



EYLEA® HD (aflibercept) Injection 8 mg Data Presentations at AAO Reinforce Efficacy and Safety Profile in Wet Age-related Macular Degeneration and Diabetic Macular Edema

November 1, 2023 at 4:00 PM EDT

Long-term data and subgroup analyses from pivotal EYLEA HD clinical program highlight durability of visual improvements and consistent safety across extended dosing intervals and patient characteristics

TARRYTOWN, N.Y., Nov. 01, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced long-term outcomes and new analyses of pivotal clinical data for EYLEA® HD (aflibercept) Injection 8 mg will be presented at the American Academy of Ophthalmology (AAO) annual meeting in San Francisco from November 3 to 6.

“Following the approval of EYLEA HD, we have continued to evaluate data from the pivotal clinical program to identify new insights that may support physicians in administering this innovative treatment to patients living with certain serious retinal diseases,” said Boaz Hirshberg, M.D., Senior Vice President, Clinical Development, Internal Medicine at Regeneron. “At this year’s AAO, we will present a wide-ranging review of results from the PULSAR and PHOTON trials in wet age-related macular degeneration and diabetic macular edema. Together, they showcase the impressive durability and consistent safety profile of EYLEA HD over the long-term across different extended dosing intervals and patient characteristics.”

Notable presentations include a detailed review of positive two-year (96 weeks) results from the pivotal PULSAR and PHOTON trials investigating EYLEA HD with 12- and 16-week dosing regimens, compared to EYLEA® (aflibercept) Injection 8-week dosing regimens, in patients with wet age-related macular degeneration (wAMD) and diabetic macular edema (DME), respectively. Additionally, subgroup data from PHOTON in DME across sex, age, race and ethnicity will be presented, as well as a pooled safety analysis from the PULSAR, PHOTON and Phase 2 CANDELA trials.

Two-year data from the pivotal PULSAR trial were previously [presented](#) at the EURETINA Congress in October 2023. Two-year data from the pivotal PHOTON trial were previously [presented](#) at the American Society of Retina Specialists (ASRS) annual meeting in July 2023.

EYLEA HD (known as aflibercept 8 mg outside of the U.S.) is being jointly developed by Regeneron and Bayer AG. In the U.S., Regeneron maintains exclusive rights to EYLEA and EYLEA HD. 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 following any regulatory approvals.

EYLEA HD and EYLEA presentations at AAO:

Abstract title	Session	Lead author	Presentation date, time (PST), location
EYLEA HD			
Aflibercept 8mg for Diabetic Macular Edema: 96-Week Results of the PHOTON Study	RET11 Podium Presentation	Diana V. Do, M.D.	Friday, November 3 5:02 – 5:08 PM WEST 3004
Aflibercept 8 mg in Patients With Neovascular AMD: Phase 3 PULSAR Trial 96-Week Results*	RET10 Podium Presentation	Jean-Francois Korobelnik, M.D.	Friday, November 3 4:13 – 4:18 PM WEST 3004
Intravitreal Aflibercept 8 mg for DME: Week 48 Efficacy Outcomes by Baseline Demographics in the Phase 2/3 PHOTON Trial	PA025 Podium Presentation	Sean Adrean, M.D.	Sunday, November 5 8:00 – 8:07 AM WEST 2006
Pooled Safety Analysis of Aflibercept 8 mg in the CANDELA, PHOTON and PULSAR Trials	PO551 ePoster	Veeral Sheth, M.D.	Available on demand
Characteristics of Patients Who Did or Did Not Maintain Aflibercept 8-mg Dosing Intervals in the Phase 2/3 PHOTON Trial	PO519 ePoster	Dennis M. Marcus, M.D.	Available on demand

Intravitreal Aflibercept 8 mg in Patients With PCV: PULSAR Subgroup Analysis*	PO508 ePoster	Timothy Y. Lai, M.D., FRCOphth, FRCS	Available on demand
Intravitreal Aflibercept 8-mg Injection in Patients With nAMD: Subgroup Analyses From the Phase 3 PULSAR Trial*	PO512 ePoster	David A. Eichenbaum, M.D.	Available on demand
Early Fluid Resolution Association With Treatment Interval Maintenance at Week 48 in Patients Receiving Aflibercept 8 mg: Phase 3 PULSAR Trial*	PO474 ePoster	Varun Chaudhary, M.D.	Available on demand
EYLEA			
Two-Year Outcomes From FIREFLY Next, a Prospective Long-Term Follow-Up Study After Treatment of ROP With Aflibercept vs. Laser*	PA021 Podium Presentation	Andreas Stahl, M.D.	Saturday, November 4 4:09 – 4:16 PM WEST 2006

**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 are being conducted in multiple centers globally. In both trials, patients were randomized into 3 treatment groups to receive either: EYLEA HD every 12 weeks, EYLEA HD every 16 weeks, or EYLEA every 8 weeks. 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 8-week interval if protocol-defined criteria for disease progression were observed. Intervals could not be extended until the second year of the study. Patients in all EYLEA groups maintained a fixed 8-week dosing regimen throughout their participation in the trials.

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 Ophthalmology 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. Over a decade ago, our breakthrough scientific research resulted in the development of EYLEA, a vascular endothelial growth factor (VEGF) inhibitor designed to block the growth of new blood vessels and decrease the ability of fluid to pass through blood vessels in the eye. EYLEA has since brought fundamental change to the retinal disease treatment landscape and is supported by a robust body of research that includes eight pivotal Phase 3 trials, 11 years of real-world experience, and more than 70 million EYLEA injections globally.

Regeneron continues to advance our anti-angiogenesis expertise with new solutions with the aim of offering optimal flexibility for a broad group of patients and eye care professionals. This includes EYLEA HD, which has been developed with the aim of extending the time between injections, while maintaining the vision gains, anatomic benefits and safety previously observed with EYLEA.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

INDICATIONS

EYLEA® HD (aflibercept) 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) 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 and retinal detachment (separation of retina from back of the eye) can occur. Inflammation in the eye has been reported with the use of EYLEA HD and EYLEA.
- 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.
- Contact your doctor right away if you think you or your baby might be experiencing any side effects, including eye pain or redness, light sensitivity, or blurring of vision, after an injection.
- 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 for 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in our laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*[®] technologies, such as *VelocImmune*[®], which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center[®], which is conducting one of the largest genetics sequencing efforts in the world.

For more information, please visit www.Regeneron.com or follow Regeneron on [LinkedIn](#).

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 patients with wet age-related macular degeneration, diabetic macular edema, and diabetic retinopathy; 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 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 (such as EYLEA HD) 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; competing drugs and product candidates 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 (such as the COVID-19 pandemic) on Regeneron's business; and 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® (afibercept) Injection 2 mg and REGEN-COV® (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, 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, 2022 and its Form 10-Q for the quarterly period ended June 30, 2023. 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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