Lynozyfic™ (linvoseltamab-gcpt) Receives FDA Accelerated Approval for Treatment of Relapsed or Refractory Multiple Myeloma

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Lynozyfic is a bispecific antibody directing T cells to kill multiple myeloma cancer cells; multiple myeloma is the second most common blood cancer

Approval based on pivotal Phase 1/2 LINKER-MM1 trial; results reported were among the highest overall (70%) and complete response rates (45%) for bispecific antibodies in heavily pre-treated multiple myeloma patients

Lynozyfic provides a patient-centric response-adapted dosing regimen

TARRYTOWN, N.Y., July 02, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval for Lynozyfic™ (linvoseltamab-gcpt) to treat adult patients with relapsed or refractory (R/R) multiple myeloma (MM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Lynozyfic was granted accelerated approval based on response rate and durability of response in the LINKER-MM1 trial. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Lynozyfic is the first FDA-approved BCMAxCD3 bispecific antibody that can be dosed every two weeks starting at week 14, and every four weeks if a very good partial response (VGPR) or better is achieved following completion of at least 24 weeks of therapy. The regimen includes hospitalization for safety during the step-up dosing period (one 24-hour period after the first step-up dose, and another 24-hour period after the second step-up dose).

“The FDA approval of Lynozyfic represents meaningful progress for the multiple myeloma community. Lynozyfic demonstrated early, deep and durable responses in heavily pre-treated patients, which I saw firsthand in clinical trials,” said Sundar Jagannath, M.D., Network Director of the Center of Excellence for Multiple Myeloma at Mount Sinai in New York City and a trial investigator. “Lynozyfic has a convenient response-adapted dosing regimen, which provides the potential to extend time between doses. This is a significant patient-centric advancement that could help reduce treatment burden.”

The FDA approval is based on results from the pivotal Phase 1/2 LINKER-MM1 trial investigating linvoseltamab in R/R MM in which patients (n=80) experienced a:

- **70% objective response rate (ORR), with 45% achieving a complete response (CR) or better**, as determined by an independent review committee.
- **0.95 month median time to first response** (range: 0.5 to 6 months).
- **Median duration of response (DoR) that was not reached** (95% Confidence Interval [CI]: 12 months to not estimable). The estimated DoR was 89% at 9 months (95% CI: 77 to 95 months) and 72% at 12 months (95% CI: 54 to 84 months) among responders who had a median follow-up of 13 months.

The prescribing information for Lynozyfic has a Boxed Warning for cytokine release syndrome (CRS) and neurologic toxicity – including immune effector cell-associated neurotoxicity syndrome – in addition to warnings and precautions for infections, neutropenia, hepatotoxicity and embryo-fetal toxicity. The most common adverse reactions (≥20%) in the safety population of LINKER-MM1 (n=117) were musculoskeletal pain, CRS, cough, upper respiratory tract infection, diarrhea, fatigue, pneumonia, nausea, headache and dyspnea. The most common Grade 3 or 4 laboratory abnormalities (≥30%) were decreased lymphocyte count, decreased neutrophil count, decreased hemoglobin and decreased white blood cell count. Lynozyfic is available only through a restricted program called the Lynozyfic Risk Evaluation and Mitigation Strategy (REMS). Details of the Important Safety Information are included below.

“The FDA approval of Lynozyfic reinforces the strength of our bispecific antibody program as well as our commitment to delivering critical medicines to the cancer community,” said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer of Regeneron. “With a 70% overall response rate in heavily pre-treated patients, we believe Lynozyfic is poised to potentially become a new standard of care for multiple myeloma. Furthermore, given the strength of the data, we are rapidly advancing our broad clinical development program for Lynozyfic – exploring its use in earlier lines of therapy as monotherapy and in novel combinations – as we aim to meaningfully advance care for patients.”

Regeneron is committed to helping patients who have been prescribed Lynozyfic access their medication. The company has launched Lynozyfic Surround™, which offers financial and educational resources to help support patients throughout their treatment journey. For more information, patients can call 1-844-RGN-HEME (1-844-746-4363).

“Even though the number of treatment options for multiple myeloma has expanded in recent years, it remains an incurable disease with considerable unmet need, especially among patients who have undergone multiple lines of treatment,” said Diane Moran, R.N., M.A., Ed.M., Chief Executive Officer (Interim) and Senior Vice President of Strategic Planning at the International Myeloma Foundation. “The FDA approval of Lynozyfic is a welcome milestone. It provides appropriate multiple myeloma patients and their care teams with a novel patient-centric treatment option that includes a dosing schedule that can be adapted based on patient response. We appreciate Regeneron’s continued research to further advance treatment for this community.”

About Multiple Myeloma

As the second most common blood cancer, there are over 187,000 new cases of MM diagnosed globally every year, with more than 36,000 diagnosed and 12,000 deaths anticipated in the U.S. in 2025. In the U.S., there are approximately 8,000 people who have MM that has progressed after three lines of therapy, and 4,000 whose disease has progressed after four or more therapies.

The disease is characterized by the proliferation of cancerous plasma cells (MM cells) that crowd out healthy blood cells in the bone marrow, infiltrate other tissues and cause potentially life-threatening organ injury. Despite treatment advances, MM is not curable and while current treatments are able to slow progression of the cancer, most patients will ultimately experience cancer progression and require additional therapies.

About Lynozyfic™ (linvoseltamab-gcpt)

Lynozyfic was invented using Regeneron’s *VelocImmune*® technology and is a fully human BCMAxCD3 bispecific antibody designed to bridge B-cell maturation antigen (BCMA) on MM cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.

Linvoseltamab is administered with an initial step-up dosing regimen followed by the full 200 mg dose administered weekly. At week 14, patients transition to every two-week dosing. A response-adapted regimen further enables patients to shift to every four-week dosing if they achieve and maintain a VGPR or better after having completed at least 24 weeks of therapy. Patients should be hospitalized for 24 hours after administration of the first step-up dose and for 24 hours after administration of the second step-up dose, with the potential for additional hospitalization if patients experience certain adverse events.

The generic name for Lynozyfic in its approved U.S. indication is linvoseltamab-gcpt with gcpt 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 of Lynozyfic in its approved indications is linvoseltamab. Lynozyfic is also approved in the European Union to treat adults with R/R MM after at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody, and have demonstrated disease progression on the last therapy. For complete product information, please see the Summary of Product Characteristics that can be found on www.ema.europa.eu in due course.

About the Linvoseltamab Clinical Development Program

The ongoing, open-label, multicenter Phase 1/2 dose-escalation and dose-expansion LINKER-MM1 trial is investigating linvoseltamab in more than 300 enrolled patients with R/R MM. The Phase 1 intravenous dose-escalation portion of the trial – which is now complete – primarily assessed safety, tolerability and dose-limiting toxicities across nine dose levels of linvoseltamab and explored different administration regimens. A subcutaneous Phase 1 portion is ongoing. The Phase 2 intravenous dose expansion portion is ongoing and assessing the safety and anti-tumor activity of linvoseltamab, with the primary endpoint of ORR. Key secondary endpoints include DoR, progression-free survival, rate of minimum residual disease negative status and overall survival.

Linvoseltamab is being investigated in a broad clinical development program exploring its use as a monotherapy as well as in combination regimens across different lines of therapy in MM, including earlier lines of treatment, as well as MM precursor and other plasma cell disorders. This includes evaluating linvoseltamab in a Phase 1b trial (LINKER-MM2) in combination with other cancer treatments in R/R MM as well as a Phase 3 confirmatory trial (LINKER-MM3) as a monotherapy in R/R MM. For more information on Regeneron’s clinical trials in blood cancer, visit the clinical trials website, or contact via clinicaltrials@regeneron.com or 1-844-734-6643.

About Regeneron in Hematology

At Regeneron, we’re applying more than three decades of biology expertise with our proprietary *VelociSuite*® technologies to develop medicines for patients with diverse blood cancers and rare blood disorders.

Our blood cancer research is focused on bispecific antibodies that are being investigated both as monotherapies and in various combinations and emerging therapeutic modalities. Together, they provide us with unique combinatorial flexibility to develop customized and potentially synergistic cancer treatments.

Our research and collaborations to develop potential treatments for rare blood disorders include explorations in antibody medicine, gene editing and gene-knockout technologies, and investigational RNA-approaches focused on depleting abnormal proteins or blocking disease-causing cellular signaling.

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® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg). In addition, REGEN-COV® (casirivimab and imdevimab) had been authorized by the FDA during the COVID-19 pandemic until 2024.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about LYNOZYFIC?

LYNOZYFIC may cause serious or life-threatening side effects, including Cytokine Release Syndrome (CRS) and infusion-related reactions (IRR), or neurologic problems.

Cytokine Release Syndrome (CRS) and infusion related reactions (IRR). CRS is common during treatment with LYNOZYFIC and can also be serious or life-threatening. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS or IRR, including:

- fever of 100.4ºF (38ºC) or higher
- chills or shaking
- trouble breathing
- fast heartbeat
- dizziness or light-headedness

Neurologic problems. LYNOZYFIC can cause neurologic problems that can be serious or life-threatening. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of neurologic problems, including:

- headache
- agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real (hallucinations)
- trouble speaking, writing, thinking, remembering things, paying attention, or understanding things
- problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms
- numbness and tingling (feeling like “pins and needles”)
- burning, throbbing, or stabbing pain
- changes in your handwriting
- seizures

Due to the risk of CRS and neurologic problems, you will receive LYNOZYFIC on a “step-up dosing schedule” and should be hospitalized for 24 hours after the first and second “step-up” doses.

- During the “step-up dosing schedule”:
  - For your first dose, you will receive a smaller “step-up” dose of LYNOZYFIC on Day 1 of your treatment.
  - For your second dose, you will receive a larger “step-up” dose of LYNOZYFIC, which is usually given on Day 8 of your treatment.
  - For your third dose, you will receive the first treatment dose of LYNOZYFIC, which is usually given on Day 15 of your treatment.
- Your healthcare provider may repeat one or both of the “step-up” doses depending on side effects or if your treatment is delayed.
- Before the “step-up” doses and the first two treatment doses of LYNOZYFIC, you will receive medicines to help reduce your risk of CRS and IRR. Your healthcare provider will decide if you need to receive medicine to help reduce your risk of side effects with future doses.

LYNOZYFIC is available only through the LYNOZYFIC Risk Evaluation and Mitigation Strategy (REMS) due to the risk of side effects of CRS and neurologic problems. You will receive a Patient Wallet Card from your healthcare provider. **Carry the LYNOZYFIC Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The LYNOZYFIC Patient Wallet Card lists signs and symptoms of CRS and neurologic problems. **Get medical help right away if you develop any of the signs and symptoms listed on the LYNOZYFIC Patient Wallet Card**. You may need to be treated in a hospital.

Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with LYNOZYFIC, as well as other side effects, and may treat you in a hospital if needed. Your healthcare provider may temporarily

stop or completely stop your treatment with LYNOZYFIC if you develop CRS, neurologic problems, or any other severe side effects.

If you have any questions about LYNOZYFIC, ask your healthcare provider.

Before receiving LYNOZYFIC, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection.
- are pregnant or plan to become pregnant. LYNOZYFIC may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with LYNOZYFIC.
  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with LYNOZYFIC.
  - You should use an effective form of birth control (contraception) during treatment with LYNOZYFIC and for 3 months after your last dose of LYNOZYFIC.
- are breastfeeding or plan to breastfeed. It is not known whether LYNOZYFIC passes into your breast milk. Do not breastfeed during treatment with LYNOZYFIC and for 3 months after your last dose of LYNOZYFIC.

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

How will I receive LYNOZYFIC?

- LYNOZYFIC will be given to you by your healthcare provider by infusion through a needle placed in a vein (intravenous infusion).
- After the “step-up dosing schedule”, the treatment dose of LYNOZYFIC is usually given 1 time each week for 11 doses, and then 1 time every other week for 5 doses. After these doses and based on how your disease responds, your healthcare provider will decide if you are able to receive LYNOZYFIC less often (every 4 weeks) or will continue to have every other week treatment.
- Your healthcare provider will decide how long you will receive treatment with LYNOZYFIC.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. It is important for you to be monitored closely for side effects during treatment with LYNOZYFIC.

What should I avoid while receiving LYNOZYFIC?

Do not drive, or operate heavy or potentially dangerous machinery, or do other dangerous activities for 48 hours after completing each of your “step-up” doses or at any time during treatment with LYNOZYFIC if you develop new neurologic symptoms, until the symptoms go away.

What are the possible side effects of LYNOZYFIC?

LYNOZYFIC may cause serious side effects, including:

- **Infections.** LYNOZYFIC can cause bacterial, viral, or fungal infections that are serious, life-threatening, or that may lead to death. Upper respiratory tract infections and pneumonia are common during treatment with LYNOZYFIC.
  - Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with LYNOZYFIC.
  - Your healthcare provider may prescribe medicines for you to help prevent infections and treat you as needed if you develop an infection during treatment with LYNOZYFIC.
  - Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with LYNOZYFIC, including:
    - fever of 100.4 °F (38 °C) or higher
    - chills
    - cough
    - shortness of breath
    - chest pain
    - sore throat
    - pain during urination
    - feeling weak or generally unwell
- **Decreased white blood cell counts**. Decreased white blood cell counts are common during treatment with LYNOZYFIC and can also be severe. Fever can happen with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will check your blood cell counts before you start treatment and during treatment with LYNOZYFIC, and will treat you as needed.
- **Liver problems.** LYNOZYFIC can cause increased liver enzymes and bilirubin in your blood. These increases can happen with or without you also having CRS. Your healthcare provider will do blood tests to check your liver before starting and

during treatment with LYNOZYFIC. Tell your healthcare provider if you develop any of the following signs or symptoms of liver problems:

- tiredness
- loss of appetite
- pain in your right upper stomach-area (abdomen)
- dark urine
- yellowing of your skin or the white part of your eyes

The most common side effects of LYNOZYFIC include:

- muscle and bone pain
- cough
- diarrhea
- tiredness or weakness
- nausea
- headache
- shortness of breath

The most common severe abnormal blood test results with LYNOZYFIC include: low white blood cell counts and low red blood cell counts.

These are not all of the possible side effects of LYNOZYFIC.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide for LYNOZYFIC.

What is LYNOZYFIC?

LYNOZYFIC is a prescription medicine used to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody to treat their multiple myeloma, **and**
- their cancer has come back or did not respond to prior treatment.

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

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 Lynozyfic™ (linvoseltamab-gcpt) to treat adults with relapsed and refractory ("R/R") multiple myeloma ("MM"); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as Lynozyfic) 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; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including linvoseltamab as a monotherapy and in combination regimens across different lines of therapy in MM and plasma cell precursor disorders as referenced in this press release; 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 (such as Lynozyfic) 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 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 in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); 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, 2024 and its Form 10-Q for the quarterly period ended March 31, 2025. 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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REGENERON

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