

Recent developments in the vision care industry



Macugen hypersensitivity alert

The US FDA has revised safety labelling for pegaptanib sodium injection (Macugen, Pfizer), following reports of a small number of cases of hypersensitivity actions including angioedema. In a Medwatch alert, the FDA noted it could not reliably estimate the frequency of the adverse events or to establish a direct relationship to pegaptanib based on voluntary post-marketing reports. It advised ophthalmologists to evaluate patients' medical histories for hypersensitivity reactions. Current recommendations call for Macugen injection to be performed under controlled aseptic conditions, including use of sterile gloves, drape and eyelid speculum, with use of adequate anaesthesia and pre-injection broad-spectrum antibiotics. www.fda.gov/medwatch
www.macugen.com

Alcon reports strong sales

Alcon reported global sales of \$1,157.1m for the first quarter of 2006, an increase of 8.1% over global sales in the first quarter of 2005. Net earnings for the first quarter of 2006 increased 18.5% to \$295.7m or \$0.95 per share on a diluted basis, compared to \$249.5m or \$0.80 per share for the first quarter of 2005. Nonetheless, the stock dipped more than 10%, spurred by analysts who had expected at least \$0.90, currency-adjusted, per share for the quarter.

Sales grew in the US and internationally. Pharmaceutical sales, including Travatan and Azept, grew 10%. Intraocular lens sales

increased 18.7%, thanks to an increase in sales of AcrySof ReSTOR lenses. Refractive revenue declined 19.3%, attributed to decreases in US procedure fees.

Alcon also announced a new collaboration with biotech giant Amgen. The agreement calls for a broad, multi-target collaboration to jointly research, develop and commercialise therapeutics for the treatment of eye diseases. Alcon will lead clinical development and commercialisation activities for molecules jointly selected by the companies. Amgen will grant Alcon an exclusive licence within the field of ophthalmology for product candidates resulting from the collaboration but will retain rights for all non-ophthalmic uses. www.alcon.com
www.amgen.com

Fusarium infections investigated

Bausch and Lomb's ReNu with Moisture Loc' contact lens solution has been removed from retail shelves in parts of Asia, North America and Europe as investigators evaluate cases of fungal keratitis possibly linked with the product. Retailers first withdrew the product in Hong Kong and Singapore this February, following reports of Fusarium infection. In April the company voluntarily stopped shipping the product in the US, where 77 cases of Fusarium infection have been confirmed and more than 100 more are being investigated by the US FDA and the US Centers for Disease Control and Prevention. Those investigations, including inspections of B&L facilities, are expected to take at least another month. Although no cases have been reported in Europe, local vendors, including

Swedish optician chains Synsam (with stores in Sweden, Finland and Norway) and Specsavers Blic Optik, have pulled the product. "The source of these infections has not been determined. Based on our extensive testing, analysis, further internal reviews and communications with leading experts, the available scientific evidence does not establish any type of ReNu solution as a cause," said Ronald L. Zarrella, chairman and CEO of Bausch and Lomb. Although ReNu accounts for a relatively modest portion of revenue for the company, the stock share price has suffered, declining from a high of \$87.89 in July 2005 to \$44.58 in mid-April 2006. www.bausch.com

www.fda.gov/cd/opacom/hottopics/contacts.html
Lumigan in Europe

Allergan announced that the Committee for Medicinal Products for Human Use (CHMP) had recommended that the European Commission (EC) approve its combination glaucoma treatment bimatoprost/timolol ophthalmic solution (Ganfort). The company believes this should lead to final EC approval by the middle of the year. The combination agent is indicated for reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who do not respond adequately to topical beta-blockers or prostaglandin analogues. www.allergan.com

Nidek consolidates

Nidek, Inc. completed its merger with Nidek Technologies America, a move the company says will lead to a significant increase in ophthalmic diagnostic product offerings. The merger consolidates the company's clinical, development, distribution, marketing and sales efforts in the US. Nidek Technologies America's most recent release was the Magellan Mapper, which provides high-resolution maps of corneal aberrations. www.nidek.com

New iris retractors

FCI Ophthalmics announced the release of two new flexible iris retractors. One is reusable, the other is disposable. The retractors are made of blue polypropylene fibre and can be inserted through 0.5mm incisions. The reusable iris retractor is packaged in a sterile box of six in a steam-autoclavable container. The disposable iris retractor comes in sterile boxes of five. The

company also markets the Morcher Capsular Tension Rings, Cicinni Capsular Tension Rings, Pupil Dilator and Mackool Capsular Support System. www.fci-ophthalmics.com

Retisert data released

The nanotech company pSivida announced promising two-year clinical trial results involving Retisert, an intravitreal implant that releases fluocinolone acetonide over a 30-month period for the treatment of uveitis. The randomised study, released at the 6th International Symposium on Ocular Pharmacology and Therapeutics in Berlin, showed the recurrence rate for uveitis was significantly lower in eyes receiving Retisert than in eyes receiving standard of care (systemic corticosteroid or other immunosuppressive agents). The study was conducted in 10 countries in Europe and the Middle East by partner Bausch and Lomb. Retisert gained US FDA approval last year. www.psvivida.com
www.bausch.com

Euro retina chip

Retina Implant GmbH received an infusion of €15m from investor Mediplan GmbH for the continuing development of active subretinal implants. Retina Implant recently reported a study that involved implanting electronic camera chips in two completely blind patients. Both patients reportedly were able to identify shapes. The new funds will be applied to clinical trials. www.retina-implant.de

Ellex gains FDA approval

Ellex Medical Lasers Ltd has announced it has received US FDA 510(k) clearance for the Integre Duo, a solid-state red and green photocoagulator. The Integre Duo utilises a patent-pending dual-wavelength laser cavity that offers simultaneous true red and green wavelength selection. The product has already been approved for sale in Japan. www.ellex.com