



Ubatamamab (MUC16xCD3) Shows a High Rate of Durable Responses in Initial Study of Patients with Advanced Low-Grade Serous Ovarian Cancer (LGSOC)

October 1, 2026 at 11:35 AM EDT

LGSOC is a biologically distinct variant of ovarian cancer, with limited treatment options, that is generally less responsive to conventional chemotherapy

Results presented in a late-breaking plenary session at IGCS demonstrated a 73% objective response rate and 11-month median progression-free survival in 11 patients with recurrent and heavily pre-treated LGSOC treated with the highest dose of ubamatamab in the trial

Regeneron has been enrolling a dedicated LGSOC cohort at this dose and will advance ubamatamab into a confirmatory Phase 3 trial of this lethal cancer with limited treatment options

TARRYTOWN, N.Y., Oct. 01, 2026 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced the first results for the investigational ubamatamab in patients with low-grade serous ovarian cancer (LGSOC). The data are from an ongoing Phase 1/2 trial in recurrent platinum-resistant high- or low-grade serous ovarian cancer that were presented in a late-breaking plenary oral session at the International Gynecologic Cancer Society (IGCS) 2026 Annual Global Meeting. Ubatamamab is a MUC16xCD3 bispecific antibody designed to bridge MUC16 on cancer cells with CD3-expressing T cells to facilitate local T-cell activation. Based on these preliminary trial results, Regeneron has been enrolling a single-arm, potentially registrational LGSOC trial and will be discussing the data with the U.S. Food and Drug Administration (FDA) in the coming months. Regeneron is also planning to initiate a confirmatory, randomized, controlled Phase 3 trial to support the use of ubamatamab in LGSOC.

LGSOC is a biologically distinct variant from the more common high-grade serous ovarian cancer (HGSOC), comprising up to 10% of serous ovarian cancer, with typically uniformly high MUC16 expression and limited treatment options. The disease often affects younger women and is characterized by slower-growing tumors than those seen in HGSOC, but frequently recurs and is less responsive to conventional chemotherapy with few treatment options. LGSOC has a median overall survival of approximately seven years from initial diagnosis, compared to approximately four years for HGSOC. In recurrent advanced LGSOC, historical trial data have shown that objective response rates (ORRs) generally remain below 15% with chemotherapy and endocrine therapy, while the only approved therapy has an ORR of 44% in biomarker-selected patient populations (representing about 30% of the overall LGSOC population).

"The high rate of durable responses observed thus far with ubamatamab in low-grade serous ovarian cancer, without requiring biomarker selection, are highly encouraging and reinforce our excitement about MUC16 as a new therapeutic target in this difficult-to-treat disease," said Israel Lowy, M.D., Ph.D., Clinical Development Unit Head, Oncology, at Regeneron. "This initial clinical evidence highlights the potential of our bispecific approach to bring a differentiated and first-in-class treatment option to patients in need. We are pleased with the safety profile of the drug as well, and are eager to build on these findings through our ongoing trial and planned confirmatory Phase 3 trial."

Data presented at IGCS focused on the LGSOC subset of 19 patients who had received a median of four prior lines of therapy and were dosed with intravenous ubamatamab ranging from 3 to 800 mg weekly or every three weeks. Ubatamamab was given either as monotherapy or in combination with Libtayo® (cemiplimab).

Included in the presentation were 11 patients treated with 800 mg of ubamatamab monotherapy, eight treated weekly and three treated every three weeks. Results at the 800 mg doses showed a:

- 73% ORR (95% Confidence Interval [CI]: 39.0 to 94.0), with all responses being partial responses
- 9-month median duration of response (95% CI: 6.9 to not estimable [NE]), per Kaplan-Meier estimate
- 11-month median progression-free survival (95% CI: 3.0 to NE), per Kaplan-Meier estimate

Safety was assessed across all 19 patients in the LGSOC subset. Treatment-emergent adverse events (TEAEs) occurred in 100% of participants (n=19). Cytokine release syndrome occurred in 90% of participants (n=17), all of which were Grade 1 or 2. Serious TEAEs grade 3 or higher occurred in 21% (n=4) of participants and treatment-related adverse events (TRAEs) occurred in 74% of participants (n=14). Grade 3 or higher TRAEs included neutropenia (21%; n=4), anemia (11%; n=2), increased alanine aminotransferase (11%; n=2), increased aspartate aminotransferase (11%; n=2), abdominal pain (5%; n=1) and ileus (5%; n=1). Most adverse events occurred during the step-up dosing period. One participant discontinued treatment due to a stroke considered unrelated to ubamatamab treatment; no TEAEs resulted in death.

The potential uses of ubamatamab described above are investigational, and its safety and efficacy have not been evaluated by

any regulatory authority.

About the Trial

The ongoing, open-label, Phase 1/2 trial is evaluating ubamatamab alone and in combination with Libtayo in adult patients with recurrent platinum-resistant ovarian cancer and other recurrent MUC16-expressing cancers.

The Phase 1 portion of the trial is primarily assessing safety, tolerability, dose-limiting toxicities and pharmacokinetics of ubamatamab, with efficacy evaluated as a secondary endpoint through measures such as ORR, duration of response and progression-free survival. The Phase 2 portion is evaluating the anti-tumor activity of ubamatamab, primarily through ORR, while continuing to assess safety and tolerability.

A prospective, dedicated, potentially registrational cohort in the Phase 2 portion of this trial is evaluating ubamatamab 800 mg monotherapy every three weeks in up to 100 patients with recurrent LGSOC and is currently enrolling. If you are interested in learning more about this trial, please contact us (clinicaltrials@regeneron.com, +1 844 734 6643), or visit our clinical trial [website](#).

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic cancers and remains a leading cause of cancer-related mortality among women. It arises from the uncontrolled growth of abnormal cells in the ovary and is frequently diagnosed at an advanced stage, when disease has spread beyond the ovary. In 2026, an estimated 21,010 new cases of ovarian cancer were expected to be diagnosed in the U.S., and approximately 12,450 women were expected to die from the disease. Despite advances in treatment, ovarian cancer remains a significant unmet medical need, with many patients ultimately experiencing disease recurrence and progression.

LGSOC is a distinct form of ovarian cancer that occurs in younger women and comprises up to 10% of new epithelial ovarian cancer cases. While LGSOC tumor cells tend to grow and divide more slowly than those seen in high-grade serous ovarian cancer, the disease frequently recurs and is less responsive to conventional chemotherapy. LGSOC has a median overall survival of approximately seven years from initial diagnosis, compared to approximately four years for HGSOC. Although endocrine therapy and targeted therapies are used in selected patients, treatment options remain limited for many people with recurrent disease.

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. Libtayo has been approved by regulatory authorities in more than 30 countries in one or more indications, including for certain adult patients with advanced basal cell carcinoma (BCC), advanced cutaneous squamous cell carcinoma (CSCC), advanced NSCLC and advanced cervical cancer.

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. FDA. Outside of the U.S., the generic name of Libtayo in its approved indications 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. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

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 or tissue.** Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ or tissue 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 or tissue transplant, including corneal 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

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
- 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 when used alone to treat CSCC that has spread or cannot be cured by surgery or radiation, BCC, or NSCLC 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 alone to help prevent CSCC from coming back include rash and itching. The most common side effects of LIBTAYO when used in combination with platinum-containing chemotherapy to treat NSCLC 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 fully human monoclonal antibodies. This includes Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara®, Evkeeza® (evinacumab-dgnb), Inmazole® (atoltivimab, maftivimab and odesivimab-ebgn), Veopoz® (pozelimab-bbfg) and Pasatru™ (garetosmab-grts). In addition, REGEN-COV® (casirivimab and imdevimab) had been authorized by the FDA during the COVID-19 pandemic until 2024. A total of 11 antibody and bispecific products have been approved or authorized worldwide that were invented or derived using *VelocImmune* technologies.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on [LinkedIn](#), [Instagram](#), [Facebook](#) or [X](#).

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 ubamatamab (MUC16xCD3 bispecific antibody), Libtayo® (cemiplimab), and the other clinical programs 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 ubamatamab as a monotherapy or in combination with Libtayo® (cemiplimab) for the treatment of low-grade serous ovarian cancer; uncertainty of the utilization, market acceptance, and/or 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 ubamatamab); 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 and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as ubamatamab) 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes to drug pricing regulations and requirements and Regeneron's pricing strategy, including in connection with Regeneron's April 2026 agreements with the U.S. government; other changes in laws, regulations, and policies affecting the healthcare industry; competing products and product candidates (including biosimilar products) 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 on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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), 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, 2025 and its Form 10-Q for the quarterly period ended June 30, 2026. 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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Source: Regeneron Pharmaceuticals, Inc.