Omidria Approved for Commercialization in EU

The European Commission granted marketing authorization for Omidria (phenylephrine and ketorolac injection; Omeros) 1%/0.3% in the European Union for use in cataract surgery and lens replacement procedures to maintain mydriasis, prevent miosis, and reduce postoperative pain, according to a company news release.

This approval allows the marketing of Omidria in all EU member states plus Iceland, Liechtenstein, and Norway. EU approval is based on the same clinical data that were the basis for FDA approval this past year and follows the previously reported unanimous positive opinion by the European Medicines Agency’s Committee for Medicinal Products for Human Use. Decisions about price and reimbursement for Omidria will occur on a country-by-country basis, the news release said.

Gluakos Receives Approval for iStent Inject in Australia

Glaukos received regulatory approval from the Australian Therapeutic Goods Administration (TGA) for its iStent inject Trabecular Micro-Bypass Stent, according to a company news release. With TGA approval, the iStent inject is indicated for use in Australia in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate glaucoma currently treated with ocular hypotensive medication.

The iStent inject relies on a similar fluidic method of action as the company’s iStent Trabecular Micro-Bypass Stent, which was approved by the TGA in 2014. Packaged in a two-stent, preloaded, auto-inject mechanism, the iStent inject allows an ophthalmic surgeon to inject stents into multiple trabecular meshwork locations through a single corneal entry point for greater IOP reduction. Made from surgical-grade nonferromagnetic titanium that is coated with heparin, each iStent inject stent is approximately 0.3 mm in diameter and 0.4 mm long, or roughly one-third the size of the original iStent.

The iStent inject is already approved in the European Union, and an initial commercial launch is under way in Germany. Glaukos is also pursuing regulatory approval in other countries, including the United States, where the company is conducting clinical trials to evaluate two versions of the iStent inject, one in combination with cataract surgery and another as a standalone procedure in phakic and pseudophakic glaucoma patients, the news release said.
Allergan Sells Global Generics Business to Teva

Allergan has entered into a definitive agreement under which Teva Pharmaceutical Industries will acquire its global generic pharmaceuticals business for US$40.5 billion, according to a company news release. The deal reportedly will allow Allergan to focus on its branded pharmaceutical business.

Under terms of the deal, Allergan will receive US$33.75 billion in cash and US$6.75 billion in Teva stock. Additionally, Allergan retains 50% of Teva’s future economics from generic lenalidomide (Revlimid). The transaction has been unanimously approved by both companies’ boards of directors and is supported by their management teams.

Teva will acquire Allergan’s legacy Actavis global generics business, including the US and international generic commercial units, third-party supplier Medis, global generic manufacturing operations, the global generic research and development unit, the international over-the-counter commercial unit (excluding over-the-counter eye care products), and some established international brands.

Allergan will retain its dynamic global branded pharmaceutical and medical aesthetic businesses as well as its biosimilars development programs and the Anda distribution business, the news release said.

Shire Acquires Foresight Biotherapeutics

Shire acquired Foresight Biotherapeutics for US$300 million, giving the company the global rights to FST-100 (topical ophthalmic drops combining 0.6% povidone iodine [PVP-I] and 0.1% dexamethasone), a therapy in late-stage development for treatment of infectious conjunctivitis, a news release said.

Currently, no therapy exists to resolve clinical signs and eradicate adenovirus, which is the most common cause of viral conjunctivitis, the news release said. Approximately 50% of infectious conjunctivitis cases have a viral etiology, and 65% to 90% of these are caused by adenovirus.

There are approximately 5.4 million cases of infectious conjunctivitis annually in the European Union and 5.9 million cases annually in the United States, the news release said.

Shire will evaluate an appropriate regulatory filing strategy for additional markets for FST-100 outside the United States. Under the terms of the agreement, Shire will make a cash payment of US$300 million to complete the acquisition of Foresight Biotherapeutics.

Ophthalmic Practice Sees 41% Return on Investment With EHR

Adoption of an electronic health record (EHR) system produced financial and operational benefits for a large ophthalmic practice over a 5-year period, including a 41% return on investment, according to a study in *Ophthalmology*.1

The study was conducted to report a detailed postimplementation financial analysis of EHR implementation at one practice, Asheville Eye Associates. Asheville Eye Associates, a private multispecialty ophthalmic practice, had 10.8 full-time equivalent providers practicing in three locations at the start of the study. Data that affected the incremental cash flows relevant to the implementation of EHR was collected for 2006, the last year the practice used paper records, and between 2007 and 2011, the first 5 years after EHR implementation.

Switching to an EHR system netted the practice roughly US$1.2 million over the 5-year period. Initially, the practice’s costs increased due to hiring of IT staff, maintaining the software, and scanning paper records. Eventually, process changes driven by the EHR led to efficiencies that lowered staffing needs related to medical records, transcription, billing, checkout, and appointment scheduling. The system also acted as a revenue driver by enabling EHR Meaningful Use incentive payments, increasing productivity in the later stages and making claims submission faster and more accurate, according to a news release from the American Academy of Ophthalmology (AAO).

"This report demonstrates that an EHR can produce financial and operational benefits in a large, single-specialty, multi-office ophthalmic practice over a 5-year period," the study authors concluded. “[Therefore], we emphasize that the introduction of EHR was not by itself responsible for the positive financial returns but rather because it was seen as an opportunity to examine workflow efficiency continuously over the 5-year period. A key factor in the outcome included physician and staff engagement, training, and workflow changes, which resulted in significant net staff reductions.”


Adaptica to Launch VisionFit Wearable Adaptive Refractor

Adaptica will launch its VisionFit Wearable Adaptive Refractor at the 2015 Annual Meeting of the European Society of Cataract and Refractive Surgeons (ESCRS), according to a company news release.

The VisionFit is an electronic, tunable, solid-state, mobile, and wearable system of adaptive lenses that performs a subjective sight examination and replaces the need for trial glasses and the manual/electronic phoropter, the news release said. By using the VisionFit in combination with Adaptica’s 2WIN binocular handheld refractometer and vision analyzer, the operator is reportedly able to perform an objective and subjective refractive exam in only a few minutes.
The VisionFit includes a computer-integrated control unit featuring a display screen, keyboard controller, commands and connectivity capabilities, and a wearable electronic trial frame with two tunable lens sets, each composed of three adaptive lenses—spherical, cylindrical, and aberration—with add-on lens support. All three lenses are controlled electronically.

**LACS May Alter Aqueous Humor pH Values**

Laser-assisted cataract surgery (LACS) may cause an acidic shift in aqueous humor pH values due to cavitation bubbles produced during the procedure, according to a study published in the *Journal of Refractive Surgery.*

Marco Rossi, MD, of Vista Monza Eye Clinic in Italy, and colleagues conducted a prospective study in 29 eyes of 29 patients who underwent cataract surgery by a single surgeon. The femtosecond laser group included 15 eyes operated on with the Catalys laser (Abbott Medical Optics), and the phacoemulsification group included 14 eyes that were operated on with conventional phacoemulsification. The femtosecond laser group was subdivided into low, medium, and high level of cavitation gas bubbles after docking and the laser procedure, according to the surgeon’s judgment. Aqueous humor samples (0.10 to 0.15 mL) were collected through a paracentesis from each patient after docking, corneal incisions, and nucleus fragmentation in the femtosecond laser group and after corneal incisions but before injection of OVD in the phacoemulsification group; the samples were then analyzed with a pH meter.

The mean pH was 6.53 ±0.09 (range, 6.42–6.70) and 7.42 ±0.07 (range, 7.28–7.48) in the femtosecond laser and phacoemulsification groups, respectively (*P*<.001). In the femtosecond laser group, no significant differences in pH were observed among the three subgroups after docking and the femtosecond laser surgical procedure: low (6.55 ±0.09 [range, 6.53–6.57]), medium (6.54 ±0.07 [range, 6.52–6.55]), and high (6.42 ±0.00 [range, 6.40–6.44]) level of gas bubbles.

“Cavitation bubbles derived from the photodisruption process in [LACS] lead to an acidic shift of the aqueous humor pH as a result of the transformation of carbon dioxide to carbonic acid,” the study authors concluded. “The level of gas bubbles visible after the laser photodisruption does not seem to correlate with this pH shift. Further analysis of [LACS] is necessary.”


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**Birth Control Pills May Cut Odds for Endometrial Cancer**

Researchers estimate that, over the past 50 years, birth control pills have prevented about 400,000 cases of endometrial cancer among women before age 75 in wealthy nations, including about 200,000 between 2005 and 2014 alone.


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**Ebola Vaccine a Potential Game Changer**

A vaccine against the Ebola virus has led to 100% protection and could transform the way Ebola is tackled, preliminary results suggest.


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**Spicy Foods Offer Beneficial Health Effects**

New research involving nearly half a million volunteers in China found that the more often people ate spicy foods, the lower their risk of dying during the course of the study.


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**Studies Fall Short on Identifying Best Cleaning Methods for Preventing Hospital Infections**

A systematic overview of studies investigating cleaning methods in hospitals has revealed a worrying lack of evidence on the best ways to protect patient health.

www.medicalnewstoday.com/articles/298056.php

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**Group Therapies for PTSD Show Promise for Veterans**

Veterans treated for post-traumatic stress disorder (PTSD) with mindfulness-based stress reduction experienced slightly more improvement in symptoms compared with active controls, according to a small study.

www.medpagetoday.com/Psychiatry/AnxietyStress/52943

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