

Recent Developments in the Vision Care Industry

VISX lasers to the UK

Optical Express, a nationwide network of 190 stores in the United Kingdom, announced that it has signed an agreement with Advanced Medical Optics (AMO) to purchase ten new VISX Star S4 IR excimer laser systems and upgrade its existing eight VISX excimer laser systems to provide the latest CustomVue procedures. Optical Express says the investment forms a central part of a \$20 million expansion of the Optical Express refractive surgery business that will have 24 surgery centres across the UK and Europe by the end of 2006.

QLT circles the wagons

QLT, maker of verteporfin (Visudyne), admitted to pressure from new competing treatments for age-related macular degeneration, saying it would reduce its workforce as part of a new strategic plan to refocus the company on key programs in an effort to enhance shareholder value. QLT is reducing its 2005 guidance on Visudyne annual sales to a range of \$480 million to \$485 million from the previous range of \$500 million to \$530 million. The strategy calls for a reduction of nearly half of its workforce. The company plans to restrict its focus to ophthalmology and one other therapeutic area, which will be selected based on milestones in 2006. Visudyne, once the sole medical treatment for wet macular degeneration, now faces competition from anti-angiogenic agents including pegaptanib (Macugen, Eyetech) and ranibizumab (Lucentis, Genentech).

Diquafosol approval delayed

Inspire Pharmaceuticals announced that the US FDA has issued a second approvable letter for diquafosol tetrasodium ophthalmic solution, a potential treatment for dry eye syndrome. The FDA approvable letter sought additional data from clinical trials on efficacy endpoints. The company said it would request a meeting with the FDA as soon as possible. The company is collaborating with Allergan in the development of the drug. Shares of Inspire plummeted on the news.

Retinal cell death targeted

MultiCell Technologies announced a research agreement with Columbia University in New York to investigate a novel anti-apoptosis compound. The project's goal is to determine whether the compound can protect against retinal ganglion cell (RGC) death in acute and chronic in vivo models of optic neuropathy. The underlying mechanisms of RGC death are not fully understood, though RGC apoptosis has been heavily implicated in many ocular neurodegenerative diseases. Given the delicate balance between the survival and death signals in neuronal cells, molecules that are capable of inhibiting apoptosis are strongly considered as future therapeutic options for the treatment of ocular neurodegenerative diseases. The researchers hope to produce a new treatment for macular degeneration.

Bausch and Lomb research projects

Bausch & Lomb has entered an agreement with privately held company PTC Therapeutics to license selected compounds as development candidates for therapeutic use in ophthalmology. PTC uses its proprietary GEMS technology - Gene Expression Modulation by Small Molecules - to develop anti-angiogenesis compounds. PTC has identified a number of promising small-molecule compounds that show anti-angiogenic activity. Bausch is interested in developing candidate molecules as therapies for diseases of ocular neovascularisation including macular degeneration. Bausch & Lomb also announced that it has signed a definitive agreement for an exclusive worldwide license from the Cephalon company to develop, market and sell ophthalmic products containing compounds that inhibit angiogenesis. Cephalon has several small-molecule angiogenesis inhibitors in development.

Intralase emergency survey

A new US survey commissioned by Intralase indicates many American adults would not feel capable without their glasses or contact lenses during emergency situations. More than one-half of 1,367 adults surveyed who wear corrective lenses say they would feel worried, fearful, and/or powerless, if they were to lose their corrective lenses during an emergency. In fact, only one-third of those surveyed said they would feel capable in an emergency if they didn't have or lost their corrective lenses. Almost one

third of those surveyed said they were considering LASIK to avoid having problems seeing in an emergency. The survey highlights concerns raised by recent floods, hurricanes and other natural disasters. Intralase also reported increased interest among police and fire fighters in having refractive surgery.

LASIK lawsuit on advertisements

The Florida-based Lasik Vision Institute settled a lawsuit brought by the State of Illinois alleging misleading advertisements. The lawsuit contended that between June 2003 and June 2004, the Lasik Vision Institute company offered LASIK surgeries in newspaper ads for "as low as \$299". Such ads are not uncommon in the US, where readers must sometimes read microfine print to notice that these offers only apply to patients -1.0 D of myopia and no astigmatism. In this case, patients were allegedly required to pay a \$100 non-refundable fee to see if they qualified for the low rate. The company apparently also claimed that ophthalmologists would conduct the exams, which was not the case. The company settled the lawsuit, agreeing to change its ads and to make a payment to a consumer education programme.

FDA closes eye drop company

The US FDA ordered eye drop maker MBI Distributing, also known as Molecular Biologics, to stop manufacturing and distributing drugs until it corrects manufacturing deficiencies and

other violations. The company makes over-the-counter eye drops sold under the brand names Oxydrops, Bright Eyes, Bright Eyes II, Clarity Vision for Life, Visitein, and Can-C. The FDA said that the company had not corrected violations noted during inspections and lacked the manufacturing controls to ensure that its eye drops were sterile.

Lumenis laser approved

Lumenis received US FDA clearance to market the new Novus 3000, a 532 nm diode-pumped solid-state photocoagulator. The system has up to 3.0 watts of power through semiconductor based technology. The company notes that instantaneous adjustments to treatment parameters can be made using the colour touch screen interface and LCD remote control. In addition, multiple memory locations allow ophthalmologists to save and recall preferred treatment parameters. This unit comes standard with built-in storage for a laser indirect ophthalmoscope, remote control, foot switch, and other accessories.

New diagnostic for viral conjunctivitis

Rapid Pathogen Screening received US FDA approval for the RPS Adeno Detector, a new, rapid point of care diagnostic test for viral conjunctivitis. The test can identify adenoviral conjunctivitis in ten minutes. In a multi-centre clinical trial, the test performed comparably with cell culture in detecting adenoviral conjunctivitis.