6.2 Postmarketing Experience

- Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection.
- Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

5.2 Steroid-related Effects

- Use of corticosteroids including ILUVIEN contains a corticosteroid and is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

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Flucinolone acetonide is a white or almost white, microcrystalline powder, practically insoluble in water, soluble in methanol, ethanol, chloroform and acetone, and sparingly soluble in ether.

Each ILUVIEN consists of a light brown 3.5mm x 0.37mm implant containing 0.19 mg of the active ingredient flucinolone acetonide and the following inactive ingredients: polyimide tube, polyvinyl alcohol, silicone adhesive and water for injection.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Corticosteroids inhibit inflammatory responses to a variety of inciting agents including multiple inflammatory cytokines. They inhibit edema, fibrin deposition, capillary dilatation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. Capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, including multiple inflammatory cytokines. They inhibit edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation.

12.2 Pharmacokinetics
In a human pharmacokinetic study of ILUVIEN, flucinolone acetonide concentrations in plasma were below the lower limit of quantification of the assay (100 pg/mL) at all post-administration time points from Day 7 through Month 36 following intravitreal administration of a 0.2 mcg/day or 0.5 mcg/day flucinolone acetonide insert.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term animal studies have not been conducted to determine the carcinogenic potential or the effect on fertility of ILUVIEN.

Flucinolone acetonide was not genotoxic, in vitro in the Ames test (S. typhimurium and E. coli) and the mouse lymphoma TK assay, or in vivo in the mouse bone marrow micronucleus assay.

14. CLINICAL STUDIES

The efficacy of ILUVIEN was assessed in two three year, randomized (2:1:1, active: sham), multicenter, double-masked, parallel-groups studies that enrolled patients with diabetic macular edema (DME) and who had previously been treated with laser photocoagulation.

The primary efficacy endpoint in both trials was the proportion of subjects in whom vision had improved by 15 letters or more from baseline after 24 months of follow-up.

Alimera Sciences, Inc.
6120 Windward Parkway
Alpharetta, GA 30005

16. HOW SUPPLIED/STORAGE AND HANDLING

ILUVIEN® (flucinolone acetonide intravitreal implant) 0.19 mg is supplied in a sterile single use prefilled applicator with a 25-gauge needle, packaged in a tray sealed with a lid inside a carton. NDC 086611-190-02

Storage: Store at 15° - 30° C (59° - 86° F).

17. PATIENT COUNSELING INFORMATION

Stereoid-related Effects
Advise patients that a cataract may occur after treatment with ILUVIEN. If this occurs, advise patients that their vision will decrease, and they will need an operation to remove the cataract and restore their vision.

Advise patients that they may develop increased intracocular pressure with ILUVIEN treatment, and the increased IOP may need to be managed with eye drops, or surgery.

Intravitreal injection-related effects
Advise patients that in the days following intravitreal injection of ILUVIEN, patients are at risk for potential complications including in particular, but not limited to, the development of endophthalmitis or elevated intracocular pressure.

When to Seek Physician Advice
Advise patients that if the eye becomes red, sensitive to light, painful, or develops a discharge, it should be evaluated by an ophthalmologist.

Driving and Using Machinery
Advise patients that they may experience temporary visual blurring after receiving an intravitreal injection. Advise patients not to drive or use machines until this has resolved.

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Patented. See: www.alimerasciences.com