimab (anti-PD-1) in patients with advanced HNSCC	#6038 Poster Presentation Session— Head and Neck Cancer	Cho, B.C.	Sunday, June 2 9:00 a.m. – 12:00 p.m.
DB-020	A phase 1 clinical trial of DB-020 intratympanic injections administered prior to high dose cisplatin chemotherapy to reduce ototoxicity	#6100 Poster Presentation Session— Head and Neck Cancer	Rischin, D.	Sunday, June 2 9:00 a.m. – 12:00 p.m.

**Study conducted in collaboration between Regeneron and ISA.*

The potential uses of Libtayo, REGN7075, odronextamab, linvoseltamab, REGN6569, fianlimab and DB-020 as described above are investigational, and their safety and efficacy in these uses have not been fully evaluated by any regulatory authority. REGN7075, odronextamab, linvoseltamab,

REGN6569, fianlimab and DB-020 are not currently approved for use in any indication.

About Regeneron in Cancer
We aspire to turn revolutionary discoveries into medicines that can transform the lives of those impacted by cancer. Our team around the world is driven to solve the needs and challenges of those affected by one of the most serious diseases of our time.

Backed by our legacy of scientific innovation and a deep understanding of biology, genetics and the immune system, we're pursuing potential therapies across more than 30 types of solid tumors and blood cancers. Our cancer strategy is powered by cutting-edge technologies and therapies that can be flexibly combined to investigate potentially transformative treatments for patients. Oncology assets in clinical development comprise nearly half of Regeneron's pipeline, and include checkpoint inhibitors, bispecific antibodies and costimulatory bispecific antibodies. Our approved PD-1 inhibitor Libtayo serves as the backbone of many of our investigational combinations.

To complement our extensive in-house capabilities, we collaborate with patients, healthcare providers, governments, biopharma companies and each other to further our shared goals. Together, we are united in the mission to serve as a beacon of transformation in cancer care.

About Libtayo
Libtayo is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T cells and was invented using Regeneron's proprietary *VelocImmune*® technology. 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 the European Union, Canada and Brazil. As of July 1, 2022, Libtayo is developed and marketed globally by Regeneron.

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 U.S. Food and Drug Administration (FDA). Outside of the U.S., the generic name of 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.

U.S. FDA-approved Indications
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.
- People with a type of skin cancer called basal cell carcinoma (BCC) when your BCC cannot be removed by surgery (locally advanced BCC) or when it has spread (metastatic BCC) and have received treatment with a hedgehog pathway inhibitor (HHI), or cannot receive treatment with a HHI.
- Adults with a type of lung cancer called non-small cell lung cancer (NSCLC).
    - LIBTAYO may be used in combination with chemotherapy that contains a platinum medicine 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 does not have an abnormal "EGFR," "ALK," or "ROS1" gene.
    - LIBTAYO may be used alone 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.

IMPORTANT SAFETY INFORMATION 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 or life-threatening.** Signs and symptoms of infusion reactions may include: nausea, vomiting, 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 received radiation treatment to your chest area
- 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
- 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

  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 to 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

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 when used alone include tiredness, muscle or bone pain, rash, diarrhea, and low levels of red blood cells (anemia). The most common side effects of LIBTAYO when used in combination with platinum-containing chemotherapy include hair loss, muscle or bone pain, nausea, tiredness, numbness, pain, tingling, or burning in your hands or feet, and decreased appetite. 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 at 1-877-542-8296.

Please see full Prescribing Information, including Medication Guide.

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 co-Founder, 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 a substantial proportion of all original, FDA-approved or authorized fully human monoclonal antibodies. This includes REGEN-COV® (casirivimab and imdevimab), Dupixent® (dupilumab), Libtayo®, Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg).

About Regeneron
Regeneron is a leading biotechnology company that invents, develops, and commercializes life-transforming medicines for people with serious diseases. Founded and led for 35 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in Regeneron's

laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its 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 Regeneron, please visit www.regeneron.com or follow Regeneron on LinkedIn.

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 products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and 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 REGN7075 in combination with Libtayo® (cemiplimab), odronextamab, linvoseltamab, fianlimab in combination with Libtayo, and other of Regeneron's Product Candidates discussed or referenced in this press release; 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 REGN7075 in combination with Libtayo in patients with advanced solid tumors, odronextamab in several lymphoma subtypes, linvoseltamab in multiple myeloma, fianlimab in combination with Libtayo in non-small cell lung cancer, melanoma, and head and neck cancer, and the other clinical programs discussed or referenced in the 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 discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates (such as those referenced above); 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 to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as those referenced above) 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; 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; 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 and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; 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), 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, 2023. 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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

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