ALIMERA SCIENCES FACT SHEET

OVERVIEW

Alimera Sciences, Inc. (NASDAQ: ALIM), based in Alpharetta, GA, is a pharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. Alimera Sciences Limited, a subsidiary of Alimera, is based in the United Kingdom and is the headquarters of Alimera’s European operations. The company also operates subsidiaries in Germany and Portugal. Presently, the company is focused on diseases affecting the back of the eye, or retina.

ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg is the company’s lead product. ILUVIEN is a multiyear intravitreal (in the vitreous of the back of the eye) nonbioerodable implant, which is a sustained drug delivery system that provides a continuous, daily submicrogram level of fluocinolone acetonide lasting for 36 months.

ILUVIEN is approved in the United States to treat diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. ILUVIEN is also approved in Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom where it is indicated for the treatment of vision impairment associated with chronic diabetic macular edema, considered insufficiently responsive to available therapies. ILUVIEN is in the national licensing phase in two additional European countries, the Czech Republic and Poland. It is available commercially in the U.S., Germany, Portugal and the United Kingdom.

MANAGEMENT TEAM

- Dan Myers, President and Chief Executive Officer
- Rick Eiswirth, Chief Operating Officer and Chief Financial Officer
- Philip Ashman, Ph.D., Senior Vice President, European Managing Director
- Ken Green, Ph.D., Chief Scientific Officer, Global Head, Research & Development
- Dave Holland, Senior Vice President, Sales and Marketing

EU MANAGEMENT TEAM

- Philip Ashman, Ph.D., Senior Vice President, European Managing Director
- John Hall, MD, Senior Vice President, Medical Director Europe
- Philip Haldar, Vice President, European Marketing

LEAD PRODUCT

ILUVIEN is a long-term, sustained-release intravitreal implant. A single, tiny ILUVIEN implant is designed to deliver submicrogram levels of the corticosteroid, fluocinolone acetonide (FAc), for 36 months. Corticosteroids have a history of effective use in treating inflammation. ILUVIEN is injected into the back of the eye with an applicator that employs a 25-gauge needle, which allows for a self-sealing wound. In the two phase 3 clinical trials, known as the FAME™ Studies, the most frequently reported adverse drug reactions included cataract development and increased ocular pressure.
ILUVIEN IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ILUVIEN is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- ILUVIEN is contraindicated in patients with glaucoma, who have cup to disc ratios of greater than 0.8.
- ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

WARNINGS AND PRECAUTIONS

- Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the intravitreal injection.
- Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
- Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

ADVERSE REACTIONS

- In controlled studies, the most common adverse reactions reported were cataract development (ILUVIEN 82%; sham 50%) and intraocular pressure elevation of >10 mmHg (ILUVIEN 34%; sham 10%).
- Patients are advised to have follow-up eye examinations at appropriate intervals following treatment with ILUVIEN. For full prescribing information, log onto www.ILUVIEN.com.

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.

Please see Full Prescribing Information below.

CORPORATE TIMELINE

- 2003: Alimera Sciences is founded by several former Novartis Ophthalmics executives.
- 2004: Soothe®, an OTC product that provides relief to sufferers of dry eye, is launched.
- 2005: The FAME Study for ILUVIEN for the treatment of diabetic macular edema is initiated.
- 2006: Alimera gains FDA New Drug Application (NDA) approval for an Rx-to-OTC switch of an anti-allergy eye product called Alaway® ketotifen fumarate ophthalmic solution. Alaway is sold to Bausch and Lomb.
- 2007: Soothe is sold to Bausch and Lomb.
- 2010: Alimera Sciences goes public, trading under the NASDAQ symbol ALIM.
- 2012: ILUVIEN receives a positive opinion for approval of its Marketing Authorization Application (MAA) from seven European countries via the Decentralized Procedure (DCP).
- 2013: ILUVIEN is commercially launched in Germany and the United Kingdom.
- 2013: The United Kingdom’s National Institute for Health and Care Excellence (NICE) published final guidance for ILUVIEN®, clearing the path to patient availability through the National Health Service (NHS).
- 2014: Through the Repeat Use Process in Europe, Alimera receives a positive opinion to approve in 10 additional European countries and receives national marketing licenses in eight.
- 2014: ILUVIEN approved in the United States by the Food and Drug Administration (FDA).
- 2015: ILUVIEN commercially launched in the U.S. in late February.
FINANCIAL INFORMATION (as reported in the 10-Q dated November 14, 2014)

Alimera Sciences, Inc. is publicly traded on NASDAQ under the symbol ALIM. Net revenue for the three months ended September 30, 2014 increased by approximately $1.6 million, or 211%, to approximately $2.4 million compared to approximately $760,000 for the three months ended September 30, 2013. The increase was attributable to increased adoption of ILUVIEN in Germany and the United Kingdom. As of September 30, 2014, Alimera had cash and cash equivalents of $61.4 million, compared to $12.6 million as of September 30, 2013.

LOCATIONS

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ILUVIEN 

Indications and Usage

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

Dosage and Administration

- For intravitreal injection
- The intravitreal injection procedure should be carried out under aseptic conditions.

1. Intravitreal Injection

   1. Place the patient in the sitting position.
   2. Visually check through the viewing window of the preloaded applicator to ensure that there is a drug implant inside.
   3. Remove the applicator tip, replace the tip with the applicator tip, and insert the implant into the eye.
   4. The implant should be positioned within the anterior chamber of the eye.

2. Postmarketing Experience

   - The following reactions have been identified during post-marketing use of ILUVIEN in clinical practice.
   - These reactions include, but are not limited to, those that occurred in clinical trials and in post-marketing experience.

Adverse Reactions

In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Alpharma Sciences, Inc. at 1-844-645-8843 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

1 INDICATIONS AND USAGE

1.1 DOSAGE AND ADMINISTRATION

1.1.1 Intravitreal Injection

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   2. Visually check through the viewing window of the preloaded applicator to ensure that there is a drug implant inside.
   3. Remove the applicator tip, replace the tip with the applicator tip, and insert the implant into the eye.
   4. The implant should be positioned within the anterior chamber of the eye.

1.1.2 Postmarketing Experience

   - The following reactions have been identified during post-marketing use of ILUVIEN in clinical practice.
   - These reactions include, but are not limited to, those that occurred in clinical trials and in post-marketing experience.

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

   - Intravitreal injection
   - The intravitreal injection procedure should be carried out under aseptic conditions.

2.2 Administration

   - The intravitreal injection procedure should be carried out under aseptic conditions.

3 DOSAGE FORMS AND STRENGTHS

   - Non-biodegradable intravitreal implant containing 0.19 mg fluocinolone acetonide in a drug delivery system.

4 CONTRAINDICATIONS

   - Ocular or periocular infections
   - Glaucoma
   - Hypersensitivity

5 WARNINGS AND PRECAUTIONS

   - Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection.

6 ADVERSE REACTIONS

   - In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure. (6.1)

7 FULL PRESCRIBING INFORMATION: CONTENTS*

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   - 2 DOSAGE AND ADMINISTRATION
   - 3 CONTRAINDICATIONS
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8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

   - Pregnancy Category C

8.4 Pediatric Use

   - There are no adequate and well-controlled studies of ILUVIEN in pregnant women.

9 ADVERSE REACTIONS

   - The most common ocular (study eye) and non-ocular adverse reactions are shown in Tables 1 and 2.

10 NON-CLINICAL TOXICOLOGY

   - Animal reproduction studies have not been conducted with fluocinolone acetonide. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. ILUVIEN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

11 DESCRIPTION

   - The chemical name for fluocinolone acetonide is (3x,11x,16α) 6-fluoro-11β,16-dihydroxy-16,17α-methylenebenz(iso)quin-4,1,4,3-dien-2,3-dione. Its chemical structure is:

12 CLINICAL PHARMACOLOGY

   - The intravitreal injection procedure should be carried out under aseptic conditions.

13 NONCLINICAL TOXICOLOGY

   - Compound containing 0.19 mg fluocinolone acetonide (190 mcg) in a 36-month sustained-release drug delivery system.

14 CLINICAL STUDIES

   - A randomized, sham-controlled, masked trial in which patients with diabetic macular edema were treated with either ILUVIEN (n=375) or sham (n=185).

15 POSTMARKETING EXPERIENCE

   - The following reactions have been identified during post-marketing use of ILUVIEN in clinical practice.