Regeneron Provides Update on Phase 3 Trial of Fianlimab (LAG-3 Inhibitor) Combination in First-Line Unresectable or Metastatic Melanoma

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The trial did not reach statistical significance for the primary endpoint of improvement in progression-free survival (PFS)

A numeric improvement of 5.1 months in median PFS was observed for the high-dose fianlimab combination compared to pembrolizumab monotherapy

Phase 3 head-to-head trial of the high-dose fianlimab combination versus Opdualag® (nivolumab and relatlimab-rmbw) is ongoing

TARRYTOWN, N.Y., May 15, 2026 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today reviewed results from the Phase 3 trial evaluating two dose levels of fianlimab (LAG-3 inhibitor) in combination with cemiplimab (PD-1 inhibitor) as a first-line treatment for patients with unresectable locally advanced or metastatic melanoma. The trial did not reach statistical significance for the primary endpoint of improvement in progression-free survival (PFS) compared to pembrolizumab (PD-1 inhibitor) monotherapy. No new safety signals were identified with the fianlimab combination.

	High-Dose Combination (n=508)	**Low-Dose Combination** (n=422)	**Pembrolizumab Monotherapy** (n=462)	**Cemiplimab Monotherapy*** (n=154)
Primary endpoint: median PFS, months (95% Confidence Interval [CI])	11.5 (6.3, 16.8)	9.6 (6.2, 13.9)	6.4 (4.4, 11.1)	6.3 (4.0, 17.2)
Hazard Ratio (95% CI) Relative to Pembrolizumab	0.845 (0.709, 1.008)	0.931 (0.773, 1.122)#		
p-Value	p=0.0627	p=0.4661#		

*Cemiplimab was used to define contribution of components and was not used in the statistical comparison
Low dose combination compared against subset of concurrently randomized patients on pembrolizumab (n=421)

Detailed results from the trial will be presented at an upcoming medical meeting.

A Phase 3 head-to-head trial, also in first-line unresectable or metastatic melanoma, evaluating the high-dose fianlimab combination versus Opdualag® (nivolumab and relatlimab-rmbw) is ongoing.

The potential uses of fianlimab and cemiplimab described above are investigational, and safety and efficacy of this combination have not been evaluated by any regulatory authority.

About the Phase 3 Trial
This randomized, double-blind Phase 3 trial is investigating the combination of fianlimab and cemiplimab versus pembrolizumab in patients 12 years of age or older with unresectable locally advanced or metastatic melanoma who have not received a previous systemic treatment for advanced disease. The trial enrolled 1,546 patients who were randomized to receive either: 1600 mg fianlimab and 350 mg cemiplimab (high-dose combination) every 3 weeks; 400 mg fianlimab and 350 mg cemiplimab (low-dose combination) every 3 weeks; placebo and 200 mg pembrolizumab every 3 weeks; or placebo and 350 mg cemiplimab every 3 weeks.

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 fianlimab (LAG-3 inhibitor); 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 fianlimab in combination with cemiplimab as a first-line treatment for patients with unresectable locally advanced or metastatic melanoma; 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 (such as the Phase 3 trial evaluating two dose levels of fianlimab in combination with cemiplimab as a first-line treatment for patients with unresectable locally advanced or metastatic melanoma and the Phase 3 head-to-head trial in first-line unresectable or metastatic melanoma evaluating the high-dose fianlimab and cemiplimab combination versus Opdualag® (nivolumab and relatlimab-rmbw)), on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates (such as fianlimab in combination with cemiplimab); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates (such as fianlimab in combination with cemiplimab) and new indications for Regeneron's Products; 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 fianlimab in combination with cemiplimab) 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 (including those discussed or referenced in this press release) 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 March 31, 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).

Contacts:

Media Relations
Ashley Buford Fredericks
Tel: +1 914-356-2235
ashley.buford@regeneron.com

Investor Relations
Ryan Crowe
Tel: +1 914-839-2614
ryan.crowe@regeneron.com

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