

Regeneron Announces Important US Prescribing Information Clarification for EYLEA® (aflibercept) Injection

TARRYTOWN, N.Y. – May 25, 2016 – Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the U.S. Food and Drug Administration (FDA) has approved an update to the dosage and administration section of the EYLEA® (aflibercept) Injection US Prescribing Information for patients with Neovascular (wet) Age-Related Macular Degeneration (wAMD) and Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in patients with DME. The label language clarification recognizes that while most patients receiving EYLEA will require dosing once every 8 weeks (2 months) after an initial monthly dosing period, some patients will still require monthly dosing. This label clarification provides clearer direction on the approved dosing option of up to an every 4-week interval that has been described in the US Prescribing Information since the initial approval for EYLEA in 2011.

The revised wAMD Dosing and Administration guidance from the U.S. Prescribing Information (USPI) is below. The new clarifying language is underlined:

The recommended dose for EYLEA is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 weeks (monthly) dosing after the first 12 weeks (3 months).

The revised DME and DR in patients with DME Dosing and Administration guidance from the U.S. Prescribing Information (USPI) is below. The new clarifying language is underlined:

The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 weeks (monthly) dosing after the first 20 weeks (5 months).

IMPORTANT SAFETY INFORMATION FOR EYLEA® (aflibercept) INJECTION

EYLEA® (aflibercept) Injection is a prescription medication administered by injection into the eye. You should not use 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, including aflibercept.

Injection into the eye with EYLEA can result in an infection in the eye and retinal detachment (separation of retina from back of the eye). Inflammation in the eye has been reported with the use of EYLEA.

In some patients, injections with 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.

There is a potential risk of serious and sometimes fatal side effects related to blood clots, leading to heart attack or stroke in patients receiving EYLEA.

Serious side effects related to the injection procedure with EYLEA are rare but can occur including infection inside the eye and retinal detachment.

The most common side effects reported in patients receiving EYLEA are increased redness in the eye, eye pain, cataract, moving spots in the field of vision, increased pressure in the eye, and vitreous (gel-like substance) detachment. It is important that you contact your doctor right away if you think you might be experiencing any side effects.

EYLEA is for prescription use only. For additional safety information, please talk to your doctor and see the full [Prescribing Information](#) for EYLEA.

Please see the full U.S. Prescribing Information for EYLEA at www.EYLEA.com.

The product information is intended only for residents of the United States. The product discussed herein may have different labeling in different countries.

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.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for high LDL cholesterol, eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Regeneron Forward-Looking Statements and Use of Digital Media

This news 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 Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (afibercept) Injection; 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 product candidates, including EYLEA; unforeseen safety issues resulting from the administration of products and product

candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA for its currently approved indications), research and clinical programs, and business, including those relating to patient privacy; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2015 and its Form 10-Q for the quarterly period ended March 31, 2016. 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 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 (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

Contacts Regeneron:

Media Relations

Ilana Tabak

Tel: + 1 (914) 847-3836

ilana.tabak@regeneron.com

Investor Relations

Manisha Narasimhan, Ph.D.

Tel: +1 (914) 847-5126

Manisha.narasimhan@regeneron.com

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