DUPILUMAB (ATOPIC DERMATITIS) – FORECAST AND MARKET ANALYSIS TO 2022
Executive Summary

The below mentioned table presents key metrics for Dupilumab in the nine major pharmaceutical markets (9MM): the US, France, Germany, Italy, Spain, the UK, Japan analyzed in this report.

<table>
<thead>
<tr>
<th>Key Events (2012–2022)</th>
<th>Level of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dupilumab launch expected in US – Q4 2016</td>
<td>↑↑↑</td>
</tr>
<tr>
<td>Dupilumab launch expected in 5EU and Japan in 2016 and 2018 respectively</td>
<td>↑↑↑</td>
</tr>
</tbody>
</table>

**2022 Market Sales**

<table>
<thead>
<tr>
<th>Region</th>
<th>Sales (2022)</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$402.83m</td>
</tr>
<tr>
<td>5EU</td>
<td>$273.62m</td>
</tr>
<tr>
<td>Japan</td>
<td>$69.74m</td>
</tr>
<tr>
<td>China and India</td>
<td>NA</td>
</tr>
<tr>
<td>Total</td>
<td>$746.18m</td>
</tr>
</tbody>
</table>

Source: GlobalData.

*For the purposes of this report, Global = US, France, Germany, Italy, Spain, UK, Japan, China, India. 7MM = US, France, Germany, Italy, Spain, UK, Japan, NA= Not applicable

Sales for Dupilumab in the Global Atopic Dermatitis Market

Dupilumab sales are expected to increase from $74.06m upon launch in 2016 to $746.18m in 2022.

Major growth drivers for Dupilumab in the atopic dermatitis market over the forecast period include:

- Qualify to utilizes Regeneron’s proprietary VelocImmune antibody technology, which leaves it patent protected and will make it more difficult for competitors to challenge the biologic over the long term
- Novel therapeutic target: interleukin 4R inhibition
- Promising efficacy and safety profile in Phase II studies
- Most clinically advanced biologic agent

Conversely, major barriers to the growth of the Dupilumab include:

- Unwanted side effects; namely, injection-site reactions, nasopharyngitis, nausea, and headache.

The figure below illustrates the Dupilumab sales by region during the 10-year forecast period.
Executive Summary

What Do the Physicians Think?

Key opinion leaders highlight that atopic dermatitis patients remain dissatisfied with the efficacy and side-effect profiles of currently available treatments.

“I am not convinced that anything [in terms of therapies] that we have now that we can go to is acceptable to a lot of people...because people also come to us [specialists] because they are not happy with the therapy they are getting [from their PCPs] and they just want to know if there is some way of using an approach that may not be harmful in terms of adverse events.”

[US] key opinion leader, May 2013

Opinion leaders highlight that there remains substantial research to be carried out to further understand the pathophysiology of atopic dermatitis, and that existing therapies cannot be used to treat all patients:

“Probably at least for each subset [of atopic dermatitis patient]; because there probably could be easily five types of AD, if not 10 [types] and so trying to [treat] everyone under the same umbrella does not work.”

[US] key opinion leader, May 2013

Leading dermatologists interviewed by GlobalData highlighted the challenges drug developers of potential atopic dermatitis treatments face. This ranges from high drug attrition due to the complex pathophysiology of atopic dermatitis, and the high pediatric population, to past actions by the US Food and Drug Administration (FDA) which may have hampered innovation:

“[In terms of drug attrition in atopic dermatitis], the problem is the target [i.e., the disease itself], and the second major problem is that the majority of patients are in the pediatric population. [Therefore], for a small company, which is sitting on the license of a new product or compound and is trying to sell it, and then trying to have some clinical evidence that their product is a good business [strategy] for one of the big Pharma companies, they usually have a really hard time to provide something which is convincing. [This is] because it is so cumbersome to be able to really provide the data in this particular pediatric patient population. Meanwhile, the regulatory framework is so rigid and so difficult and safety is [a major concern for the pediatric group] that most of the companies are in fact stopping the development of their [atopic dermatitis pipeline] product. [That is] even if they have some positive signals, they still have to stop because they cannot find the investors or enough money to continue the clinical program. That is the typical valley of death phenomenon that we see in drug development [for atopic dermatitis].”

[EU] key opinion leader, May 2013
Executive Summary

“Unfortunately, the FDA stuck a black box on [Protopic and Elidel] many years ago, which was unwarranted, [and] has never proved [to be an issue with these therapies]... It was a theoretical reason and it has never shown over the last 12 years to be a problem. But the FDA never removes black boxes so it is stuck there, and it has been another reason why we cannot get [calcineurin inhibitors] very easily for patients. A lot of dermatologists do not even bother trying to, because it is so much of a hassle and it takes so much time for doctors and staff.”

[US] key opinion leader, September 2013

“The initial release of the calcineurin inhibitors [Protopic and Elidel] lead to the black box [warning on their labels], and the black box was more a reflection of the lack of knowledge regarding long-term side effects. I think that now that they are 10 years out from [their first] release [i.e., launch] there could be more use of them because they really have not caused the skin cancer that the FDA was concerned about. I think the [greater] problem [with the calcineurin inhibitors] is cost. Most patients would be happy to use them but because the major manufacturers have abandoned these [products] their cost is great and a lot of patients do not have it covered under their insurance.”

[US] key opinion leader, May 2013

GlobalData identified palpable excitement over the late-stage therapies in the atopic dermatitis pipeline and the potential hope they bring for the pediatric atopic dermatitis population:

“It is just so exciting to finally have some new drugs and I hope that they are tested and approved for children. Because children unfortunately do not get a lot of these drugs easily and it becomes hard without the [clinical trial] testing to be able to utilize them [in this patient group]. It is the school age or above who need this type of therapy with respect to the systemic [dupilumab], for the new PDE4 inhibitor [AN2728] that would be great if the toxicity testing was good so that we would be able to use it for younger children.”

[US] key opinion leader, September 2013
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Introduction

2 Introduction

2.1 Catalyst

Although the past decade has seen the atopic dermatitis market remain relatively unchanged and a saturated, highly genericized arena, the coming decade could see the launch of the first biologic, which will set a precedent and pave the way for others to follow suit.

By the mid-to-late term of GlobalData's 2012 to 2022 forecast, Sanofi/Regeneron’s pipeline biologic dupilumab is expected to reshape the moderate and severe treatment landscape.

Other events that are expected to invoke change to the previously stagnant atopic dermatitis market include the launch of a non-steroidal topical from Anacor, AN2728, generic erosion of branded topicals Protopic and Elidel in the US, and the increasing use of pharmacological treatments in the growing markets of India and China.

Exciting times lay ahead for the atopic dermatitis marketplace, as the above events are due to occur against the backdrop of increasing research into the multiple etiologies that give rise to the disease. With existing unmet need for a better treatment armamentarium for severe, refractory/recalcitrant disease and an estimated drug-treated population that hovers around the 54 million mark over the next decade, atopic dermatitis represents an attractive dermatology sector for drug developers, and this in turn should fuel commercial interest into this marketplace.

2.2 Related Reports

- GlobalData (2013). Atopic Dermatitis – France Drug Forecast and Market Analysis to 2022, November 2013, GDHC184CFR.
Introduction

- GlobalData (2013). Atopic Dermatitis – Germany Drug Forecast and Market Analysis to 2022, November 2013, GDHC185CFR.
- GlobalData (2013). Atopic Dermatitis – Italy Drug Forecast and Market Analysis to 2022, November 2013, GDHC186CFR.
- GlobalData (2013). Atopic Dermatitis – UK Drug Forecast and Market Analysis to 2022, November 2013, GDHC188CFR.
- GlobalData (2013). Atopic Dermatitis – China Drug Forecast and Market Analysis to 2022, November 2013, GDHC190CFR.
- GlobalData (2013). Atopic Dermatitis – India Drug Forecast and Market Analysis to 2022, November 2013, GDHC191CFR.
- GlobalData (2013). Protopic (Atopic Dermatitis) - Forecast and Market Analysis to 2022, November 2013, GDHC294DFR.
- GlobalData (2013). Elidel (Atopic Dermatitis) - Forecast and Market Analysis to 2022, November 2013, GDHC295DFR.
- GlobalData (2013). AN2728 (Atopic Dermatitis) - Forecast and Market Analysis to 2022, November 2013, GDHC297DFR.

2.3 Upcoming Related Reports

Appendix

9.8 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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