February 28, 2018

Statement:

Regeneron Letter to Healthcare Professionals Re: EYLEA® (aflibercept) Injection

Today Regeneron issued a letter to healthcare professionals providing updated guidance around reports of intraocular inflammation (IOI) following EYLEA injections.

IOI is a known risk factor of intraocular injections; rates of IOI with EYLEA during clinical studies are described in the EYLEA label. Since launch, the annualized reporting rate of IOI based on post-marketing surveillance has ranged from 1 to 4 cases per 10,000 injections. Although overall reporting rates remain within these historical ranges, increased reporting rates were noted with certain recent lots distributed in the U.S.

In order to determine the cause of this variability, Regeneron has conducted an extensive review of our manufacturing and distribution processes. This review did not identify any association of IOI rates with the EYLEA drug itself; however, an association was seen with certain batches of the syringe that were included in specific lots of final packaged EYLEA kits.

Patient safety is of the utmost importance to Regeneron. Out of an abundance of caution, we are ceasing distribution of the impacted EYLEA kits and recommending that practitioners already in receipt of the affected kits not use the included syringes. We will also exchange affected kits as needed. We have communicated our findings and action plan to the U.S. Food and Drug Administration (FDA) and the American Society of Retina Specialists (ASRS).

The letter to healthcare professionals may be found here.

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. In the United States, EYLEA is the number one prescribed FDA-approved anti-VEGF treatment for its approved indications and 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.

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