



Preservative Free Triamcinolone Acetonide (PFTA)

(Preservative Free Triamcinolone acetonide suspension in balanced salt solution 40mg/ml)

HUENENBERG, Switzerland – November 30, 2007 – Alcon (NYSE:ACL) announced today that the United States Food and Drug Administration (FDA) has approved TRIESENCE™ (triamcinolone acetonide injectable suspension) 40 mg/mL, a preservative-free synthetic corticosteroid for visualization during vitrectomy and treatment of sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.

The active ingredient in TRIESENCE™, triamcinolone acetonide, has been used for many years to treat retinal disease. This new approval brings ophthalmologists a sterile, preservative-free formulation of the compound specifically developed for use in the eye to treat various retinal inflammatory conditions.

- Triamcinolone acetonide has held regulatory approvals since 1957 for general use in humans, and has been approved by the USFDA for retinal injections since 2007.
- Triamcinolone acetonide is a synthetic corticosteroid indicated for various diabetic and neovascular retinal diseases and inflammatory conditions which are unresponsive to topical corticosteroids. It has been used as a mono-therapy and co-therapy for various back of eye conditions and is also indicated for visualisation during vitrectomy.
- In 2006 the American Academy of Ophthalmology released a bibliography of literature pertaining to the intravitreal injection of **Triamcinolone Acetonide** (see below).
- Its use in eye care was pioneered by **Dr Philip Penfold** (Associate Professor, Australian National University) and others in Australia. [2] Additional more recent publications and examples are posted on the EYE CO website www.eyeco.com.au

Preservative Free Triamcinolone Acetonide has been employed in the treatment of a number of eye conditions including: diabetic retinopathy, occult macular degeneration and as co-therapy with products such as Visudyne and Avastin, for example:

Repeated intravitreal injections of bevacizumab as a mono-therapy in exudative AMD seemed to be associated with decreased bio-efficacy. However, combined pharmacotherapy with triamcinolone acetonide lessened this effect. Thus, multitargeted pharmacotherapy in exudative AMD may have a therapeutic benefit. Ophthalmology 2008;115:2199–2205 © 2008 American Academy of Ophthalmology.

December 8, 2006

BIBLIOGRAPHY OF INTRAVITREAL KENALOG, 1995-October 2006

Foreword:

The off label use of medications and devices is part of the practice of medicine. Not all medications have or will have studies for every possible use. The physician must use his/her judgment in weighing the risks of such use versus the benefits for the patient. Patients should be informed of such use along with the risks and benefits and alternative therapies. There may be circumstances where the use is so common that informing the patient of the off label aspects is not relevant. The use of aspirin for prophylaxis of coronary artery disease is one example.

In an effort to help practitioners make informed decisions about off label use, the Academy has compiled pertinent bibliography concerning Intravitreal Kenalog injections, with links to the abstracts.

This list is not exhaustive and recent studies may not be included. For an exhaustive list of published studies, please use PubMed (www.pubmed.gov) to search for the therapy and the disease.

Reference # [1]

Preservative Free Triamcinolone Acetonide (PFTA) is produced by a licensed compounding pharmacist which is a preferred provider to one of the major medical associations. The sterility of each product batch is independently validated by a reputable Pathology Group. The product has a recommended (refrigerated) shelf life of three months, and used by leading Independent Ophthalmologists in Australia.

*In Australia, RANZCO announced on February 15, 2010 the availability of **Medicare Item Number 42740** is again available for drugs such as **Triamcinolone**. The item number, with care and specific informed consent from the patient, may also be used when employing **Triamcinolone Acetonide** with cataract surgery.*