Eyes on New Product Development

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IN THIS REPORTING PERIOD, there was news of 2 generic/biosimilar products, announcements of numerous corporate relationships ranging from dry eye to gene therapy, and advanced development of 2 drug delivery systems for anterior segment indications. In retina, there was news for treatment of edema and degenerative conditions by various types of treatments, including drug delivery and gene therapy, as well as a novel device for patients with advanced vision loss. In the regulatory area, the U.S. House of Representatives passed a bill with incentives for drug development, and the U.S. FDA increased its enforcement on manufacturing issues. Finally, I recently discovered that Kowa received approval for Glanatec® (ripasudil, previously known as K-115) in Japan. As far as I know, this is the first approval worldwide for a topical Rho-kinase inhibitor for the lowering of intraocular pressure.

Ophthalmic Pharmaceuticals and Biologics

- Akorn is developing a generic cyclosporine emulsion in the United States (July 2015). www.prnewswire.com/news-releases/allergan-notes-receipt-of-paragraph-iv-notification-on-restasis-300113958.html
- Allergan is acquiring Kythera Biopharmaceuticals (June 2015). www.allergan.com/news/news/thomson-reuters/allergan-to-acquire-kythera-biopharmaceuticals
- Allergan is acquiring Oculeve (July 2015). www.allergan.com/news/news/thomson-reuters/allergan-to-acquire-oculeve-dry-eye-disease-develop
- Ampio announced results from a controlled study of Optina™ (low-dose danazol) in patients with diabetic macular edema (June 2015). <http://ampiopharma.com/news/ampio-pharmaceuticals-announces-additional-statistically-significant-study-results-for-optina-in-the-treatment-of-diabetic-macular-edema-dme/>
- Avalanche Biotechnologies (AAVL) presented results of its Phase 2a clinical study testing AVA101 for wet age-related macular degeneration (June 2015). <http://investors.avalanchebiotech.com/phoenix.zhtml?c=253634&p=irol-newsArticle&ID=2059444>
- Biogen and Applied Genetic Technologies Corp (AGTC) announced a broad collaboration and license agreement to develop gene-based therapies for multiple ophthalmic diseases (July 2015). www.agtc.com/
- Claritas Genomics and Genetic Alliance announced a partnership to help patients and families find and participate in relevant research opportunities that will advance understanding of individual genetic disorders and development of new therapies, in particular, pediatric rare diseases (June 2015). <http://claritasgenomics.com/genetic-alliance-partnership/>
- Clearside Biomedical conducted an end-of-phase 2 meeting with the FDA on their lead product, triamcinolone acetate administered through injection into the suprachoroidal space (SCS) for the treatment of macular edema associated with noninfectious uveitis (June 2015). <http://finance.yahoo.com/news/clearsidebiomedicalinc-announcesfavorable113000543>
- Eyegate Pharmaceuticals announced the dosing of the first patient in its Phase 1b/2a trial testing their lead product candidate EGP-437 for macular edema. The company also announced a licensing arrangement with Valeant for this product in anterior uveitis (July 2015). www.eyegatepharma.com/press-release/eyegate-signs-licensing-agreement-with-valeant-pharmaceuticals-for-egp-437-combination-product-in-uveitis/
- Gensight Biologics recently completed a Phase 2b study of GS010, which delivers a corrective copy of the ND4 gene, in patients with certain forms of Leber's hereditary optic neuropathy (July 2015). www.fiercebiotech.com/node/452696/print
- InSite Vision submitted a New Drug Application (NDA) for BromSite™ (bromfenac) for the treatment of inflammation and prevention of pain in cataract surgery (June 2015). <http://phx.corporate-ir.net/phoenix.zhtml?c=86061&p=irol-newsArticle&ID=2058520>
- Intas Pharmaceuticals launched a biosimilar of ranibizumab in India (June 2015). www.business-standard.com/article/companies/intas-becomes-first-global-company-to-launch-a-biosimilar-version-of-lucentis-115061900567_1.html
- Kowa received approval for Glanatec® (ripasudil, previously known as K-115) in Japan. This is reported to be the first approval worldwide for a topical rho-kinase inhibitor for glaucoma (December 2014). www.kowa-souyaku.co.jp/upload/item/67/94/7-pse_168.pdf
- NightstaRx Ltd announced that the University of Alberta has begun enrolling and dosing subjects in a Phase 2 clinical trial of the company's gene therapy for the treatment of choroideremia (June 2015). www.medicalnewstoday.com/releases/296030.php?tw

- Ocular Therapeutix began enrollment of the first patients in a Phase 3 clinical trial to evaluate the safety and efficacy of DEXTENZA™ (sustained release dexamethasone, 0.4 mg) for the treatment of allergic conjunctivitis (June 2015). <http://investors.ocutx.com/phoenix.zhtml?c=253650&p=irol-newsArticle&ID=2059620>
- QLT, Inc. entered into a definitive agreement to acquire InSite Vision (June 2015). www.businesswire.com/news/home/20150608006051/en/InSite-Vision-Merge-Canadian-Biotechnology-Company-QLT#.Va_nVPIVhBc
- Tracon Pharmaceuticals announced that its partner, Santen Pharmaceutical, filed an Investigational New Drug (IND) Application with the FDA for DE-122 (an anti-endoglin antibody, TRC105) in patients with wet age-related macular degeneration (July 2015). www.traconpharma.com/clinical_trials.php

Medical Devices

- Wicab, Inc. received an approval through the *de novo* pathway for BrainPort V100, a battery-powered device that includes a video camera mounted on a pair of glasses and a small, flat, intraoral device containing a series of electrodes that allows visual images to be processed through the tongue (June 2015). www.fda.gov/newsevents/newsroom/pressannouncements/ucm451779.htm

Regulatory, Government, and Pharmaceutical Industry

- The German Institute for Quality and Efficiency in Healthcare (IQWiG) reviewed aflibercept for patients with impaired vision due to macular edema following blockage of branch veins of the central retinal vein (branch retinal vein occlusion, BRVO). They opined that an added benefit cannot be derived from this molecule (June 2015). www.medicalnewstoday.com/releases/295811.php?tw
- Tekmira Pharmaceuticals announced that the Phase II clinical trial of TKM-Ebola-Guinea reached a pre-defined statistical endpoint and enrollment closed. The endpoint indicated that continuing enrollment was not likely to demonstrate an overall therapeutic benefit (June 2015). www.fiercebitech.com/node/451146/print

- The U.S. FDA, based on reviews of additional safety reports from patients treated with the anti-seizure drug Potiga (ezogabine), determined that the potential risks of vision loss due to pigment changes in the retina and of skin discoloration can be adequately managed by following the current recommendations in the package insert (June 2015). www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm451181.htm
- The U.S. FDA, responding to a lawsuit filed by Amarin Corp over information the company wants to disseminate for its fish oil drug, said it had no objection to Amarin sharing the data with healthcare providers (June 2015). www.reuters.com/article/2015/06/09/us-amarin-fda-idUSKBN0OP2GP20150609
- The U.S. FDA released an import alert tagging more than 40 drug companies to ban their imports from India (July 2015). www.techtimes.com/articles/69709/20150717/fdabansdrugsfromdrugplantsinindia
- The U.S. House of Representatives passed H.R. 6, the 21st Century Cures Act (July 2015). www.ascrs.org/node/22795
- The U.S. National Institutes of Health (NIH) Clinical Center suspended operations of its Pharmaceutical Development Section (PDS) due to the discovery of serious manufacturing problems and lack of compliance with standard operating procedures (June 2015). The U.S. White House hosted a forum on antibiotic stewardship (June 2015). www.nih.gov/news/health/jun2015/nih-04.htm

Author Disclosure Statement

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