Eyes on New Product Development

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IN THIS REPORTING PERIOD, in cornea and external disease, China approved a cross-linking system for keratoconus, and a Phase 3 study with a novel drug delivery product was started in allergic conjunctivitis. In pharmacological treatment of dry eye, there has been a regulatory submission of a multidose nonpreserved system. To date, there is no approved ophthalmic pharmaceutical so packaged in the United States. Several firms continue to develop novel pharmacotherapies and other technologies. In glaucoma, an application to the US Food and Drug Administration (FDA) has been submitted for a Minimally Invasive Glaucoma Surgery device, another company moved forward a topical therapeutic, starting a Phase 3 study with a new chemical entity, and several firms provided Phase 2 data with external and internal drug delivery technologies. In retina, work continues on many fronts, including results on expanded indications for existing products, and novel genetic or RNA interference (RNAi) technology for relatively rare retinal diseases. Additional new chemical entities (including one with topical delivery) and intraocular drug delivery technologies are also being evaluated in retinal therapeutics. Mergers and acquisitions continue in ophthalmology. Also, the pharmaceutical industry is responding to 1 firm taking advantage of a monopoly with a generic drug.

Ophthalmic Pharmaceuticals and Biologics

- [Alimera](#) presented data on 3-year treatment with Iluvien® (fluocinolone acetonide intravitreal implant) on progression of diabetic retinopathy (November 2015).
- [Allergan](#) entered into a licensing agreement with Mimetogen Pharmaceuticals to develop and commercialize tavilermide (MIM-D3) to treat dry eye. They also presented data on a Phase 1/2 study of erodible bimatoprost anterior chamber implant in patients with glaucoma. Finally, the firm submitted a Prior Approval Supplement for Restasis® (cyclosporine ophthalmic emulsion) 0.05%, seeking approval of a Multi-Dose Preservative-Free (MDPF) presentation (November 2015).
- [Applied Genetic Technologies Corp.](#) filed an investigational new drug application with the FDA to conduct a Phase 1/2 clinical trial of its adeno-associated virus-based gene therapy product candidate for treating achromatopsia due to mutations in the CNGB3 gene. The firm also received US FDA orphan designation for this treatment and indication (November 2015).
- [Astellas Pharma, Inc.](#) announced it will acquire Ocata Therapeutics, Inc. Ocata is focused on the research and development of new therapies in the field of regenerative medicine, primarily cell therapy addressing unmet medical needs in ophthalmology patients (November 2015).
- [Eyegate Pharmaceuticals](#) announced interim data of an open-label study of iontophoretic delivery of their EGP-437 ophthalmic solution (dexamethasone) on patients with macular edema (November 2015).
- [ForSight VISION5](#) announced results of a randomized controlled Phase 2 study of its bimatoprost insert delivery system for the treatment of glaucoma (November 2015).
- [Genentech](#) began a Phase 2 clinical trial [Long Acting Delivery of Ranibizumab (LADDER)] of the ranibizumab port delivery system implant in patients with wet age-related macular degeneration (AMD) (November 2015).
- [Inotek Pharmaceuticals](#) initiated dosing in MATRx-1, a Phase 3 clinical trial of trabodenoson (an adenosine modulator) for the treatment for glaucoma (October 2016).
- [Ionis Pharmaceuticals, Inc.](#) earned a milestone payment from GSK related to the initiation of a Phase 1 study of ISIS-GSK4-LRx (formerly ISIS-GSK4Rx) in healthy volunteers (October 2015).
- [Ocular Therapeutix, Inc.](#) announced enrollment of the first patients in a second Phase 3 clinical trial to evaluate the safety and efficacy of Dextenza® (sustained release dexamethasone), 0.4 mg intracanalicular depot for the treatment of allergic conjunctivitis (November 2015).
- [Ohr Pharmaceutical](#) announced submission of a Special Protocol Assessment to the FDA on OHR-102 (squalamine) for the treatment of wet AMD. The firm also presented results from its OHR-102 Phase 2 IMPACT Study in Wet-AMD (November 2015) and also announced preclinical results of a proprietary SKS sustained release technology for ocular drug delivery (December 2015).
- [Ophthotech](#) announced completion of patient recruitment for its second Phase 3 trial of Fovista® (pegpleranib) in combination with Lucentis® (ranibizumab) for the treatment of wet AMD (October 2015).

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- [PanOptica](#) presented preliminary Phase 1/2 data for PAN-90806, a topical anti-VEGF treatment delivered topically, for the treatment of wet AMD (November 2015).
- [QLT](#) is continuing to develop QLT091001, a retinoid, for the treatment of inherited retinal disease caused by retinal pigment epithelium protein 65 ("RPE65") (autosomal recessive) and lecithin:retinol acyltransferase ("LRAT") mutations ("IRD"). The firm initiated a retrospective, uncontrolled, multicenter, case history study to determine the natural history of visual function in these disorders (October 2015).
- [Quark Pharmaceuticals, Inc.](#) initiated the US arm of a global Phase 2/3 pivotal study of QPI-1007, an RNAi therapy against caspase 2, for treatment of acute nonarteritic anterior ischemic optic neuropathy (November 2015).
- [RXi Pharmaceuticals](#) initiated RXI-109-1501, a Phase 1/2 clinical trial evaluating the safety and clinical activity of RXI-109, a self-delivering RNAi treatment, to prevent the progression of retinal scarring (November 2015).
- [Santen's](#) has been asked by the UK National Institute for Health and Care Excellence to provide more information on its Ikervis® (ciclosporin ophthalmic) (November 2015).
- [Shire's](#) announced results of its OPUS-3 Phase 3 Trial of lifitegrast for treatment of dry eye (October 2015).
- [Spark Therapeutics](#) announced additional secondary endpoint data from the Phase 3 pivotal trial of SPK-RPE65 for the treatment of RPE65-mediated inherited retinal dystrophies (November 2015).

Ophthalmic Devices

- [Avedro](#) received approval from the China FDA for its KXL cross-linking system for the treatment of keratoconus and post-LASIK ectasia (November 2015).

- [Transcend Medical and Glaukos Corporation](#) reached a settlement on patent litigation regarding their minimally invasive glaucoma surgery technologies (October 2015).
- [Transcend Medical, Inc.](#) announced the submission to the FDA of the final module of the company's Premarket App application for the CyPass® Micro-Stent (October 2015).

Regulatory, Government, and Pharmaceutical Industry

- [Express Scripts](#) plans to partner with Imprimis in providing a low-cost, alternative to Daraprim® (pyrimethamine) for the treatment of toxoplasmosis (December 2015). Daraprim was recently offered by Turing Pharmaceuticals at US \$750 per dose. Imprimis, a drug-compounding firm, said in October that it will supply capsules with pyrimethamine and leucovorin, at a reduced cost as well.
- [Pfizer](#) acquired [Allergan](#). The new firm will be based in Ireland (November 2015).

URLs for these products can be viewed online at www.liebertpub.com/jop.

Author Disclosure Statement

The author consults for numerous ophthalmic, pharmaceutical, and medical device firms.

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