Eyes on New Product Development

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IN THIS PERIOD, regulatory approvals were received for a new biologic treating neuromyelitis optica (NMO) spectrum disorder, as well as a novel formulation of an α -adrenergic agonist. The U.S. Food and Drug Administration (FDA) showed its willingness to consider a novel biomarker in the treatment of ocular surface disease. Public policy discussions continue on therapeutics containing cannabis and related compounds, and the antiscience sentiment in the United States.

Ophthalmic Pharmaceuticals and Biologics

- Alcon received U.S. FDA approval for a switch of their olopatadine hydrochloride ophthalmic solution 0.7% from prescription to over-the-counter (July 2020).
- Aldeyra announced an agreement with the FDA for the use of reactive aldehyde species as an objective sign for the treatment of dry eye disease, and is pursuing phase 3 studies using this endpoint (June and July 2020).
- Allergan/Molecular Partners' abicipar pegol for the treatment of wet age-related macular degeneration was not approved by the FDA (June 2020).
- Novartis' Xiidra® (lifitegrast) was not approved for the treatment of dry eye by the European Medicines Agency (June 2020).
- Osmotica Pharmaceuticals received FDA approval for its Upneeq™ (oxymetazoline hydrochloride ophthalmic solution, 0.1%, RVL-1201) for the treatment of acquired blepharoptosis, or ptosis (July 2020).
- Roche received approval from Japan's Ministry of Health, Labour and Welfare for its Enspryng® (satralizumab) to treat adults and children with NMO spectrum disorder (June 2020).

Medical Devices

- Kubota Vision started enrollment in a clinical study to examine a wearable myopia control device (June 2020).

Regulatory, Government, and Pharmaceutical Industry

- H. Holden Thorpe PhD, editor of *Science*, proposed that education alone will not counter the problem of science denial in the population. Rather, he proposes that "...The only way to win this fight is to harness the same sophisticated tools in the name of science that are being used to tear science down"—meaning to use social media to promote science."¹
- The National Institutes of Health (NIH) selected Michael F. Chiang, MD, as the 3rd director of NIH's National Eye Institute (NEI, July 2020).
- The U.S. FDA issued a draft guidance outlining the agency's current thinking on the development of drugs containing cannabis or cannabis-derived compounds (July 2020).
- The University of California announced a transformative open access publishing agreement with Springer Nature (June 2020).

Author Disclosure Statement

The author consults for numerous ophthalmic, pharmaceutical, and medical device firms. A complete listing of all of Dr. Novack's consulting affiliations can be found online.

Reference

1. Thorp, H.H. Persuasive words are not enough. *Science*. 368: 1405, 2020.

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