ALLERGIC CONJUNCTIVITIS – OPPORTUNITY ANALYSIS AND FORECASTS TO 2018
The table above summarizes the key metrics for allergic conjunctivitis in the six major pharmaceutical markets (US, France, Germany, Italy, Spain, and UK) covered in this report during the forecast period from 2013–2018.

**Flat Growth in the Allergic Conjunctivitis Market is Expected from 2013–2018**

- GlobalData estimates that the allergic conjunctivitis market was valued at approximately $1.4 billion in 2013 across the six major markets (6MM). The market is expecting to lose patent exclusivity on several key branded products, which will further increase genericization of the market. New pipeline products are anticipated to launch during the forecast period and will partially offset the declining sales of the mature brands; however, the new drugs are not expected to have a substantial impact on the overall sales. By 2018, the allergic conjunctivitis market will increase marginally to $1.4 billion at a Compound Annual Growth Rate (CAGR) of 0.88%. The US will continue to generate the vast majority of sales, owning 79% of the market value in 2018 as a result of higher drug prices and a larger population.
Executive Summary

- The major growth drivers of the allergic conjunctivitis market over the forecast period include:
  - The introduction of three new therapies across the 6MM: AC-170, OTX-DP, and Vekacia. These will stimulate market growth towards the end of the forecast period, providing alternative choices to physicians, as well improving the convenience of drug administration for patients.
  - The US Food and Drug Administration’s (FDA’s) granting of an orphan drug designation to Vekacia will make it eligible for tax exemptions, shorten its approval time, and extend its patent protection.
  - An increase in the prevalence of allergic conjunctivitis is expected due to population growth, which will subsequently expand the number of treated patients.

- The major barriers to the allergic conjunctivitis market during the forecast period include:
  - The impending patent expiries of Lotemax (2014, US), Lastacaft (2016, US), and Patanol from the Pataday/Patanol franchise (2015, US; 2017, 5EU). This will have a negative impact on market growth.
  - Some key opinion leaders (KOLs) are content with the current therapy options, particularly the dual-acting products, which are effective first-line therapies. This increases the barriers to entry for therapies in that are in development, requiring incentives for switching to new treatments.
The figure shown below illustrates the global allergic conjunctivitis sales in the 6MM by region during the forecast period.

Source: GlobalData
Executive Summary

Lack of Novel Drugs Will Limit Growth in the Allergic Conjunctivitis Market

The allergic conjunctivitis market consists of a variety of therapy classes: antihistamines, mast cell stabilizers, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroids. Over the years, increased understanding of eye allergies has shifted the research focus to antihistamines, mast cell stabilizers, and corticosteroids, which has consequently influenced the development of more effective anti-inflammatory eye care products. The development of second generation antihistamines and ester-based corticosteroids has greatly improved the efficacy and safety aspects of existing products.

Following these developments, global leaders in the eye care arena, such as Alcon (now Novartis), Allergan, and Bausch & Lomb, further altered the market landscape by developing dual-acting products (combinations of antihistamines and mast cell stabilizers). Dual-acting products have further increased the effectiveness of single acting products and are currently the mainstay treatments for allergic conjunctivitis. These companies have also pursued the strategy of increasing the convenience of drug application by developing once-daily ophthalmic solutions. In particular, Alcon launched Pataday, a once-daily formulation, following its original twice-daily product, Patanol. Pataday is currently the market-leading product, thanks to its once-daily application and Alcon’s strong marketing strategies. Alcon is continuing to expand its franchise by launching a stronger formulation of its flagship brand, in the expectation that Patanol will suffer from generic erosion.

Other companies are attempting to take a share of the allergic conjunctivitis market by developing “me-too” drugs or reformulating the existing products. The active ingredients in these products are well known in other indications. For example, Aciex Therapeutic’s antihistamine, AC-170, contains the active ingredient, cetirizine, from another established allergy medication, but it is administered in an eye-drop formulation. Also, Ocular Therapeutix’s OTX-DP delivers dexamethasone, which is already available as an ophthalmic solution; and Santen Therapeutic’s Vekacia is a cyclosporine that has already been prescribed off-label (as Restasis, indicated for dry eye disease) for allergic conjunctivitis sufferers in the US. Notably, despite the “me-too” nature of these drugs, the companies have attempted to differentiate their products from the brands that are already available on the market. Ocular Therapeutix’s OTX-DP features the first and only biodegradable intracanalicular plug in the allergic conjunctivitis market, providing sustained drug release over a period of four weeks. Santen Therapeutic has focused on developing Vekacia for a niche population of the chronic allergic conjunctivitis market, targeting vernal keratoconjunctivitis (VKC) patients. Thanks to this strategy, the drug has gained orphan drug status with the FDA.
Executive Summary

High Unmet Need for Alternative Efficacious Therapies and Safer Treatments for Long-Term Use

Overall, GlobalData’s research indicates that the level of unmet need in the allergic conjunctivitis market is in the moderate-to-high range. The therapy options for both the acute and chronic allergic conjunctivitis markets have remained unchanged in recent years, with new formulations focusing mainly on the length of treatment. The markets for the most commonly used therapy classes, antihistamines and mast cell stabilizers, are largely saturated, and these drugs have now been incorporated into more effective dual-acting products. Corticosteroids are reserved for more severe cases of allergic conjunctivitis, although their associated side effects limit their long-term use. Additionally, this presents a problem for patients who become resistant to the current therapy choices; the limited number of choices, as well as the lack of potent drugs with long-term safety, creates an opportunity to market a wider variety of effective therapies as well as potent therapies that are suited for long-term use.

There is also a need for greater awareness and understanding of drug indications by both patients and physicians, because inadequate treatment and misdiagnosis can advance the more severe forms of allergic conjunctivitis.

Market Opportunities for New Entrants

The launch of three new therapies in the 6MM will expand the allergic conjunctivitis market minimally, only partially addressing the unmet needs. In addition to providing an alternative treatment choice, Vekacia will form a new therapy class, immunosuppressants, which will be targeted solely at the niche VKC population. OTX-DP’s biodegradable formulation may provide a convenient solution for the long-term use of corticosteroids, overcoming the issue of patient compliance. With these therapies taken into account, there will still be a market for additional treatment choices, either for the general allergic conjunctivitis population or for specific allergic conjunctivitis subtypes. From a commercial perspective, companies developing future pipeline products will need to show significant overall efficacy benefits over the current standard of care. These products will also have to maintain or improve upon the safety and side effect profiles of the existing products in order to launch successfully.

The figure shown below (Competitive Assessment of the Late-Stage, First-Line Pipeline Agents in Allergic Conjunctivitis, 2013–2018) provides a schematic representation of GlobalData’s competitive assessment of the key first-line, late-stage pipeline drugs for allergic conjunctivitis during the forecast period. The figure shown below (Competitive Assessment of the Late-Stage Second-Line Pipeline Agents in Allergic Conjunctivitis, 2013–2018) provides a similar representation for the second-line agents.
Conjunctivitis, 2013–2018) shows the same for the second-line, late-stage pipeline drugs.

**Entry of Pipeline Therapies Will Modestly Impact the Allergic Conjunctivitis Drug Landscape**

A diverse class of products is expected to enter the allergic conjunctivitis market during the forecast period from 2013–2018. Vekacia will become a first-in-class treatment in the 5EU (France, Germany, Italy, Spain, and UK) markets (2016), while AC-170 and OTX-DP are set to enter the US market (2016). Although these products have unique clinical features, GlobalData believes that they will not boost the overall market size sufficiently. Given that most late-stage pipeline products are being developed by companies that have small footprints in the ophthalmology market, or that have limited experience in the 6MM, upon approval, they will need to seek partnership opportunities with larger players. This will ensure that they gain the benefits of the global reach and marketing strength of the larger companies, enabling them to capture the full market potential.

By the end of the forecast period, there is likely to be minimal change in treatment regimen across the 6MM. GlobalData forecasts that the combined sales of these products will reach $63.4m by 2018.

**What Do Physicians Think?**

Physician KOLs interviewed by GlobalData highlighted the significant unmet need for safer, stronger therapies for allergic conjunctivitis that can be used over the long term.
“That’s what we’re all looking for in the treatment of these patients who have inflammatory conditions....I mean, [with] all these types of inflammatory surface corneal and conjunctiva disease stages, they’re probably better off with chronic corticosteroids, but we don’t have a chronic steroid that we can use safely….If someone can come up with a corticosteroid or corticosteroid-like decrease in inflammation that doesn’t cause increase[d] IOP (intraocular pressure) and cataracts and other things like that of [a] chronic nature, then I think that would be what we’re all looking for.”

US Key Opinion Leader

“I think there is always a market for something that may work better in some people than others…. [An] H1 antagonist…[is] what most of these combo products…[have] in them…for the antihistamine component…. Unless it has some targeted ability different than the others, I don’t know how it would really compete with the combination products.”

US Key Opinion Leader

“...Yes, dexamethasone is [an] excellent steroid and [has a] tremendous level of potency over prednisone. But again, the only problem that I have with this is over the long term [the] effects on [patients’] ocular pressure.”

US Key Opinion Leader

KOLs acknowledged that the allergic conjunctivitis landscape is competitive for introducing new potential products. These would need to override the benefits currently offered by the dual-acting products. Cost and convenience (and therefore compliance) are also important factors. KOLs are happy with the treatment options that are currently available, but would welcome any new therapies offering superior efficacy.

“...In many cases, we are now pretty good. There are once-a-day [therapies], [which are] the best you can hope for. They are very effective, very safe. I think they are very fast-acting in most cases. So, if there is any other unmet need, [it] is that the medication would be more potent right off the bat. I think that, again, the dosage is fine, the safety profiles are all fine.... [but] if you get the potency of steroids and non-steroids [to] go up.... [and the product is] approved for allergic conjunctivitis, that will be ideal.”

US Key Opinion Leader
Executive Summary

“I think there is [room for new drug classes,] but…what’s the cost? How much is it going to cost…? For patients, how much is it going to cost…? How effective is it going to be versus what we have now? I think convenience and compliance [are] more important with anything.”

US Key Opinion Leader

Physicians also had conflicting thoughts about a new formulation of an existing therapy in development, OTX-DP, which is poised to enter the market.

“You are concerned about a couple of things in [the] intracanalicular department: one is, you know, the release of the drug and how well it can release in, you know, in a same state as far as the same concentration over a sustained release, so I am sure they would be working on that to make sure that the drug-release pattern is appropriate. But…, it’s still a steroid, so we have to worry about the same issues [with the use] of chronic steroids in this type of new treatment.”

US Key Opinion Leader

“Well, as far as the most promising [products go, it will probably will be the intracanalicular plug. That sounds very interesting because dexamethasone is probably the most effective anti-inflammatory eye drop, and if you can deliver it in a safer way, then that would possibly be the most exciting one. And then the cyclosporine, obviously in the more severe cases that just don’t respond to anything.”

EU Key Opinion Leader
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Introduction

2 Introduction

2.1 Catalyst

The allergic conjunctivitis market has remained relatively static over the last few years, due to a limited number of new products. It is currently dominated by dual-acting products and corticosteroid therapies, which form the core treatment options for both acute and chronic allergic conjunctivitis sufferers. Although these therapies provide effective treatment regimens, there are opportunities for the development of alternative treatment choices, improvements in efficacy, safety and compliance. By 2018, there will be three new entrants to the allergic conjunctivitis market, including a new antihistamine, AC-170 (cetirizine); a first-in-class immunosuppressant, Vekacia (cyclosporine); and an intracanalicular plug, OTX-DP (dexamethasone), which will provide a novel route of administration. These new products will help drive market growth and offset the impending patent expiries of the majority of the remaining brands (Lotemax [loteprednol etabonate], Patanol [olopatadine], and Lastacaft [alcaftadine]) during the forecast period, which will permit the entry of inexpensive generics. Despite these advancements in the treatment landscape, the allergic conjunctivitis market is not expected to experience a noticeable change in terms of growth.

2.2 Related Reports


2.3 Upcoming Related Reports

Appendix

10.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

GlobalData has offices in New York, Boston, London, India, and Singapore.

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