EYLEA HD® (aflibercept) Injection 8 mg Presentations at ARVO Reinforce Continued Safety and Efficacy and Highlight Early Real-World Outcomes for Patients with Serious Retinal Disease

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Initial real-world data from nearly 40,000 EYLEA HD patients will provide early insights on effectiveness of EYLEA HD in everyday clinical practice

New indirect comparisons will evaluate EYLEA HD and faricimab on measures of efficacy, dosing frequency and potential economic benefits in patients with wet age-related macular degeneration and diabetic macular edema

TARRYTOWN, N.Y., April 28, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced the upcoming presentation of 27 abstracts, including eight oral presentations on EYLEA HD® (aflibercept) Injection 8 mg in wet age-related macular degeneration (wAMD), diabetic macular edema (DME) and diabetic retinopathy (DR). Among the new results and analyses are initial insights on the real-world use of EYLEA HD in clinical practice, which reinforce the outcomes seen in pivotal trials. These data will be presented at the Association for Research in Vision and Ophthalmology (ARVO) 2025 Annual Meeting from May 4 to 8 in Salt Lake City.

"Our data presentations at ARVO reflect the robust and rapidly growing body of evidence that support the use of EYLEA HD becoming the new standard of care for people living with wet age-related macular degeneration, diabetic macular edema and diabetic retinopathy," said Boaz Hirshberg, M.D., Senior Vice President, Clinical Development, Internal Medicine at Regeneron. "This includes new analyses examining the initial real-world experiences of nearly 40,000 patients treated with EYLEA HD showing, in everyday clinical practice, a positive impact through improved vision and longer dosing intervals for patients. Although early, these data reinforce the value EYLEA HD is bringing to patients with serious retinal diseases."

Notable new presentations at ARVO include:

- Four analyses evaluating initial real-world experiences with EYLEA HD among patients with wAMD or DME, including both those who were previously naive to treatment and those who switched from other anti-vascular endothelial growth factor (VEGF) therapies
- A network meta-analysis indirectly comparing the efficacy and number of injections received for EYLEA HD and faricimab in patients with DME or wAMD, based on the longest follow-up data from Phase 3 clinical trials
- A modeling analysis of the potential economic benefit of EYLEA HD compared to faricimab for the treatment of patients with wAMD or DME in the U.S. over three years

The most common adverse reactions (≥3%) reported in patients treated with EYLEA HD were cataract, conjunctival hemorrhage, intraocular pressure increased, ocular discomfort/eye pain/eye irritation, vision blurred, vitreous floaters, vitreous detachment, corneal epithelium defect and retinal hemorrhage.

Key EYLEA HD presentations at ARVO:

Abstract title	Lead author	Presentation date, time (MST), location
Early insights on the real-world use of aflibercept 8 mg among treatment-naive eyes with diabetic macular edema	Nitish Mehta, MD	Poster Presentation Date: May 5 Time: 3:00–4:45 PM MST Session: Diabetic Macular Edema: Anti-VEGF
Early insights from real-world use of aflibercept 8 mg among eyes with diabetic macular edema (DME) switching from other anti-VEGF agents	Michael Javaheri, MD	Poster Presentation Date: May 5 Time: 3:00–4:45 PM MST Session: Diabetic Macular Edema: Anti-VEGF

Economic benefit of aflibercept 8 mg versus faricimab in the treatment of patients with neovascular age-related macular degeneration (nAMD) or diabetic macular edema (DME) in the United States	Andreas Kuznik	Paper Presentation Date: May 5 Time: 4:00–4:15 PM MST Session: Economic Impact of AI Tools and Treatments
Early real-world use of aflibercept 8mg in treatment-naïve patients with neovascular age-related macular degeneration	Ferhina Ali, MD	Poster Presentation Date: May 6 Time: 8:30–10:15 AM MST Session: AMD 2 (anti-VEGF)
Early insights from real-world use of aflibercept 8mg among eyes with neovascular age-related macular degeneration (nAMD) switching from other anti-VEGF agents	Theodore Leng, MD	Poster Presentation Date: May 6 Time: 8:30–10:15 AM MST Session: AMD 2 (anti-VEGF)
Network meta-analyses (NMAs) of number of injections (NoI) with high-dose (HD) aflibercept (AFL) versus faricimab (FAR) in patients with diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD)	Steven Sherman	Poster Presentation Date: May 8 Time: 8:00–9:45 AM MST Session: Telemedicine, Health Service Delivery and Health Economic Studies
Volumetric fluid assessment comparing high-dose aflibercept to standard dose aflibercept in neovascular age-related macular degeneration in the CANDELA phase 2 trial	John Mamone, MD	Poster Presentation Date: May 4 Time: 1:00–2:45 PM MST Session: AMD 1 (Clinical Research)
PULSAR extension: clinical improvements maintained over 156 weeks with aflibercept 8 mg in patients with neovascular age-related macular degeneration*	Timothy Lai, MD	Paper Presentation Date: May 4 Time: 1:00–1:15 PM MST Session: AMD antiVEGF I
A PULSAR phase 3 trial post-hoc analysis: evaluating the timing and magnitude of control of disease activity with aflibercept 8 mg and faricimab, applying similar disease activity criteria across different pivotal Phase 3 trials for nAMD*	Jean-Francois Korobelnik, MD	Paper Presentation Date: May 4 Time: 1:15–1:30 PM MST Session: AMD antiVEGF I
SPECTRUM: early clinical experience from the first global real-world study of aflibercept 8 mg in patients with treatment-naïve neovascular age-related macular degeneration*	Vasileois Konidaris, MD	Paper Presentation Date: May 4 Time: 1:30–1:45 PM MST Session: AMD antiVEGF I
SPECTRUM: early clinical experience from the first global real-world study of aflibercept 8 mg in patients with pretreated neovascular age-related macular degeneration*	Clare Bailey, MD	Paper Presentation Date: May 5 Time: 3:00–3:15 PM MST Session: AMD antiVEGF II
Aflibercept 8 mg in diabetic macular edema: 156-week results from the PHOTON extension study	Ghassan Ghorayeb, MD	Poster Presentation Date: May 5 Time: 3:00–4:45 PM MST

		Session: Retina: Physiology and Pharmacology
Intraocular pressure outcomes with aflibercept 8 mg and 2 mg in patients with diabetic macular edema through week 96 of the phase 2/3 PHOTON trial	Anita Barikian, MD	Poster Presentation Date: May 5 Time: 3:00–4:45 PM MST Session: Diabetic Macular Edema: Anti-VEGF
Differential anatomic response to aflibercept 8 mg versus 2 mg during the matched dosing phase of the PHOTON trial in patients with diabetic macular edema who subsequently met criteria for shortening	Dilsher Dhoot, MD	Poster Presentation Date: May 5 Time: 3:00–4:45 PM MST Session: Diabetic Macular Edema: Anti-VEGF
SPECTRUM: early clinical experience from the first global real-world study of aflibercept 8 mg in patients with treatment-naïve diabetic macular edema*	Aires Lobo, MD	Poster Presentation Date: May 5 Time: 3:00–4:45 PM MST Session: Diabetic Macular Edema: Anti-VEGF
SPECTRUM: early clinical experience from the first global real-world study of aflibercept 8 mg in patients with pretreated diabetic macular edema*	Thomas Dervos, MD	Poster Presentation: Date: May 5 Time: 3:00–4:45 PM MST Session: Diabetic Macular Edema: Anti-VEGF
Rapid fluid resolution with aflibercept 8 mg may be associated with extended dosing intervals at W96 in nAMD: a PULSAR post-hoc analysis*	Michael Stewart, MD	Poster Presentation Date: May 6 Time: 8:30–10:15 AM MST Session: AMD 2 (anti-VEGF)
Greater and more durable fluid resolution with aflibercept 8 mg versus aflibercept 2 mg in the PULSAR trial: a 96-week post-hoc analysis*	Richard Gale, MD	Poster Presentation Date: May 6 Time: 8:30–10:15 AM MST Session: AMD 2 (anti-VEGF)
Clinical outcomes with aflibercept 8 mg and aflibercept 2 mg are generally comparable in patients grouped by CNV type: a post hoc analysis of the 96-week PULSAR trial*	Sobha Sivaprasad, MD	Poster Presentation Date: May 6 Time: 8:30–10:15 AM MST Session: AMD 2 (anti-VEGF)
A pooled analysis of the CANDELA, PHOTON, and PULSAR trials through 96 weeks: comparably low intraocular inflammation (IOI)-related events with aflibercept 8 mg and 2 mg*	Justus Garweg, MD	Poster Presentation Date: May 6 Time: 8:30–10:15 AM MST Session: AMD 2 (anti-VEGF)
Baseline characteristics and outcomes of patients treated with aflibercept 8 mg at shortened, maintained, or extended dosing intervals through 96 weeks in PHOTON	Mark Barakat, MD	Paper Presentation Date: May 7 Time: 11:15–11:30 AM MST Session: Diabetic Macular Edema: Anti-VEGF

Week 96 outcomes in aflibercept 8 mg- and 2 mg-treated patients by prior DME treatment status: a subgroup analysis of the phase 2/3 PHOTON trial	Manjot Gill, MD	Paper Presentation Date: May 7 Time: 11:30–11:45 AM MST Session: Diabetic Macular Edema: Anti-VEGF
Lower socioeconomic status is associated with increased bevacizumab use among patients initiating anti-vascular endothelial growth factor (anti-VEGF) therapy for diabetic macular edema (DME)	Judy Kim, MD	Paper Presentation Date: May 7 Time: 11:45–12:00 PM MST Session: Diabetic Macular Edema: Anti-VEGF
A pooled analysis of the PULSAR and PHOTON trials through 96 weeks: Minimal impact of aflibercept 8 mg and 2 mg on intraocular pressure changes *	Sergio Leal, MD	Poster Presentation Date: May 8 Time: 2:00–3:45 PM MST Session: AMD 5 (Clinical Research)

**Bayer-run trial*

About the EYLEA HD Clinical Trial Program
PULSAR in wAMD and PHOTON in DME/diabetic retinopathy (DR) are double-masked, active-controlled pivotal trials that were conducted in multiple centers globally. In both trials, patients were randomized into 3 treatment groups to receive either: EYLEA HD every 3 months, EYLEA HD every 4 months, or EYLEA every 2 months. The lead sponsors of the trials were Bayer for PULSAR and Regeneron for PHOTON.

Patients treated with EYLEA HD in both trials had 3 initial monthly doses, and patients treated with EYLEA received 3 initial doses in PULSAR and 5 in PHOTON. In the first year, patients in the EYLEA HD groups could have their dosing intervals shortened down to an every 2-month interval if protocol-defined criteria for disease progression were observed. Intervals could not be extended until the second year of the trial. Patients in all EYLEA groups maintained a fixed 2-month dosing regimen throughout their participation in the two-year trials.

In both trials, there was an optional extension study starting at week 96, with all participating patients receiving EYLEA HD through week 156. Patients initially randomized to EYLEA in PULSAR, were switched to EYLEA HD at the start of the extension study and immediately assigned to a 3-month dosing interval. Dosing intervals for all patients in the extension study could be shortened or extended by 2-week increments if protocol-defined criteria were met, with a minimum dosing interval of every 2 months and a maximum dosing interval of every 6 months.

CANDELA was a Regeneron-sponsored Phase 2 trial investigating the safety and efficacy of EYLEA HD extended dosing regimens compared to EYLEA in wAMD patients.

About wAMD and Diabetic Eye Disease
wAMD is a retinal disease that may affect people as they age. It occurs when abnormal blood vessels grow and leak fluid under the macula, the part of the eye responsible for sharp central vision and seeing fine detail. This fluid can damage and scar the macula, which can cause vision loss. An estimated 1.4 million Americans have wAMD.

DR is an eye disease characterized by microvascular damage to the blood vessels in the retina often caused by poor blood sugar control in people with diabetes. The disease generally starts as nonproliferative diabetic retinopathy (NPDR) and often has no warning signs or symptoms. NPDR may progress to proliferative diabetic retinopathy (PDR), a stage of the disease in which abnormal blood vessels grow onto the surface of the retina and into the vitreous cavity, potentially causing severe vision loss.

DME can occur at any stage of DR as the blood vessels in the retina become increasingly fragile and leak fluid, potentially causing visual impairment. In the U.S., approximately 1.5 million adults are diagnosed with DME, while approximately 6 million people have DR without DME.

About EYLEA HD
Over a decade ago, Regeneron introduced EYLEA, a vascular endothelial growth factor inhibitor, and transformed the treatment paradigm for certain serious chorioretinal vascular diseases. With a well-established efficacy and consistent safety profile from 16 pivotal trials, EYLEA is approved to treat vision-threatening conditions that impact patients from their earliest days, such as retinopathy of prematurity (ROP), to their later years, including diabetic macular edema (DME), diabetic retinopathy (DR), macular edema following retinal vein occlusion (RVO) and wet age-related macular degeneration (wAMD).

Pushing the boundaries of science further to meet patient needs, EYLEA HD was developed to achieve comparable efficacy and safety to EYLEA, but with fewer injections. EYLEA HD is supported by a robust body of research and is currently approved in the

U.S. to treat patients with wAMD, DME and DR.

EYLEA HD (known as Eylea™ 8 mg in the European Union and Japan) is being jointly developed by Regeneron and Bayer AG. Regeneron maintains exclusive rights to EYLEA and EYLEA HD in the U.S. Bayer has licensed the exclusive marketing rights outside of the U.S., where the companies share equally the profits from sales of EYLEA and EYLEA HD.

About Ophthalmology Development at Regeneron
At Regeneron, we relentlessly pursue groundbreaking innovations in eye care science to help maintain the eye health of the millions of Americans impacted by vision-threatening conditions. Our expertise in angiogenesis and decades of research serve as our foundation, fueling our ongoing ambition to further innovate new solutions for patients. Our robust and diverse research and development program in ophthalmology includes efforts to potentially address additional serious eye diseases, including geographic atrophy (ongoing Phase 3 SIENNA clinical trial), glaucoma and certain inherited retinal diseases.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

INDICATIONS
EYLEA HD® (aflibercept) Injection 8 mg is a prescription medicine approved for the treatment of patients with Wet Age-Related Macular Degeneration (AMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

EYLEA® (aflibercept) Injection 2 mg is a prescription medicine approved for the treatment of patients with Wet Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Retinopathy of Prematurity (ROP) (0.4 mg).

IMPORTANT SAFETY INFORMATION

- EYLEA HD and EYLEA are administered by injection into the eye. You should not use EYLEA HD or EYLEA if you have an infection in or around the eye, eye pain or redness, or known allergies to any of the ingredients in EYLEA HD or EYLEA, including aflibercept.
- Injections into the eye with EYLEA HD or EYLEA can result in an infection in the eye, retinal detachment (separation of retina from back of the eye) and, more rarely, serious inflammation of blood vessels in the retina that may include blockage. Call your doctor right away if you or your baby (if being treated with EYLEA for Retinopathy of Prematurity) experience eye pain or redness, light sensitivity, or a change in vision after an injection.
- In some patients, injections with EYLEA HD or EYLEA may cause a temporary increase in eye pressure within 1 hour of the injection. Sustained increases in eye pressure have been reported with repeated injections, and your doctor may monitor this after each injection.
- In infants with Retinopathy of Prematurity (ROP), treatment with EYLEA will need extended periods of ROP monitoring.
- There is a potential but rare risk of serious and sometimes fatal side effects, related to blood clots, leading to heart attack or stroke in patients receiving EYLEA HD or EYLEA.
- The most common side effects reported in patients receiving EYLEA HD were cataract, increased redness in the eye, increased pressure in the eye, eye discomfort, pain, or irritation, blurred vision, vitreous (gel-like substance) floaters, vitreous detachment, injury to the outer layer of the eye, and bleeding in the back of the eye.
- The most common side effects reported in patients receiving EYLEA were increased redness in the eye, eye pain, cataract, vitreous detachment, vitreous floaters, moving spots in the field of vision, and increased pressure in the eye.
- The most common side effects reported in pre-term infants with ROP receiving EYLEA were separation of the retina from the back of the eye, increased redness in the eye, and increased pressure in the eye. Side effects that occurred in adults are considered applicable to pre-term infants with ROP, though not all were seen in clinical studies.
- You may experience temporary visual changes after an EYLEA HD or EYLEA injection and associated eye exams; do not drive or use machinery until your vision recovers sufficiently.
- For additional safety information, please talk to your doctor and see the full Prescribing Information for EYLEA HD and EYLEA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for EYLEA HD and EYLEA.

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 EYLEA HD® (aflibercept) Injection 8 mg; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as EYLEA HD) 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; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products (such as EYLEA HD) 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 of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; 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 2 mg), 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. 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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