Regeneron Announces FDA Acceptance of sBLA Filing for 12-Week Dosing of EYLEA® (aflibercept) Injection for Patients with Wet AMD

December 11, 2017

TARRYTOWN, N.Y., Dec. 11, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's supplemental Biologics License Application (sBLA) for a 12-week dosing interval of EYLEA® (aflibercept) Injection in patients with wet age-related macular degeneration (wet AMD) based on physician's assessment. Under the Prescription Drug User Fee Act (PDUFA), the goal for a standard review of an sBLA is ten months from submission for a target action date of August 11, 2018.

For wet AMD, the current recommended dose for EYLEA is 2 mg administered by injection in the eye every two months (eight weeks) following three initial monthly (every four weeks) injections. EYLEA may also be dosed once per month.

"EYLEA is a cornerstone treatment approved for many retinal diseases, and we remain committed to advancing new research to optimize its use and extend its benefits to other retinal diseases and patient populations," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron.

The sBLA submission is based on an integrated analysis of two-year results from VIEW 1 and VIEW 2 - two pivotal, randomized, double-masked, Phase 3 trials that investigated the treatment of EYLEA in patients with wet AMD. The integrated analysis found that 51 percent of study patients had their EYLEA dosing interval extended to every 12 weeks at the beginning of the second year (week 52) of treatment, based on an evaluate and extend approach, and were able to maintain this every 12-week dosing interval and their best-corrected visual acuity (BCVA) gains when they were assessed at the end of the second year (week 96). No new safety signals were identified. Criteria for patients to receive EYLEA on a 12-week dosing interval included having no evidence of new or progressive wet AMD as determined by anatomic and visual measures.

About EYLEA® (aflibercept) Injection

EYLEA® (aflibercept) Injection is a vascular endothelial growth factor (VEGF) inhibitor formulated as an injection for the eye. It is designed to block the growth of new blood vessels and decrease the ability of fluid to pass through blood vessels (vascular permeability) in the eye by blocking VEGF-A and placental growth factor (PLGF), two growth factors involved in angiogenesis. EYLEA is supported by a robust body of research that includes seven pivotal Phase 3 studies.

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, including eye pain or redness, light sensitivity, or blurring of vision, after an injection.

EYLEA is for prescription use only. For additional safety information, please talk to your doctor and visit www.EYLEA.us to see the full Prescribing Information for 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.

Indications

EYLEA® (aflibercept) Injection is a prescription medicine approved for the treatment of patients with:

Wet Age-related Macular Degeneration (AMD): The recommended dose for EYLEA is 2 mg administered by injection in the eye every 2 months (8 weeks) following 3 initial monthly (every 4 weeks) injections. EYLEA may be dosed once per month, but in most patients, additional benefit was not seen with this dosing plan. Some patients may need monthly (every 4 weeks) dosing after the first 3 months (12 weeks).

Macular Edema following Retinal Vein Occlusion (RVO): The recommended dose for EYLEA is 2 mg administered by injection in the eye monthly (every 4 weeks).

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in patients with DME: The recommended dose for EYLEA is 2 mg administered by injection in the eye every 2 months (8 weeks) following 5 initial monthly (every 4 weeks) injections. EYLEA may be dosed once per month, but in most

patients, additional benefit was not seen with this dosing plan. Some patients may need monthly (every 4 weeks) dosing after the first 5 months (20 weeks).

Please visit www.EYLEA.us to see the full Prescribing Information for EYLEA.

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for nearly 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, including *VelocImmune*® to yield optimized fully-human antibodies, and ambitious initiatives such as the Regeneron Genetics Center, one of the largest genetics sequencing efforts in the world.

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® (aflibercept) Injection; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, such as U.S. Food and Drug Administration's potential approval of the regular 12-week dosing interval of EYLEA in some patients with wet age-related macular degeneration discussed in this news release; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in later studies and lead to therapeutic applications; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation EYLEA; serious complications or side effects in connection with the use of Regeneron's products and product candidates (such as EYLEA) in clinical trials; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; 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, such as EYLEA; 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; 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, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), 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, including without limitation the patent litigation proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, 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 United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2016 and its Form 10-Q for the quarterly period ended September 30, 2017. 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
Daren Kwok
Tel: +1 (914) 847-1328
daren.kwok@regeneron.com

Investor Relations
Manisha Narasimhan, Ph.D.
Tel: +1 (914) 847-5126
manisha.narasimhan@regeneron.com

View original content:http://www.prnewswire.com/news-releases/regeneron-announces-fda-acceptance-of-sbla-filing-for-12-week-dosing-of-eylea-aflibercept-injection-for-patients-with-wet-amd-300569395.html

SOURCE Regeneron Pharmaceuticals, Inc.