

A multi-center, pediatric comparison of polymyxin B sulfate/trimethoprim ophthalmic solution and moxifloxacin in the treatment of bacterial conjunctivitis

§Mark Dorfman, MD; *David B Granet, MD; ‡David Stroman, PhD; ‡Paul Cockrum, PharmD

§Joe DiMaggio Children's Hospital, Hollywood, FL; *Ratner Children's Eye Center, University of California—San Diego, La Jolla, CA; ‡Alcon Research, Ltd, Fort Worth, TX

Objective: To compare the clinical efficacy of two currently available topical antibiotics; polymyxin B sulfate 10,000 IU/trimethoprim 1.0% (polymyxin/trimethoprim) and 0.5% moxifloxacin ophthalmic solution. **Design:** This was a prospective, randomized, double-masked, parallel, two-arm, multi-center study. **Methods:** Eighty-four eyes of 56 patients 18 years of age or younger with clinical diagnosis of bacterial conjunctivitis (BC) were enrolled. The average age was 4.47 ± 4.17 years (range, 2 months to 16.2 years). There were 32/41 and 36/43 culture positive eyes in the polymyxin/trimethoprim and the moxifloxacin group, respectively. Patients were randomly assigned 1:1 to receive either polymyxin/trimethoprim or 0.5% moxifloxacin ophthalmic solution. The polymyxin/trimethoprim group administered 1 drop in the affected eye(s) 4 times daily for 7 days versus 1 drop 3 times daily for 7 days in the moxifloxacin group. Ocular signs and symptoms were evaluated at the baseline visit and at 24 and 48 hours after the start of dosing. Microbiological cultures were collected at the baseline and 48 hours visits. Patients rated ocular symptoms and adverse events (AE) on Day 7 via phone interview. Primary efficacy assessment included relief of all signs and symptoms of BC. **Results:** All patients but one completed all visits. At the 48-hour visit, complete resolution of

ocular signs and symptoms was observed in 81% and 44% of the moxifloxacin- and polymyxin/trimethoprim-treated culture positive eyes, respectively ($p = 0.001$). Improvement of symptoms occurred in an additional 17% and 34%, respectively, and treatment failure occurred in 3% and 22%, respectively ($p = 0.001$). No AEs were reported. **Conclusion:** This is the first head-to-head study to compare clinically polymyxin/trimethoprim with moxifloxacin 0.5% for the treatment of BC. Moxifloxacin 0.5% dosed 3 times daily is safe and cures bacterial conjunctivitis faster and more effectively than polymyxin B sulfate/ trimethoprim dosed 4 times daily. **Disclosure code:** The study was sponsored by Alcon Research, Ltd. Fort Worth, TX