EYLEA HD® (aflibercept) Approved by FDA as First and Only Injectable Anti-VEGF with Dosing Intervals Up to 5 Months for Wet Age-related Macular Degeneration (wAMD) and Diabetic Macular Edema (DME)

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Approval is based on 96-week data from 2 pivotal trials showing majority of EYLEA HD patients maintained their visual and anatomic improvements with extended dosing intervals

New EYLEA HD dosing regimen allows patients with wAMD and DME to be treated as infrequently as 2 to 3 times a year, further extending the widest range of dosing intervals of any approved injectable anti-VEGF

TARRYTOWN, N.Y., April 02, 2026 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the extension of dosing intervals for EYLEA HD® (aflibercept) up to every 20 weeks for patients with wet age-related macular degeneration (wAMD) and diabetic macular edema (DME) following one year of successful response based on visual and anatomic outcomes. As part of the approval, the FDA has updated the EYLEA HD label to include 96-week (2-year) data from the pivotal PULSAR trial in wAMD and the pivotal PHOTON trial in DME, demonstrating sustained efficacy and safety through 2 years with extended dosing intervals.

“The potential for needing only 2 or 3 EYLEA HD injections a year to manage certain retinal diseases is an exciting advance that could benefit my patients who have been successfully treated for a year, particularly as safety, durability and flexibility continue to be driving forces behind treatment decisions,” said Michael A. Klufas, M.D., Wills Eye Hospital - Retina Service. “With the extended EYLEA HD dosing schedule and the addition to the label of the compelling 96-week data from PULSAR and PHOTON, I have further confidence that when initiating treatment with EYLEA HD, patients can maintain their visual and anatomic improvements in the long term with a comparable safety profile to EYLEA 2 mg.”

With this latest approval, dosing with EYLEA HD can now be individualized for patients with wAMD and DME, some of whom may need treatment as frequently as every 4 weeks, as well as those who can successfully be extended to treatment as infrequently as every 20 weeks, based on criteria described in the U.S. Prescribing Information. This further extends the widest range of dosing intervals of any approved injectable anti-VEGF.

The EYLEA HD label was also updated to include data through 96 weeks from both trials. Of the EYLEA HD patients who completed week 96 (PULSAR n=583, PHOTON n=395), the vast majority maintained or further extended their dosing intervals while visual and anatomic improvements remained consistent with those achieved in the first 48 weeks, including:

- 71% and 47% of wAMD patients attained last assigned dosing intervals of ≥16- and ≥20-week intervals, respectively, at week 96
- 72% and 44% of DME patients attained last assigned dosing intervals of ≥16- and ≥20-week intervals, respectively, at week 96

“We have once again raised the bar by offering the first and only injectable anti-VEGF therapy that gives patients the potential to be treated as infrequently as every 5 months, significantly reducing the treatment burden for patients who demonstrate a successful response after one year of extended dosing,” said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer at Regeneron, and a principal inventor of EYLEA. “With EYLEA HD, retina specialists have a treatment option with unparalleled durability - and with the widest range of approved dosing options of any approved injectable anti-VEGF - to meet the individual needs of their patients.”

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

Beyond today’s approval, the FDA also has a target action date in April 2026 for the EYLEA HD prefilled syringe, which is under review through a Chemistry, Manufacturing and Controls Prior-Approval Supplement.

About PULSAR and PHOTON
PULSAR in wAMD and PHOTON in DME/Diabetic Retinopathy (DR) were double-masked, active-controlled pivotal trials that were conducted in multiple centers globally. The lead sponsors of the trials were Bayer for PULSAR and Regeneron for PHOTON.

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. 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 to an every 2-month interval if protocol-defined criteria for disease progression were observed. Beginning in the second year, intervals could also be extended. Patients in all EYLEA groups maintained a fixed 2-month dosing regimen throughout their participation in the two-year trials.

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® (aflibercept), 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, DR and RVO.

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. This includes the ongoing Phase 3 SIENNA clinical trial in geographic atrophy, as well as additional novel candidates for uveitis, glaucoma and thyroid eye disease.

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.

DOSAGE AND ADMINISTRATION

Neovascular (Wet) Age-Related Macular Degeneration (nAMD)

- The recommended dose for EYLEA HD is 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week.
- Some patients did not maintain a response with 8 mg once every 8 to 16 weeks, +/- 1 week, after successful response to the three initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).
- Extended dosing intervals (8 mg once every 20 weeks, +/- 1 week) may be considered after one year of successful response based on visual and anatomic outcomes.

Diabetic Macular Edema (DME)

- The recommended dose for EYLEA HD is 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week.
- Some patients did not maintain a response with 8 mg once every 8 to 16 weeks, +/- 1 week, after successful response to the three initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).
- Extended dosing intervals (8 mg once every 20 weeks, +/- 1 week) may be considered after one year of successful response based on visual and anatomic outcomes.

Diabetic Retinopathy (DR)

- The recommended dose for EYLEA HD is 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 12 weeks, +/- 1 week.
- Some patients did not maintain a response with 8 mg once every 8 to 12 weeks, +/- 1 week, after successful response to the three initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).

Macular Edema Following Retinal Vein Occlusion (RVO)

- The recommended dose for EYLEA HD is 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three to five doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 weeks, +/- 1 week.
- Some patients did not maintain a response with extended dosing intervals after successful response to the first three to five initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).

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 for the treatment of wet age-related macular degeneration and diabetic macular edema; 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 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 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 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. 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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