Lynozyfic™ (linvoseltamab) Monotherapy in Newly Diagnosed Multiple Myeloma (NDMM) Shows Impressive Responses, Supporting Rationale as a Potential Foundation in Frontline Treatment

December 7, 2025 at 4:30 PM EST

All three dose groups (50 mg, 100 mg and 200 mg) showed impressive monotherapy efficacy, with VGPR+ (very good partial response or better) of ≥70% despite limited follow-up; evidence shows that these responses are expected to deepen over time

Across all dose groups, 95% (19 of 20 patients) of all evaluable VGPR+ patients achieved minimal residual disease negative status

Data featured in an ASH oral presentation; LINKER-MM4 is the first clinical trial to evaluate a BCMAxCD3 bispecific monotherapy in NDMM and is part of a broad clinical development program evaluating Lynozyfic-based regimens in earlier lines of treatment

Regeneron to host virtual 'Regeneron Roundtable' investor event to discuss its multiple myeloma development program on Wednesday, December 10 at 8:30 a.m. ET

TARRYTOWN, N.Y., Dec. 07, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced encouraging data from the Phase 1/2 LINKER-MM4 trial evaluating Lynozyfic™ (linvoseltamab) in adults with newly diagnosed multiple myeloma (NDMM) who were transplant eligible or ineligible were shared in an oral presentation at the American Society of Hematology (ASH) Annual Meeting. These data build on results from a broad clinical development program evaluating Lynozyfic in early lines of treatment, including precursor conditions, as monotherapy and in combination with standard-of-care or novel agents.

"The treatment of newly diagnosed multiple myeloma often relies on complicated combinations of quadruplet or triplet regimens, each with its own toxicities, in order to achieve rapid and durable responses, which can be incredibly burdensome for these patients," said Robert Orlowski, M.D., Ph.D., Deputy Chair, Professor of Medicine, and Director of Translational Myeloma Research in the Departments of Lymphoma/Myeloma and Experimental Therapeutics at The University of Texas MD Anderson Cancer Center and the lead investigator for the LINKER-MM4 trial. "As the first to evaluate a BCMAxCD3 bispecific monotherapy in this setting, LINKER-MM4 seeks to understand whether frontline intervention with a single agent can deliver strong efficacy, enabling the simplification and potentially greater tolerability of these regimens. Lynozyfic monotherapy is already achieving MRD negativity rates comparable to quadruplet regimens but earlier in the treatment course, and these compelling results are expected to deepen with longer follow up. These results underscore Lynozyfic's potential as a foundational component of frontline treatment regimens for multiple myeloma – or even a monotherapy regimen – for both transplant-eligible and transplant-ineligible patients."

LINKER-MM4 is an ongoing, open-label Phase 1/2 trial investigating Lynozyfic in adults with NDMM. During a Phase 1A (dose escalation) cohort, patients were treated with a step-up dosing regimen followed by 50 mg, 100 mg or 200 mg doses of Lynozyfic. The lowest (50 mg) and highest (200 mg) tolerated doses were selected for further evaluation in the Phase 1B (dose-expansion) cohort. Among the 45 treated patients in both Phase 1A and 1B, 28 were transplant eligible, and 17 were transplant ineligible.

Across all dose levels (n=45), there was a 1.2 months median time to onset of response (range: 1-4.5 months). All three dose groups (50 mg, 100 mg and 200 mg) showed impressive efficacy, with a VGPR+ (very good partial response or better) of ≥70% with limited follow-up. Evidence shows that these responses are expected to deepen over time. Across all dose groups, 95% (19 of 20 patients) of all minimum residual disease (MRD) evaluable VGPR+ patients achieved MRD negative status at 10^{-5} sensitivity.

Across all dose levels, the most common treatment-emergent adverse events (TEAEs) were cytokine release syndrome (CRS; all Grade 1: 44%) and neutropenia (any Grade: 38%; Grade 3/4: 33%). Among other adverse events of special interest, one patient in the 50 mg cohort experienced Grade 1 immune effector cell-associated neurotoxicity syndrome (ICANS). Infections occurred in 84% of patients (Grade 1/2: 51%; Grade 3: 33%) with the majority occurring within the first three months of treatment and the rate of infections decreased over time. There were no ≥Grade 4 infections, Grade 5 TEAEs or dose-limiting toxicities. Ten patients elected to undergo an autologous stem cell transplant, all of whom had an acceptable CD34+ stem cell yield post-induction (range: 2.5-11.5 x 10^6/kg).

A broad clinical development program investigating Lynozyfic in early stages of the disease is underway. This includes the Phase 2 portion of the LINKER-MM4 trial evaluating Lynozyfic at the recommended 200 mg dose, as well as LINKER-MM6 (EMN39), a trial evaluating a combination of daratumumab, lenalidomide and dexamethasone (DRd) followed by Lynozyfic monotherapy compared with continued DRd in transplant-ineligible NDMM.

The use of Lynozyfic described above is investigational, and its safety and efficacy has not been evaluated by any regulatory authority for this indication.

About the 'Regeneron Roundtable' Investor Event
Regeneron will host a virtual investor event to discuss its multiple myeloma program on Wednesday, December 10 at 8:30 a.m. ET. This is the next webcast in a new investor event series called the 'Regeneron Roundtable,' intended to highlight programs from the company's innovative investigational pipeline.

Links to the webcast and to register via telephone may be accessed from the 'Investors and Media' page of Regeneron's website at https://investor.regeneron.com/events-and-presentations. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the company's website for at least 30 days.

About 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. 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
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. Lynozyfic is approved to treat certain adults with R/R MM: in the U.S. after four lines of therapy and in the European Union after at least three prior therapies.

In the U.S., the generic name for Lynozyfic in its approved indications is linvoseltamab-gcpt, with gcpt 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 Lynozyfic in its approved indications is linvoseltamab.

Lynozyfic 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 plasma cell precursor disorders. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

In addition to LINKER-MM4, ongoing trials include:

- LINKER-MM1: Phase 1/2 dose-escalation and dose-expansion trial evaluating the safety, tolerability, dose-limiting toxicities and anti-tumor activity of Lynozyfic monotherapy in R/R MM
- LINKER-MM2: Phase 1b, open-label trial evaluating Lynozyfic in combination with other cancer treatments in patients with R/R MM
- LINKER-MM3: Phase 3 confirmatory trial evaluating Lynozyfic monotherapy compared to the combination of elotuzumab, pomalidomide and dexamethasone in R/R MM
- LINKER-MM5: Phase 3 trial evaluating Lynozyfic monotherapy or in combination with carfilzomib compared to standard of care combination regimens in patients with R/R MM
- LINKER-MM6 (EMN39): Phase 3 trial, in collaboration with the European Myeloma Network, evaluating daratumumab, lenalidomide and dexamethasone induction followed by Lynozyfic monotherapy compared to continued daratumumab, lenalidomide, and dexamethasone in NDMM who are transplant-ineligible
- Phase 1 trial evaluating Lynozyfic in combination with a Regeneron CD38xCD28 costimulatory bispecific in R/R MM
- LINKER-SMM1: Phase 2 trial evaluating Lynozyfic monotherapy in high-risk smoldering MM
- LINKER-MGUS1: Phase 2 dose-ranging trial evaluating Lynozyfic monotherapy in high-risk monoclonal gammopathy of unknown significance and non-high-risk SMM
- LINKER-AL2: Phase 1/2 trial evaluating Lynozyfic monotherapy in R/R systemic light chain amyloidosis

For more information on Regeneron's clinical trials in blood cancer, visit the clinical trials website, or contact via clinicaltrials@regeneron.com or 844-734-6643.

IMPORTANT SAFETY INFORMATION FOR U.S. PATIENTS

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 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 or authorized 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.

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) 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 Lynozyfic as a monotherapy and/or in combination with standard-of-care agents across different lines of therapy in multiple myeloma ("MM") and plasma cell precursor disorders, including the treatment of adults with newly diagnosed MM as discussed in this press release; 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 or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; 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 to drug pricing regulations and requirements and Regeneron's pricing strategy; other 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 September 30, 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).

Contacts:

Media Relations
Tammy Allen
Tel: +1 914-306-2698
tammy.allen@regeneron.com

Investor Relations
Mark Hudson
Tel: +1 914-847-3482
mark.hudson@regeneron.com

REGENERON

Source: Regeneron Pharmaceuticals, Inc.