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Unmet needs and challenges with sustained drug delivery to the eye

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Data confirm that many patients are unable to self-administer chronic eye drops effectively, including the arthritic aging population and uncooperative pediatric glaucoma patients. Patient videos and questionnaires have demonstrated the inability for patients to effectively self dose and administer the drops accurately and as prescribed. Recent data revealed that only 71% of 204 glaucoma patients were able to get a drop into the eye, and only 39% did so without touching the bottle to the surface of the eye. Such studies confirm eye drop wastage, potential contamination of the eye drop bottles, and poor understanding of the situation among participants. Furthermore, the current standard of care for Age Related Macular Degeneration has removed the patient from the equation, yet it is still time and resource intensive requiring roughly monthly in office intraocular injections over years.

Thus an alternative delivery mode, with decreased frequency of administration and sustain release potential could 1) greatly improve local ocular and systemic safety and tolerability profiles by decreasing the amount of drug delivered locally, as well as 2) more effectively and efficiently manage ocular disease and resources by effectively targeting the disease and reducing patient visits. There are currently several novel and innovative sustained release (SR) delivery methods in various stages of development for both front of the eye (anterior segment and ocular surface) and back of the eye (intraocular retinal) pathologies. To develop a viable, reproducible, SR technology one must consider 1) formulation work; standardizing the release kinetics, and duration of action, 2) clinical study design and patient population (determining the timing of replacement or refill, and identifying the acceptable safety risk profile compared to the comparator), 3) encouraging physician and patient acceptance of perhaps a more invasive procedure, and 4) navigation of reimbursement issues to establish the rationale of a perhaps more costly product over the current comparator.

This presentation will review some broad drug delivery platforms, the current landscape for treating ocular pathology with these SR delivery modes, will discuss what data are needed in development to allow such a novel technology to be a clinically viable marketed product, as well as the novel biodegradable polymer film being developed by my company Jade Therapeutics for anterior segment/ corneal pathology.

Biography

Barbara M Wirostko is co founder and Chief Scientific Officer of Jade Therapeutics Inc, an Ophthalmic drug delivery company located in Utah. Prior to founding Jade, She served as CMO of Altheos, a biotech company developing an NCE for glaucoma. A board certified ophthalmologist, she maintains an academic research and clinical practice with the University of Utah, Moran Eye Center, as a Clinical Adjunct Associate Professor in Ophthalmology. From 2006-2010 she was Senior Medical Director within the Clinical Development Specialty division at Pfizer. She completed her glaucoma fellowship at Cornell University, and received her Ophthalmology training as well as her medical degree at Columbia University, College of Physicians and Surgeons, NY. She serves on the editorial board of Acta Ophthalmologica, various non-profit scientific advisory boards, and consults for companies focused on drug delivery including SKS Ocular. She is an active member and fellow of the AAO, ARVO, Women in Ophthalmology, and various local state societies.

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