FDA Approves Fluoroquinolone For Conjunctivitis

The Food and Drug Administration has approved an ophthalmic formulation of a fluoroquinolone antibiotic, besifloxacin, for the treatment of bacterial conjunctivitis. Besifloxacin ophthalmic suspension will be marketed as Besivance 0.6%, by Bausch & Lomb Inc. The recommended dosage is one drop in the affected eye or eyes three times a day, 4-12 hours apart for 7 days. The prescribing information summarizes a randomized study of almost 400 patients (aged 1-98 years) with bacterial conjunctivitis who were treated with besifloxacin or received placebo drops for 5 days. Clinical symptoms resolved in 45% of those on besifloxacin, compared with 33% of those on the vehicle. The eradication rate for causative pathogens in the besifloxacin group was statistically significant at 91%, compared with 60% in the vehicle group.

The most commonly reported ocular adverse event reported in treated patients has been conjunctival redness in about 2% of patients. To collect more safety data on besifloxacin, the FDA is requiring that the company conduct a postmarketing study comparing the recommended dosage of besifloxacin to vehicle in at least 300 patients with signs and symptoms of bacterial conjunctivitis.

Elizabeth Mechcatie

Call for School Mandate to Aid HPV Vaccination

BY DENISE NAPOLI

BALTIMORE — The notion that the future burden of human papillomavirus will be greatly decreased thanks to the HPV vaccine may be unrealistic without a national school mandate, according to a new model.

That’s because voluntary vaccination among the target population of 11- to 17-year-old girls so far has been modest, with just 7% of this cohort receiving all three doses in the first year of the vaccine’s availability, according to Dr. Amanda Dempsey of the University of Michigan, Ann Arbor.

“Under no-mandate conditions, our model suggests that vaccine utilization may be suboptimal and that coverage of even 70% could take decades to achieve,” Dr. Dempsey and David Mendez, Ph.D., also of the university, wrote in a poster presented at the annual meeting of the Pediatric Academic Societies.

The researchers created a model of HPV vaccine uptake among 11- to 17-year-old girls based on census data, published literature on parental attitudes toward HPV vaccination, adolescent health care utilization patterns, and expert physician opinion. The model assumed that a school mandate would be applied on a national level, and would be such that vaccination would be required for school attendance, with exceptions similar to those of other vaccine mandates.

They adjusted their model to accurately predict the numbers reported by the Centers for Disease Control and Prevention during the first year of the vaccine’s availability: 25% of U.S. 11- to 17-year-old girls received the first dose, 17% received the first and second dose, and 7% received all three recommended doses of the vaccine.

Without a mandate in place, the authors predicted that 70% utilization of the vaccine would be reached by year 23 of its availability, or 2030. Under that model, by year 50 (in 2057) just 78% of the cohort will have received all three doses, they predicted. With a mandate, 70% of the 11- to 17-year-old cohort would be vaccinated with all three doses by year 8 (in 2015). At year 41 (by 2048), 90% would be vaccinated.

In an interview, Dr. Dempsey added that she and Dr. Mendez did not account for vaccination of other groups, including those aged 18-26 years. Dr. Dempsey said that at the time the study was done and at the time of its presentation, she had no ties to the pharmaceutical industry. However, shortly after the conclusion of the PAS meeting, she said she agreed to serve on a Merck & Co. advisory board for male HPV vaccination.