INFORMED CONSENT FOR INTRAVITREAL EYLEATM (AFLIBERCEPT) INJECTION

INDICATIONS

EYLEATM (aflibercept) is approved by the Food and Drug Administration (FDA) to treat Neovascular (Wet) Age-Related Macular Degeneration (AMD), which is the leading cause of blindness in people over 50 years of age. There are two types of macular degeneration: dry and wet. In the “wet” form of AMD, abnormal blood vessels grow in the back of the eye. Sometimes these vessels leak blood or fluid that causes blurred or distorted vision. Without treatment, vision loss may be quick and severe. EYLEATM (aflibercept) is also approved to treat macular edema following central retinal vein occlusion (CRVO).

POSSIBLE BENEFITS AND LIMITATIONS

EYLEATM (aflibercept) works by inhibiting the growth of the abnormal blood vessels that cause AMD; it also decreases swelling of the macula. The goal of treatment is to prevent further loss of vision. Although some patients have regained vision, the medication may not restore vision that has already been lost, and may not ultimately prevent further loss of vision caused by the disease.

ADMINISTRATION

After the pupil is dilated and the eye is numbed with anesthesia, the medication is injected into the vitreous, or jelly-like substance in the back chamber of the eye. EYLEATM (aflibercept) is administered by an injection into your eye as needed at regular intervals. Your ophthalmologist will tell you how often you will receive the injection, and for how long.

ALTERNATIVES

You do not have to receive treatment for your condition, although without treatment, wet macular degeneration and macular edema may lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available. At present, there are three other FDA-approved treatments for neovascular age-related macular degeneration (AMD): photodynamic therapy with a drug called VisudyneTM (verteporfin) and injection into the eye of the drugs MacugenTM (pegaptanib) and LucentisTM (ranibizumab). Although VisudyneTM (verteporfin) and MacugenTM (pegaptanib) have been proven to slow down the rate of visual loss, most people do not get back better vision. LucentisTM (ranibizumab) and EYLEATM (aflibercept) have been compared and found to have equivalent efficacy and safety. LucentisTM (ranibizumab), EYLEATM (aflibercept), and OzurdexTM (dexamethasone) are all approved for RVO; LucentisTM (ranibizumab) has also been approved for diabetic macular edema (DME). Some eye surgeons use an anti-VEGF drug called AvastinTM (bevacizumab) to treat AMD and refractory macular edema; this use of AvastinTM is “off-label.” Eye surgeons also use triamcinolone acetonide, a long-acting cortisone-like drug (KenalogTM, TriesenceTM, or TrivarisTM) to treat eye conditions like yours. Your doctor will discuss with you the benefits and risks associated with these other choices of treatment.
COMPLICATIONS FROM THE MEDICATION AND INJECTION

Your condition may not get better or may become worse. Any or all of these complications may cause decreased vision and/or have a possibility of causing blindness. Additional procedures may be needed to treat these complications. During the follow-up visits or phone calls, you will be checked for possible side effects and the results will be discussed with you.

COMPLICATIONS OF EYLEATM (aflibercept)

Possible complications of the administration of EYLEATM (aflibercept) include but are not limited to eye-related adverse events such as retinal detachment, a serious infection (endophthalmitis), swelling within the eye (inflammation), cataract formation (clouding of the lens of the eye), glaucoma (increased pressure in the eye), hypotony (reduced pressure in the eye), damage to the retina or cornea (structures of the eye), and bleeding. You may receive eye drops with instructions on when to use them to reduce the possibility of this occurring. Any of these rare complications may lead to severe, permanent loss of vision. The most common side effects to your eye are increased redness in the whites of your eye (conjunctival hemorrhage), eye pain, cataract, vitreous detachment, small specks in vision (floaters), increased intraocular pressure, and the feeling that something is in your eye.

There is a potential risk of arterial thromboembolic events (ATEs), defined as nonfatal stroke, nonfatal heart attack, and arterial death, following intravitreal use of anti-VEGF drugs. The rate of ATEs was low during the clinical trials. Whenever a medication is used in a large number of patients, a small number of coincidental life-threatening problems may occur that have no relationship to the treatment. For example, patients with diabetes are already at increased risk for heart attacks and strokes, and the clinical trial conducted in order to approve a similar drug for diabetic macular edema showed that diabetic patients had slightly more deaths. There were not many deaths, and the cause was typical of patients with advanced diabetic complications. It is not clear, therefore, whether the drug or the diabetes caused the deaths. Similarly, if one of these patients being treated with EYLEATM (aflibercept) suffers a heart attack or stroke, it may be caused by the diabetes and not the EYLEATM (aflibercept) treatment.

KNOWN RISKS OF INTRAVITREAL EYE INJECTIONS

Patients receiving an injection of EYLEATM (aflibercept) may experience less severe side effects related to the pre-injection preparation procedure (eyelid speculum, anesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anesthetic). These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances.

PATIENT RESPONSIBILITIES

I will immediately contact my ophthalmologist (eye surgeon) if any of the following signs of infection or other complications develop: pain, blurry or decreased vision, sensitivity to light, redness of the eye (compared to immediately after the injection), or discharge from the eye. I have been instructed NOT to rub my eyes or swim for three days after each injection. I will keep all post-injection appointments or scheduled telephone calls so my doctor can check for complications.
PATIENT CONSENT

The above explanation has been read by/to me. The nature of my eye condition has been explained to me and the proposed treatment has been described. The risks, benefits, alternatives, and limitations of the treatment have been discussed with me. All my questions have been answered.

I hereby authorize Dr. _________________ to administer the intravitreal injection of EYLEATM (aflibercept) in my ______________________ (state “right eye” or “left eye” or “both eyes”) at regular intervals as needed.

This consent will be valid until I revoke it or my condition changes to the point that the risks and benefits of this medication for me are significantly different.

________________________________________
Patient Signature (or Person Authorized to Sign for Patient) Date