Affecting more than 40 million people in its severe form, dry eye disease represents a large, commercially attractive market that is currently underserved across the major markets in our study, of which only Japan can claim more than one approved prescription drug for the disease. Since the FDA approval of the immunosuppressant cyclosporine ophthalmic emulsion (Actavis’s [formerly Allergan’s] Restasis) over a decade ago, no other prescription medicine has been specifically approved for dry eye in the United States, and one prescription drug has been recently approved for dry eye in Europe. Significant opportunity exists for additional therapies that target inflammation as well as other disease pathways characteristic of dry eye.

Questions Answered in This Report:

- Improving signs and alleviating symptoms are key goals in the treatment of dry eye. What are the key primary and secondary clinical trial end points on which new therapies are evaluated? How do U.S. and European ophthalmologists weight specific efficacy end points and other drug attributes in their prescribing decisions for dry eye?

- Cyclosporine ophthalmic emulsion 0.05% is the 2013 major-market sales leader for dry eye. What weaknesses exist in the profile of this drug that would allow emerging therapies to gain a foothold in the market? Have emerging therapies demonstrated strengths on the attributes that surveyed ophthalmologists indicate are the most important in their prescribing decisions? Which emerging therapies will offer clinical improvements over the currently available therapy that surveyed managed care organization pharmacy directors (MCO PDs) seek from new therapies?

- Effect on corneal fluorescein staining (CFS) and effect on symptoms are key drivers of physicians’ prescribing decisions and are only the focus of drug development for new dry eye therapies. What trade-offs across these and other clinical attributes are U.S. ophthalmologists willing to make when considering the use of emerging therapies for the treatment of dry eye? Based on the trade-offs in price and performance across key drug attributes that U.S. ophthalmologists are willing to make, how do physician preference and prescribing likelihood vary across different target product profiles for dry eye?

- By 2018, cyclosporine cationic emulsion 0.1% (Santen’s Ikervis) will emerge as the gold-standard therapy in our Drug Comparator Model because of its superior clinical profile over the key current therapy that we evaluated. Lifitegrast (Shire) was similarly superior to the benchmark therapy in our Drug Comparator Model. On what clinical attributes is cyclosporine cationic emulsion 0.1% most differentiated from its competitors? How will emerging therapies
be incorporated into the dry eye treatment algorithm?

**Scope:**
Attributes included in conjoint analysis based assessment of target product profiles for dry eye:
- Change from baseline on CFS versus placebo.
- Change from baseline on Schirmer’s test versus placebo.
- Change from baseline on the ocular surface disease index (OSDI) whole or in parts versus placebo.
- Change from baseline on dry eye symptoms relative to placebo.
- Risk of eye burning side effect relative to placebo.
- Administration profile.
- Price per day.
Attributes included in assessment of U.S. payers’ receptivity to new therapies for dry eye:
- Efficacy: effect on both dry eye signs and symptoms.
- Efficacy: effect on dry eye signs but not symptoms.
- Efficacy: effect on dry eye symptoms but not signs.
- Safety: reduction in the side effect of eye burning.
Payers surveyed: 21 U.S. MCO PDs.

**Comprehensive List of Therapies Included in Our Research and Modeling:**

**Current Therapies**
- Cyclosporine ophthalmic emulsion 0.05%

**Emerging Therapies**
- Lifitegrast (Shire)
- Cyclosporine cationic emulsion 0.1% (Santen’s Ikervis)
- MIM-D3 (Mimetogen)
- EBI-005 (Eleven BioTherapeutics)
- Loteprednol etabonate + cyclosporine ophthalmic emulsion 0.05% (Valeant/Bausch & Lomb’s Lotemax + Actavis’s [formerly Allergan’s] Restasis)
Report Details

- Pub Date: April 2015