EYLEA HD® (aflibercept) Injection 8 mg Approved by FDA for the Treatment of Macular Edema Following Retinal Vein Occlusion (RVO) and for Monthly Dosing Across Approved Indications

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First and only FDA-approved treatment for RVO indicated for up to every 8-week dosing after an initial monthly dosing period

Monthly dosing option in all approved indications provides greater dosing flexibility for more personalized patient care

TARRYTOWN, N.Y., Nov. 19, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has approved EYLEA HD® (aflibercept) Injection 8 mg for the treatment of patients with macular edema following retinal vein occlusion (RVO) with up to every 8-week dosing after an initial monthly dosing period. The FDA also approved an every 4-week (monthly) dosing option for some patients who may benefit from resuming this dosing schedule across approved indications: wet age-related macular degeneration (wAMD), diabetic macular edema (DME), diabetic retinopathy (DR) and RVO.

"We believe these approvals further position EYLEA HD as a treatment of choice for certain retinal diseases and underscore our relentless commitment to meeting the needs of patients and the retina specialists who treat them," said George D. Yancopoulos, M.D., Ph.D., co-Founder, Board Co-Chair, President and Chief Scientific Officer, at Regeneron. "EYLEA HD is the first treatment for retinal vein occlusion that can potentially cut the number of injections that patients receive in half compared to existing therapies. And with the addition of a monthly dosing option for all four approved EYLEA HD indications, physicians now have greater flexibility and optionality to tailor treatment to meet individual patient needs."

The FDA approval for the treatment of RVO is based on data from the Phase 3 QUASAR trial that evaluated the efficacy and safety of EYLEA HD compared to EYLEA® (aflibercept) Injection 2 mg in patients with RVO. QUASAR met its primary endpoint at 36 weeks, with EYLEA HD patients dosed every 8 weeks (after either 3 or 5 monthly doses) achieving non-inferior visual acuity gains compared to those receiving EYLEA dosed every 4 weeks. The EYLEA HD results were consistent across patients with branch retinal vein occlusions, and those with central retinal or hemiretinal vein occlusions. In RVO, the most common adverse reactions reported in ≥3% of patients treated with EYLEA HD were intraocular pressure increased, vision blurred, cataract, conjunctival hemorrhage, ocular discomfort/eye pain/eye irritation and vitreous detachment.

In regard to the EYLEA HD pre-filled syringe (PFS), Regeneron continues to coordinate with Catalent Indiana, LLC (part of Novo Nordisk A/S) as it works to resolve the outstanding issues identified from a July 2025 FDA general site inspection (not specific to EYLEA HD). As previously disclosed, Regeneron also plans to submit to the FDA an application to include an alternate PFS manufacturing filler for the EYLEA HD BLA by January 2026.

EYLEA HD is approved with dosing intervals from every 8 to 16 weeks for patients with wAMD and DME (following 3 initial monthly doses), every 8 to 12 weeks for patients with DR (following 3 initial monthly doses), and every 8 weeks for patients with RVO (following 3 to 5 initial monthly doses). In clinical trials, some EYLEA HD patients did not maintain a response with extended dosing intervals after successful response to initial monthly doses; these patients may benefit from resuming every 4-week dosing.

Regeneron is committed to helping patients who have been prescribed EYLEA HD access their medication. EYLEA 4U helps patients understand how EYLEA HD may be covered by their health insurance plans and assists eligible patients who need financial assistance for their EYLEA HD prescription. For more information, please call 1-855-EYLEA4U (1-855-395-3248) Option 4, or visit www.EYLEAHD.com.

About the QUASAR Trial
QUASAR is a global double-masked, active-controlled Phase 3 trial evaluating the efficacy and safety of EYLEA HD in patients with macular edema secondary to RVO, including those with central retinal vein occlusion, branch retinal vein occlusion, or hemiretinal vein occlusion.

In the trial, patients were randomized into three groups to receive either: EYLEA HD every 8 weeks following 3 initial monthly doses; EYLEA HD every 8 weeks following 5 initial monthly doses; or EYLEA every 4 weeks. The primary endpoint was mean change in BCVA from randomization through week 36, as measured by the Early Treatment Diabetic Retinopathy Study letter score.

QUASAR is being operationalized by Bayer under a collaboration agreement with Regeneron.

About Retinal Vein Occlusion
RVO is a common cause of vision loss in adults and the second most common retinal vascular disease. RVO occurs when there is a blockage in a vein in the retina, which leads to a buildup of blood, restricted blood flow, increased pressure and sometimes pain in the eye. RVO may cause sudden blurry vision or vision loss and can ultimately result in serious complications like swelling in the eye called macular edema.

A protein called vascular endothelial growth factor (VEGF) is instrumental in causing the vascular leakage that leads to macular edema. When a vein in the retina is blocked, the levels of VEGF increase, which spurs new blood vessel growth. Too much VEGF can lead to the
formation of abnormal blood vessels and may cause vision to become blurry. Anti-VEGF injections are commonly used to treat macular edema due to RVO.

There are two main types of RVO: central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). In CRVO, the buildup occurs in the eye's central retinal vein and in BRVO, the buildup occurs in one of the smaller branch veins. Globally, RVO affects over 28 million people.

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) and Macular Edema following Retinal Vein Occlusion (RVO).

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, injury to the outer layer of the eye, increased pressure in the eye, eye discomfort, pain, or irritation, bleeding in the back of the eye, blurred vision, vitreous (gel-like substance) detachment, and vitreous floaters.
- 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.
- These are not all the possible side effects of EYLEA HD or EYLEA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 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, including whether Regeneron will ultimately be able to obtain U.S. Food and Drug Administration approval for EYLEA HD in a prefilled syringe and, if so, the timing of any such approval; whether Regeneron will be able to submit an application to include an additional manufacturing filler in the EYLEA HD Biologics License Application in the currently expected time frame; 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 (such as EYLEA HD) 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 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 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).

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