

Recent Developments in the Vision Care Industry

NIH Announces new ethics campaign.

Responding to massive public complaints, the US National Institutes of Health announced a dramatic transformation of its rules regarding its employees' interactions with the pharmaceutical industry. Henceforth, NIH researchers are banned from all outside consulting work for drug or biotechnology companies, hospitals, insurance companies and health providers. The ban also applies to universities or research institutes that receive NIH funding. Many NIH employees would also be banned from holding stock in pharmaceutical or biotechnology companies.

The changes came after reports in leading US newspapers detailed extensive interactions and questionable financial dealing between federally supported scientists and industry. The NIH, which includes the National Eye Institute, oversees an annual budget of \$28 billion. NIH funding supports basic and clinical research in all areas of medicine.

Medicare to cover Macugen

Eyetech Pharmaceuticals got a big boost upon receiving word that Medicare, the US public health insurer, would pay for Macugen (pegaptanib sodium injection), at \$1,054.70 per injection. The drug received FDA approval in December of 2004 for treatment of wet AMD. The drug, co-developed with Pfizer Inc., targets vascular endothelial growth factor (VEGF), a protein that acts as a signal in triggering the abnormal

blood vessel growth and leakage that is the hallmark of neovascular AMD.

Staar braces for more FDA attention

Staar Surgical Co., maker of the Implantable Contact Lens, announced that it expects that the US FDA may take further action against the company. In September 2004, Staar reported that the FDA had issued a report, detailing numerous ongoing quality control issues. Staar met again with the FDA on January 27, 2005 to update the agency on corrective actions taken by the company in response to an FDA inspection of its Monrovia, California, manufacturing facility.

Pfizer announces cutbacks

Facing patent expirations and a declining stock price, Pfizer announced plans to cut costs by \$2 billion, and to transform its marketing practices. While widespread layoffs are not anticipated the company is expected to rationalise domestic sales force, eliminating redundant marketing practices. The company is believed to be looking at cutting administrative and support functions worldwide. Information systems and research and development support functions are also possible targets for cuts. However, the company appears to be maintaining its strategy of acquisition. It has confirmed an agreement to buy Angiosyn Inc., a small California biotech company. Angiosyn is working on anti-angiogenesis treatments for diseases including macular degeneration.

Allergan streamlines European operations

Allergan announced plans to streamline its research and development and select commercial activities throughout Europe. It plans to fold some operations into its facilities in the United Kingdom, Ireland and United States. The company says the decision to streamline these operations is in keeping with its long-term strategic plan to focus its resources on developing new products with high-market potential and to continue its significant growth and increase its competitiveness as a global specialty pharmaceutical company.

Diquafosol fails to inspire

Inspire Pharmaceuticals announced disappointing results of a Phase 3 clinical study of diquafosol tetrasodium for treatment of dry eye. In that study, the drug failed to demonstrate statistically significant improvement as compared to placebo for the primary endpoint of the incidence of corneal clearing. The six-week randomised, double-masked, placebo controlled study enrolled 640 patients at 34 clinical sites across the U.S. Diquafosol tetrasodium is a P2Y2 receptor agonist that stimulates fluid and mucin secretion on the ocular surface. As in previous studies, the most common ocular adverse event was burning/stinging on instillation.

ThromboGenics announces clinical trial

Irish company ThromboGenics Ltd. announced the start of a Phase II trial evaluating recombinant

microplasmin in patients with vitreoretinal disorders. The Phase II trial began treating patients in December 2004. The trial will enrol up to 50 patients with vitreoretinal disease at three centres in the Netherlands and Germany. Microplasmin is a truncated form of the human protein plasmin. The hope is that giving the drug prior to vitrectomy could facilitate more rapid surgery with fewer complications.

Iridex sees stock drop

Laser maker Iridex saw a big drop in its stock price following a downgrade by a major financial consulting firm. The Maxim Group downgraded the stock based on doubts about future ophthalmic laser sales. A widely anticipated clinical trial of transpupillary thermotherapy treatment for wet age-related macular degeneration concluded that TTT technology was no more efficacious in treating wet AMD than existing or competing treatments. The company derives more than 80% of its revenue from ophthalmic lasers.

Intralase goes north

Intralase received a device license from Health Canada, that nation's regulatory body. The company plans to immediately begin marketing the FS femtosecond laser system in Canada. This will expand its global presence to 18 countries worldwide. As of Sept. 30, 2004, the company said 180 INTRALASE FS lasers had been sold worldwide. The company has already claimed a 15% annual market share of all corneal flap procedures in the United States.

New slit-lamps from Haag-Streit

Haag-Streit announced the rollout of three new slit lamps: the BD, the BP-900 and the BX 900. The BD slit lamp is optimised for eyecare professionals specialising in the anterior segment. A built-in video port accepts commercially available C-mount cameras, allowing high-resolution digital and video imaging. The BP 900 was designed for the routine practice and features a redesigned optical system with two optional beam splitters for video and digital photography. The BX 900 provides features for the professional ophthalmic photographer, including integrated synchronised flash, slit and background illumination and adaptors for 35 mm and digital cameras.