Eyes on New Product Development

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IN THIS REPORTING PERIOD, there were approvals in Europe and Asia for two retina products and one glaucoma product. A phase 3 study of a novel dry-eye agent completed enrollment, and, at the other end of the development spectrum, a firm announced preclinical data for an agent used to treat a retinal disease. In response to the Ebola virus epidemic, the U.S. National Institutes of Health (NIH) has evaluated the safety of a novel therapy in normal volunteers. There were numerous corporation relationships and acquisitions announced. Finally, in the regulatory area, the U.S. government is involved in expanding clinical trial registration requirements, expanding exclusivity for novel fixed-dose combinations, and is concerned about the pricing of generic drugs.

Ophthalmic Pharmaceuticals

- Alimera received approval for Iluvien[®] (triamcinolone acetonide intravitreal implant) for the treatment of chronic diabetic macular edema (DME) in Ireland and Belgium (November 2014).
- Amaranthus BioScience Holdings, Inc. has investigated mesencephalic astrocyte-derived neurotrophic factor in an animal model of retinitis pigmentosa (November 2014).
- Eleven Biotherapeutics completed patient enrollment in a phase 3 clinical study of EBI-005, a topical, novel interleukin-1 receptor blocker in patients with dry eye (November 2014).
- Regeneron announced that Eylea[®] (aflibercept injection) has received approval in Japan for the treatment of DME. This is through Bayer Yakuhin, Ltd. (November 2014).
- Santen received a positive outcome from the Reference Member State, the Federal Institute for Drugs and Medical Devices of Germany, and the agreement of all the Concerned Members states for Taptiqom[™] (a preservative-free fixed-dose combination of tafluprost and timolol) in Europe (October 2014).

Regulatory, Government, and Pharmaceutical Industry

- Actavis is planning to acquire Allergan. This proposal has been accepted by the boards of both firms (November 2014).
- Apellis Pharmaceuticals is planning to acquire Potentia Pharmaceuticals. As part of the acquisition agreement, Apellis obtained the necessary intellectual property rights to develop its complement inhibitor drug com-

pound (APL-2) in ophthalmology and plans its first clinical trial in dry age-related macular degeneration (November 2014).

- Isis Pharmaceuticals received a milestone payment from GlaxoSmithKline related to the designation of ISIS-GSKsRx as a development candidate for an undisclosed ocular disease.
- The U.S. Department of Health and Human Services and NIH announced their intent to expand the regulation for clinical trial registration. This refers to Title VIII of the Food and Drug Administration Amendments Act of 2007. The proposed rule specifies how data collected and analyzed in a clinical trial would be required to be submitted to ClinicalTrials.gov (November 2014).
- The U.S. Congress is considering legislation regarding pricing of generic drugs. Note that the FDA is prohibited from pricing matters. Market and regulatory factors have resulted in some generic drugs having only one manufacturer and thus a monopoly (November 2014).
- The FDA finalized a new policy that potentially extends the period of exclusivity for fixed-dose combinations (October 2014).
- The NIH has conducted a study in normal volunteers of an investigational vaccine to prevent Ebola virus disease. The study is the first of several phase 1 clinical trials that will examine the investigational NIAID/GSK Ebola vaccine and an experimental Ebola vaccine developed by the Public Health Agency of Canada and licensed to NewLink Genetics Corp. (November 2014).
- Valeant has acquired the U.S. ophthalmic diagnostics business of Nicox (November 2014).

Author Disclosure Statement

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Received: November 29, 2014

Accepted: December 4, 2014

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