

REGENERON

Media Statement

October 13, 2025

Regeneron Provides Update on EYLEA HD® (aflibercept) Injection 8 mg Regulatory Applications Under Review by the FDA

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) was notified by Catalent Indiana, LLC, part of Novo Nordisk, that they received an “official action indicated” (OAI) letter on October 9 from the U.S. Food and Drug Administration (FDA) following a July 2025 FDA general site inspection. There are two regulatory applications under review by the FDA consisting of a Chemistry, Manufacturing and Controls (CMC) Prior-Approval Supplement (PAS) for the EYLEA HD® (aflibercept) Injection 8 mg prefilled syringe device, and a supplemental Biologics License Application (sBLA) for the use of EYLEA HD as a treatment for macular edema following retinal vein occlusion (RVO) and for broadening the EYLEA HD dosing schedule to include every 4-week (monthly) dosing across approved indications. Catalent Indiana, LLC is the manufacturing filler included in the EYLEA HD Biologics License Application (BLA). While Catalent Indiana, LLC continues to work with the FDA to resolve the outstanding issues, Regeneron is planning to submit an application to include an additional manufacturing filler in the EYLEA HD BLA within the next three months.

EYLEA HD remains available in the U.S. through vial administration for patients with wet age-related macular degeneration (wAMD), diabetic macular edema (DME) and diabetic retinopathy (DR). In the European Union, the Eylea™ 8 mg prefilled syringe is approved for use in patients with wAMD and DME.

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 media statement 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® (afibercept) 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 the “official action indicated” (OAI) letter issued by the U.S. Food and Drug Administration (“FDA”) to Catalent Indiana, LLC referenced in this media statement on the EYLEA HD regulatory applications under review by the FDA; whether Regeneron will ultimately be able to obtain FDA approval for EYLEA HD in a prefilled syringe, for the treatment of macular edema following retinal vein occlusion (“RVO”), and/or for every 4-week (monthly) dosing across approved indications and, if so, the timing of any such approvals; 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 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 EYLEA HD for the treatment of RVO; 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; 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; and ongoing regulatory obligations and oversight impacting Regeneron’s Products, research and clinical programs, and business, including those relating to patient privacy. 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 June 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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