ATOPIC DERMATITIS –
GLOBAL DRUG FORECAST AND MARKET ANALYSIS
TO 2022
The above mentioned table presents key metrics for atopic dermatitis in the nine major pharmaceutical markets (9MM): the US, France, Germany, Italy, Spain, the UK, Japan, China, and India, analyzed in this report.

**New Product Launches in the Mid-forecast Will Fuel Growth to 2022**

In 2012, GlobalData estimates that the global atopic dermatitis market reached $3.9 billion across the nine healthcare markets covered in our forecast: US, France, Germany, Italy, Spain, UK, Japan, China, and India. By the forecast-end, in 2022, sales across these markets will grow to $5.6 billion, representing a compound annual growth rate (CAGR) of 3.8% over the 10-year period.

Focusing on country dynamics, the US – in line with expectations – dominated the global atopic dermatitis market in 2012, contributing $1.35 billion to overall sales and commanding 34.9% of the global market. Across the five major European markets (France, Germany, Italy, Spain, and the UK), Germany emerges as the highest-grossing country by value in 2012, owing to physicians' high prescribing rates and the high annual cost of current therapies. Meanwhile, owing to a high drug-treatable population relative to other markets, Japan will play a key role in driving growth in the global market through to 2022, while the emerging markets India and China will experience rapid uptake of topical calcineurin inhibitors and systemic vitamin derivatives.
Executive Summary

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

- The anticipated launch of the first biologic – Sanofi/Regeneron’s dupilumab – for the treatment of moderate to severe disease.

- Strong uptake of branded and generic topical calcineurin inhibitors, particularly within the emerging markets of India and China.

- Continued uptake of systemic therapies; namely the immunomodulators cyclosporine and mycophenolate mofetil, as well as vitamin derivatives and off-label agents such as Novartis/Genentech’s Xolair (omalizumab) and Boehringer Ingelheim/Vidara Therapeutics’ Actimmune (interferon gamma-1b).

Conversely, major barriers to the growth of the atopic dermatitis market include:

- Continued uptake of low-cost, genericized topical drugs at first and second line of therapy, which creates a hurdle for novel drugs hoping to penetrate the market.

- Pediatric sufferers remaining the largest patient segment, which raises the bar in terms of the ideal safety profile for the target product profile of any new atopic dermatitis drug.

- The complexity of the multiple etiologies that give rise to the disease, which means that treatment outcome with drug therapy is not universal in all patients.

A significant proportion of atopic dermatitis patients continue to experience disease remission in their early adolescent years, which may occur without drug intervention.

The figure below illustrates the global atopic dermatitis sales by region during the 10-year forecast period.

Sales for Atopic Dermatitis by Region, 2012–2022

Source: GlobalData.
Executive Summary

Increasing R&D Focus on Novel Biologics Will Shape Future Corporate Strategies

As the atopic dermatitis market is currently highly genericized and there are only two key patent-protected (US only) brands, no distinct trends in corporate strategy exist. However, over the coming decade, the introduction of biologics, in particular interleukin inhibitors, will emerge as a key future strategy for this marketplace.

Historically, Astellas and Novartis were the dominant market players in the atopic dermatitis space for almost a decade, with the launch of their respective topical calcineurin inhibitor brands Protopic (tacrolimus) and Elidel (pimecrolimus), in the US in 2001. Although Astellas continues to maintain its strong standing in the current market, Novartis exited the space in April 2011, with the sale of Elidel’s rights to Meda. To some extent, Novartis continues to have a presence in this market, as some dermatologists opt for its branded versions of cyclosporine, Sandimmune or Neoral, for their atopic dermatitis patients requiring a systemic immunomodulator.

By the forecast-end, in 2022, of the two prominent current market players, Astellas’ position will be weakened to a greater extent than Meda’s. This is because although both of their brands are due to face generic competition in the US in 2014 and 2016, respectively, Protopic is the favored brand and as such will experience greater generic erosion. With no pipeline drugs in Astellas’ 2013 R&D portfolio for atopic dermatitis, the ability of Astellas to retain sales by the end of the forecast period will be dependent on physician familiarity and any tactical pricing or marketing strategy the company employs to counteract generic competition. For Meda, its market share will have declined by almost a third in 2022, but akin to Astellas’ Protopic, Elidel’s loss in sales in the established healthcare markets will be offset by the increasing uptake of the brand in the growing markets of India and China.

That said, over the coming decade, the most pertinent change in the atopic dermatitis competitive landscape will be the emergence of two new market players – Sanofi/Regeneron and Anacor – in the mid-term of the forecast. Although both companies are expected to enter the atopic dermatitis space in 2016, Sanofi/Regeneron displays the greatest commercial prospects as its pipeline candidate, dupilumab, is touted as a potential breakthrough therapy for moderate to severe disease, owing to its potential to either compete with or displace gold-standard systemic agent cyclosporine. This in turn could address the high unmet need for an effective systemic drug for severe refractory disease. As a result, Sanofi and Regeneron are expected to emerge as the market leaders across the established atopic dermatitis markets.
High Unmet Need Exists for a Better Treatment Armamentarium for Severe Recalcitrant Patients

According to key opinion leaders interviewed by GlobalData, there remains high unmet need within atopic dermatitis for a better treatment armamentarium for severe, recalcitrant patients. This patient segment remains underserved as physicians have few to no pharmacological options following treatment failure with or intolerability to cyclosporine, and as a result physicians often resort to prescribing off-label therapies. Further compounding this issue is the fact that although cyclosporine is indicated for the short-term treatment of atopic dermatitis in some European countries, leading dermatologists believe that no true systemic drug for the disease exists, and this remains the most pressing unmet need for developers to address.

Having the most clinically advanced systemic drug in the atopic dermatitis pipeline, Sanofi and Regeneron appear to be the best-positioned companies to address the high unmet need in this marketplace, and could set a precedent with their pipeline biologic candidate dupilumab. The palpable excitement over dupilumab stems from its novelty as an interleukin (IL)-4R inhibitor, and its initial promising clinical trial data from Phase IIa studies.

A Highly Genericized Atopic Dermatitis Market Leaves Opportunities for New Entrants within the Refractory Population

Although Sanofi/Regeneron’s dupilumab is forecast to gain a foothold in the severe population by late-forecast, it will not completely eradicate the high unmet need within the refractory group in this patient segment and there will still be a gap for other novel systemics, as leading dermatologists stress a desire for more than one treatment option to be added to their armamentarium.

As a monoclonal antibody, dupilumab is expected to be an expensive therapy relative to existing treatments. This in turn may hinder widespread adoption and signifies opportunity for other
Executive Summary

developers to tap into the severe refractory market. Therefore, a novel systemic agent that specifically targets this patient group would undoubtedly be welcomed by physicians and in turn gain strong uptake; that is, if other factors such as an appropriate price and payer backing are satisfied. Furthermore, key opinion leaders highlight that to maximize patient uptake, a new systemic drug should be orally delivered, although a subcutaneously administered therapy could also have a place in the current treatment landscape and in fact would be the more preferable choice for physicians after an oral therapy. An intravenous injection, however, would struggle to gain traction in the atopic dermatitis space.

Besides targeting the IL-4/13 pathway, which is the case for dupilumab, IL-31 inhibition emerges as a promising early phase strategy. This cytokine is up-regulated in atopic dermatitis skin lesions and plays a role in the characteristic pruritus (unpleasant sensation that elicits the desire to scratch) of the disease. In September 2013, GlobalData identified two anti-IL-31 drugs in the early stage pipeline: Bristol-Myers Squibb's BMS-981164 and Chugai's CIM331. These are key products to be watched over the coming years, as leading dermatologists expressed excitement about the clinical potential of anti-IL-31 therapies.

High Hopes for Sanofi/Regeneron’s Dupilumab and its Potential to Reshape the Moderate-to-Severe Competitive Landscape

Sanofi/Regeneron’s dupilumab is expected to reshape the moderate-to-severe treatment paradigm, and serve as an alternative therapeutic option for patients that are typically prescribed the gold-standard systemic agent cyclosporine, and for those that have become refractory to all available treatments. Its 2016 launch across the major healthcare markets will be the most pertinent event in the atopic dermatitis market space in the near-term.

With optimism over the drug’s future prospects from key opinion leaders, GlobalData expects strong uptake and forecasts the biologic to garner sales of $746.2m by 2022. Overall, dupilumab’s uptake across the 7MM will be fueled by its potential to address the high unmet need for a systemic agent for patients that fall into the severe recalcitrant category, and its potential to displace cyclosporine, which currently does not serve as a viable long-term maintenance treatment, due to the associated risk of nephrotoxicity with its prolonged use.

The excitement surrounding dupilumab is further compounded by its novelty as a monoclonal antibody against the alpha subunit of the IL-4 receptor and its promising clinical trial data thus far. This indicates that dupilumab has the potential to be a game-changing therapy, as it could be the first-in-class IL-drug and the first biologic for the
Executive Summary

treatment of atopic dermatitis. Its ability to be a game-changer will be heavily dictated by the balance between its clinical and commercial factors, such as its long-term efficacy and safety together with an appropriate price and payer backing.

“[Dupilumab is a] blockbuster drug. Over time, it would probably take over any other medication that is used systemically for patients. The big problem is going to be knowing a little bit more about long-term safety. Of course I am sure that when it comes out it will be just like other biologics, incredibly expensive and so even though it may be safer, even though it may be really something that people will much rather use as compared to what we are using right now, the cost may preclude some patients from getting it.”

[US] key opinion leader, September 2013
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
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

“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

“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
## Table of Contents

1. **Table of Contents**

   1.1 List of Tables ................................................................. 18
   1.2 List of Figures ................................................................. 23

2. **Introduction** ................................................................. 25
   2.1 Catalyst ........................................................................... 25
   2.2 Related Reports ............................................................... 25
   2.3 Upcoming Related Reports ............................................... 25

3. **Disease Overview** ............................................................ 26
   3.1 Etiology and Pathophysiology .......................................... 26
       3.1.1 Etiology ..................................................................... 26
       3.1.2 Pathophysiology ......................................................... 27
   3.2 Symptoms ......................................................................... 31

4. **Epidemiology** ................................................................. 33
   4.1 Disease Background ........................................................... 33
   4.2 Risk Factors and Comorbidities ......................................... 33
       4.2.1 Children ages ≤10 years are three times more likely to develop atopic dermatitis ......................................................................................... 34
       4.2.2 Family history of atopic disease increases the risk of atopic dermatitis six-fold ......................................................................................... 35
       4.2.3 Allergens are associated with a six-fold risk of atopic dermatitis ................................................................................................. 36
       4.2.4 Breastfeeding for more than four months protects children from atopic dermatitis ................................................................. 37
       4.2.5 Asthma, allergic rhinitis and allergic conjunctivitis commonly occur with atopic dermatitis .............................................................................. 38
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2.6 Atopic dermatitis patients are up to three times more likely to have psychiatric disorders</td>
<td>39</td>
</tr>
<tr>
<td>4.3 Global Trends</td>
<td>40</td>
</tr>
<tr>
<td>4.3.1 US</td>
<td>41</td>
</tr>
<tr>
<td>4.3.2 5EU</td>
<td>41</td>
</tr>
<tr>
<td>4.3.3 Japan</td>
<td>45</td>
</tr>
<tr>
<td>4.3.4 China</td>
<td>45</td>
</tr>
<tr>
<td>4.3.5 India</td>
<td>46</td>
</tr>
<tr>
<td>4.4 Forecast Methodology</td>
<td>47</td>
</tr>
<tr>
<td>4.4.1 Sources Used</td>
<td>50</td>
</tr>
<tr>
<td>4.4.2 Sources Not Used</td>
<td>57</td>
</tr>
<tr>
<td>4.5 Forecast Assumptions and Methods</td>
<td>58</td>
</tr>
<tr>
<td>4.5.1 US</td>
<td>58</td>
</tr>
<tr>
<td>4.5.2 France</td>
<td>59</td>
</tr>
<tr>
<td>4.5.3 Germany</td>
<td>59</td>
</tr>
<tr>
<td>4.5.4 Italy</td>
<td>60</td>
</tr>
<tr>
<td>4.5.5 Spain</td>
<td>61</td>
</tr>
<tr>
<td>4.5.6 UK</td>
<td>61</td>
</tr>
<tr>
<td>4.5.7 Japan</td>
<td>62</td>
</tr>
<tr>
<td>4.5.8 China</td>
<td>63</td>
</tr>
<tr>
<td>4.5.9 India</td>
<td>63</td>
</tr>
<tr>
<td>4.6 Epidemiology Forecast of Atopic Dermatitis (2012–2022)</td>
<td>64</td>
</tr>
<tr>
<td>4.6.1 Lifetime Prevalent Cases of Atopic Dermatitis</td>
<td>64</td>
</tr>
</tbody>
</table>
# Table of Contents

4.6.2 Age-Specific Prevalent Cases of Lifetime Atopic Dermatitis ........................................66
4.6.3 Sex-Specific Prevalent Cases of Lifetime Atopic Dermatitis ........................................69
4.6.4 Age-Standardized Lifetime Prevalence of Atopic Dermatitis ........................................70
4.6.5 Prevalent Cases of Atopic Dermatitis by Severity ..........................................................71
4.7 Discussion ...............................................................................................................................73
  4.7.1 Conclusions on Epidemiological Trends ...........................................................................73
  4.7.2 Limitations of the Analysis ...............................................................................................75
  4.7.3 Strengths of the Analysis ..................................................................................................76

5 Disease Management .................................................................................................................77
  5.1 Diagnosis .............................................................................................................................77
  5.2 Treatment Overview .............................................................................................................79
  5.3 US ........................................................................................................................................84
    5.3.1 Diagnosis .......................................................................................................................84
    5.3.2 Clinical Practice ...............................................................................................................87
  5.4 France ...................................................................................................................................89
    5.4.1 Diagnosis .......................................................................................................................89
    5.4.2 Clinical Practice ...............................................................................................................90
  5.5 Germany ...............................................................................................................................93
    5.5.1 Diagnosis .......................................................................................................................93
    5.5.2 Clinical Practice ...............................................................................................................95
  5.6 Italy ......................................................................................................................................97
    5.6.1 Diagnosis .......................................................................................................................97
    5.6.2 Clinical Practice ...............................................................................................................98
# Table of Contents

5.7 Spain ................................................................................................................................. 99

5.7.1 Diagnosis ..................................................................................................................... 99

5.7.2 Clinical Practice ........................................................................................................... 101

5.8 UK ................................................................................................................................... 102

5.8.1 Diagnosis ..................................................................................................................... 102

5.8.2 Clinical Practice ........................................................................................................... 104

5.9 Japan .............................................................................................................................. 106

5.9.1 Diagnosis ..................................................................................................................... 106

5.9.2 Clinical Practice ........................................................................................................... 108

5.10 China ............................................................................................................................. 109

5.10.1 Diagnosis ................................................................................................................... 109

5.10.2 Clinical Practice ....................................................................................................... 110

5.11 India ............................................................................................................................. 111

5.11.1 Diagnosis ................................................................................................................... 111

5.11.2 Clinical Practice ....................................................................................................... 112

6 Competitive Assessment .................................................................................................... 114

6.1 Overview ......................................................................................................................... 114

6.2 Strategic Competitor Assessment ................................................................................... 115

6.3 Product Profiles – Major Brands .................................................................................... 116

6.3.1 Protopic (tacrolimus) ................................................................................................. 116

6.3.2 Elidel ............................................................................................................................. 124

6.3.3 Cyclosporine (numerous generic names) ..................................................................... 131

6.3.4 Other Therapeutic Drug Classes Used in Atopic Dermatitis ..................................... 135
# Table of Contents

6.4  Product Profiles – Off-Label Therapies ........................................................................... 137  
6.4.1  Xolair (omalizumab) ................................................................................................. 137  
6.4.2  Actimmune (interferon gamma-1b) .............................................................................. 142  
7  Opportunity and Unmet Need ........................................................................................ 148  
7.1  Overview ......................................................................................................................... 148  
7.2  Unmet Needs .................................................................................................................... 149  
7.2.1  A Systemic Drug for Severe Recalcitrant Patients .................................................... 149  
7.2.2  Tests that Stratify Patients and Allow for a Tailored Treatment Approach ............... 150  
7.2.3  A Drug that Effectively Controls Patients’ Pruritus .................................................... 151  
7.2.4  Further Research into the Pathophysiology of Atopic Dermatitis .............................. 153  
7.2.5  A Drug that Induces Disease Remission .................................................................... 154  
7.2.6  Improved Quality of Life for Both Patients and their Carers ........................................ 154  
7.3  Unmet Needs Gap Analysis ............................................................................................ 155  
7.4  Opportunities ................................................................................................................... 156  
7.4.1  Increase Treatment Armamentarium for Severe Recalcitrant Patients ...................... 156  
7.4.2  Predictive Tests for Patient Stratification .................................................................... 156  
7.4.3  More Therapeutic Options that Address Patients’ Pruritus .......................................... 157  
8  Pipeline Assessment .......................................................................................................... 158  
8.1  Overview .......................................................................................................................... 158  
8.2  Clinical Trial Mapping ...................................................................................................... 159  
8.2.1  Clinical Trials by Country ............................................................................................ 159  
8.3  Clinical Trials by Phase and Trial Status ........................................................................ 160  
8.4  Promising Drugs in Clinical Development .................................................................... 161
# Table of Contents

8.4.1 Dupilumab (SAR231893/ REGN668) ................................................................. 163
8.4.2 AN2728 .............................................................................................................. 174
8.4.3 Phase II Pipeline Products .................................................................................. 184

9 Current and Future Players ......................................................................................... 186
9.1 Overview .................................................................................................................. 186
9.2 Trends in Corporate Strategy .................................................................................... 188
9.3 Company Profiles ..................................................................................................... 189
  9.3.1 Astellas ............................................................................................................... 190
  9.3.2 Meda .................................................................................................................. 193
  9.3.3 Regeneron ......................................................................................................... 195
  9.3.4 Anacor ............................................................................................................... 197

10 Market Outlook .......................................................................................................... 200
10.1 Global Markets ....................................................................................................... 200
  10.1.1 Forecast .......................................................................................................... 200
  10.1.2 Global Drivers and Barriers .............................................................................. 204
10.2 US ........................................................................................................................... 209
  10.2.1 Forecast .......................................................................................................... 209
  10.2.2 Key Events ..................................................................................................... 212
  10.2.3 Drivers and Barriers ......................................................................................... 213
10.3 France ...................................................................................................................... 215
  10.3.1 Forecast .......................................................................................................... 215
  10.3.2 Key Events ..................................................................................................... 218
  10.3.3 Drivers and Barriers ......................................................................................... 218
# Table of Contents

10.4 Germany .................................................................................................................. 220
10.4.1 Forecast .............................................................................................................. 221
10.4.2 Key Events ......................................................................................................... 224
10.4.3 Drivers and Barriers .......................................................................................... 224
10.5 Italy ......................................................................................................................... 227
10.5.1 Forecast .............................................................................................................. 227
10.5.2 Key Events ......................................................................................................... 230
10.5.3 Drivers and Barriers .......................................................................................... 230
10.6 Spain ....................................................................................................................... 233
10.6.1 Forecast .............................................................................................................. 233
10.6.2 Key Events ......................................................................................................... 235
10.6.3 Drivers and Barriers .......................................................................................... 236
10.7 UK .......................................................................................................................... 237
10.7.1 Forecast .............................................................................................................. 237
10.7.2 Key Events ......................................................................................................... 240
10.7.3 Drivers and Barriers .......................................................................................... 240
10.8 Japan ....................................................................................................................... 243
10.8.1 Forecast .............................................................................................................. 244
10.8.2 Key Events ......................................................................................................... 246
10.8.3 Drivers and Barriers .......................................................................................... 247
10.9 China ....................................................................................................................... 249
10.9.1 Forecast .............................................................................................................. 250
10.9.2 Key Events ......................................................................................................... 252
# Table of Contents

10.9.3 Drivers and Barriers ................................................................................................. 253

10.10 India ......................................................................................................................... 254

10.10.1 Forecast .............................................................................................................. 254

10.10.2 Key Events .......................................................................................................... 256

10.10.3 Drivers and Barriers ......................................................................................... 257

11 Appendix ..................................................................................................................... 259

11.1 Bibliography ............................................................................................................. 259

11.2 Abbreviations ......................................................................................................... 275

11.3 Methodology ............................................................................................................ 277

11.4 Forecasting Methodology ....................................................................................... 277

11.4.1 Diagnosed Atopic Dermatitis Patients ............................................................. 277

11.4.2 Percent Drug-treated Patients ........................................................................... 278

11.4.3 Drugs Included in Each Therapeutic Class ....................................................... 278

11.4.4 Launch and Patent Expiry Dates ....................................................................... 278

11.4.5 General Pricing Assumptions ........................................................................... 279

11.4.6 Individual Drug Assumptions ........................................................................... 280

11.4.7 Generic Erosion ................................................................................................. 282

11.4.8 Pricing of Pipeline Agents .................................................................................. 283

11.5 Physicians and Specialists Included in this Study ................................................. 284

11.6 Primary Research – Prescriber Survey .................................................................. 285

11.7 About the Authors .................................................................................................. 286

11.7.1 Author ................................................................................................................. 286

11.7.2 Epidemiologist ................................................................................................... 287
1.1 List of Tables

Table 1: Symptoms of Atopic Dermatitis .......................................................... 32
Table 2: Atopic Dermatitis, Risk Factors and Comorbidities .............................. 34
Table 3: Diagnostic Criteria for Atopic Dermatitis ........................................... 47
Table 4: The Hanifin and Rajka Diagnostic Criteria for Atopic Dermatitis ........ 48
Table 5: All Markets, Epidemiological Sources for Lifetime Atopic Dermatitis Prevalence ................................................................. 49
Table 6: All Markets, Epidemiological Sources of Atopic Dermatitis Severity Data ................................................................. 50
Table 7: All Markets, Prevalent Cases of Lifetime Atopic Dermatitis, All Ages, Both Sexes, N (Millions), 2012–2022 ................................................................. 65
Table 8: All Markets, Prevalent Cases of Lifetime Atopic Dermatitis, by Age, N (Millions), (Row %), 2012 ..... 67
Table 9: All Markets, Prevalent Cases of Lifetime Atopic Dermatitis, by Sex, All Ages, N (Row %), 2012 ..... 69
Table 10: All Markets, Prevalent Cases of Lifetime Atopic Dermatitis by Severity, All Ages, Both Sexes, N (Millions) (Row %), 2012 .................................................. 72
Table 11: Treatment Guidelines for Atopic Dermatitis ..................................... 82
Table 12: Most Prescribed Drugs for Atopic Dermatitis by Severity in the Global Markets, 2013 .................. 84
Table 13: Referral Rates to a US Dermatologist, Split by Severity and Specialist Type, 2013 .................. 86
Table 14: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in the US, 2013 ................................................................. 87
Table 15: Referral Rates to a French Dermatologist, Split by Severity and Specialist Type, 2013 .............. 90
Table 16: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in France in 2012 ................................................................. 90
Table of Contents

Table 17: Referral Rates to a German Dermatologist, Split by Severity and Specialist Type, 2013 ...............94
Table 18: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in Germany in 2012 ...........................................................................................................94
Table 19: Referral Rates to an Italian Dermatologist, Split by Severity and Specialist Type, 2013 ..........97
Table 20: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in Italy in 2012 ..............................................................................................................98
Table 21: Referral Rates to a Spanish Dermatologist, Split by Severity and Specialist Type, 2013 .......100
Table 22: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in Spain in 2012 ..............................................................................................................100
Table 23: Referral Rates to a UK Dermatologist, Split by Severity and Specialist Type, 2013 ...........103
Table 24: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in the UK in 2012 ................................................................................................................104
Table 25: Stepped Treatment Approach Used by UK Dermatologists in the Management of Atopic Dermatitis ..................................................................................................................................105
Table 26: Referral Rates to a Japanese Dermatologist, Split by Severity and Specialist Type, 2013 ..........107
Table 27: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in Japan in 2012 ................................................................................................................108
Table 28: Referral Rates to a Chinese Dermatologist, Split by Severity and Specialist Type, 2013 ........109
Table 29: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in China in 2012 ................................................................................................................110
Table 30: Referral Rates to an Indian Dermatologist, Split by Severity and Specialist Type, 2013 ..........111
Table 31: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in India in 2012 ..................................................................................................................................112
Table 32: Leading Treatments for Atopic Dermatitis, 2013 ..................................................................116
Table 33: Product Profile – Protopic ..............................................................................................................118
Table 34: Clinical Response Data of Protopic (0.03% and 0.1%) versus Vehicle Ointment at Week 12 from One Study in Pediatric Patients and Two Combined Studies in Adult Patients ..................119
Table of Contents

Table 35: Protopic SWOT Analysis, 2013 ........................................................................... 122
Table 36: Global Sales Forecasts ($m) for Protopic, 2012–2022 ........................................ 124
Table 37: Product Profile – Elidel ....................................................................................... 126
Table 38: Combined Clinical Efficacy Results of Elidel versus Vehicle Cream at Week 6 from Two Phase III Studies ............................................................................................. 127
Table 39: Elidel SWOT Analysis, 2013 ............................................................................. 129
Table 40: Global Sales Forecasts ($m) for Elidel, 2012–2022 ............................................... 130
Table 41: Product Profile – Cyclosporine ........................................................................... 132
Table 42: Cyclosporine SWOT Analysis, 2013 ................................................................. 134
Table 43: Global Sales Forecasts ($m) for Cyclosporine, 2012–2022 .............................. 135
Table 44: Summary of Other Therapeutic Classes for Atopic Dermatitis, 2013 .............. 136
Table 45: Product Profile – Xolair ...................................................................................... 138
Table 46: Xolair SWOT Analysis, 2013 .......................................................................... 140
Table 47: Global Sales Forecasts ($m) Xolair, 2012–2022 .................................................. 142
Table 48: Product Profile – Actimmune ............................................................................ 144
Table 49: Actimmune SWOT Analysis, 2013 ................................................................. 146
Table 50: Global Sales Forecasts ($m) Actimmune, 2012–2022 ......................................... 147
Table 51: Overall Unmet Needs in Atopic Dermatitis – Current Level of Attainment ....... 149
Table 52: Clinical Unmet Needs in Atopic Dermatitis – Gap Analysis, 2013 ..................... 156
Table 53: Atopic Dermatitis – Clinical Trials by Phase and Status, 2013 ......................... 161
Table 54: Late-Stage Atopic Dermatitis Pipeline, 2013 ................................................... 161
Table 55: Comparison of Therapeutic Classes in Development for Atopic Dermatitis, 2013 .................................................................................................................. 163
Table 56: Product Profile – Dupilumab ............................................................................ 165
Table 57: Ongoing Clinical Trials of Dupilumab in Atopic Dermatitis Patients, as of September 2013 ................................................................. 167
Table 58: Dupilumab SWOT Analysis, 2013 ................................................................... 172
Table of Contents

Table 59: Global Sales Forecasts ($m) for Dupilumab, 2012–2022 ................................................................. 173
Table 60: Product Profile – AN2728 .................................................................................................................. 175
Table 61: Efficacy Results for AN2728 in Mild to Moderate Adolescent Atopic Dermatitis Patients (Day 29) . 176
Table 62: AN2728 SWOT Analysis, 2013 ........................................................................................................ 181
Table 63: Global Sales Forecasts ($m) for AN2728, 2012–2022 ................................................................. 184
Table 64: Phase II and Phase I Atopic Dermatitis Pipeline, 2013 ................................................................. 184
Table 65: Key Companies in the Atopic Dermatitis Market, 2013 ................................................................. 187
Table 66: Astellas Pharma’s Atopic Dermatitis Portfolio Assessment, 2013 .............................................. 192
Table 67: Astellas Pharma SWOT Analysis, 2013 .......................................................................................... 192
Table 68: Meda’s Atopic Dermatitis Portfolio Assessment, 2013 ................................................................. 194
Table 69: Meda SWOT Analysis, 2013 ........................................................................................................... 194
Table 70: Regeneron’s Atopic Dermatitis Portfolio Assessment, 2013 ........................................................... 196
Table 71: Regeneron SWOT Analysis, 2013 .................................................................................................... 196
Table 72: Anacor’s Atopic Dermatitis Portfolio Assessment, 2013 .............................................................. 198
Table 73: Anacor’s SWOT Analysis, 2013 ....................................................................................................... 199
Table 74: Global Sales Forecasts ($m) for Atopic Dermatitis, 2012–2022 ..................................................... 202
Table 75: Global Atopic Dermatitis Market – Drivers and Barriers, 2012–2022 ........................................... 204
Table 76: Sales Forecasts ($m) for Atopic Dermatitis in the US, 2012–2022 ................................................. 211
Table 77: Key Events Impacting Sales for Atopic Dermatitis in the US, 2012–2022 ................................. 212
Table 78: Atopic Dermatitis Market in the US – Drivers and Barriers, 2012–2022 ....................................... 213
Table 79: Sales Forecasts ($m) for Atopic Dermatitis in France, 2012–2022 ................................................ 217
Table 80: Key Event Impacting Sales for Atopic Dermatitis in France, 2012–2022 ................................. 218
Table 81: Atopic Dermatitis Market in France – Drivers and Barriers, 2012–2022 ..................................... 219
Table 82: Sales Forecasts ($m) for Atopic Dermatitis in Germany, 2012–2022 ............................................ 223
Table of Contents

Table 83: Key Event Impacting Sales for Atopic Dermatitis in Germany, 2012–2022 ............................................. 224
Table 84: Atopic Dermatitis Market in Germany – Drivers and Barriers, 2012–2022 .................................................. 225
Table 85: Sales Forecasts ($m) for Atopic Dermatitis in Italy, 2012–2022 ................................................................. 229
Table 86: Key Event Impacting Sales for Atopic Dermatitis in Italy, 2012–2022 ......................................................... 230
Table 87: Atopic Dermatitis Market in Italy – Drivers and Barriers, 2012–2022 ....................................................... 231
Table 88: Sales Forecasts ($m) for Atopic Dermatitis in Spain, 2012–2022 ............................................................... 234
Table 89: Key Event Impacting Sales for Atopic Dermatitis in Spain, 2012–2022 .................................................... 235
Table 90: Atopic Dermatitis Market in Spain – Drivers and Barriers, 2012–2022 .................................................. 236
Table 91: Sales Forecasts ($m) for Atopic Dermatitis in the UK, 2012–2022 ............................................................ 239
Table 92: Key Event Impacting Sales for Atopic Dermatitis in the UK, 2012–2022 .................................................. 240
Table 93: Atopic Dermatitis Market in the UK – Drivers and Barriers, 2012–2022 ........................................ 241
Table 94: Sales Forecasts ($m) for Atopic Dermatitis in Japan, 2012–2022 ............................................................ 245
Table 95: Key Event Impacting Sales for Atopic Dermatitis in Japan, 2012–2022 .................................................. 246
Table 96: Atopic Dermatitis Market in Japan – Drivers and Barriers, 2012–2022 ............................................. 247
Table 97: Sales Forecasts ($m) for Atopic Dermatitis in China, 2012–2022 ............................................................ 251
Table 98: Key Event Impacting Sales for Atopic Dermatitis in China, 2012–2022 ................................................ 252
Table 99: Atopic Dermatitis Market in China – Drivers and Barriers, 2012–2022 .............................................. 253
Table 100: Sales Forecasts ($m) for Atopic Dermatitis in India, 2012–2022 ............................................................ 255
Table 101: Key Event Impacting Sales for Atopic Dermatitis in India, 2012–2022 ................................................ 256
Table 102: Atopic Dermatitis Market in India – Drivers and Barriers, 2012–2022 ............................................ 257
Table 103: Key Launch Dates ........................................................................................................................................... 278
Table 104: Key Patent Expiries ....................................................................................................................................... 279
Table 105: Physicians Surveyed, By Country ............................................................................................................. 285
# Table of Contents

## 1.2 List of Figures

- **Figure 1:** Immunologic Pathway Involved in Healthy, Acute Atopic Dermatitis, and Chronic Atopic Dermatitis Skin .................................................................................................................................29
- **Figure 2:** All Markets, Prevalent Cases of Lifetime Atopic Dermatitis, All Ages, Both Sexes, N (Millions), 2012–2022.................................................................................................................................................................65
- **Figure 3:** All Markets, Prevalent Cases of Lifetime Atopic Dermatitis, by Age, N (Millions), 2012 ........................................................................68
- **Figure 4:** All Markets, Prevalent Cases of Lifetime Atopic Dermatitis, by Sex, N (Millions), 2012................................................70
- **Figure 5:** All Markets, Age-Standardized Prevalence of Lifetime Atopic Dermatitis, All Ages, Both Sexes, %, 2012 ..................................................................................................................................................................71
- **Figure 6:** All Markets, Prevalent Cases of Lifetime Atopic Dermatitis by Severity, All Ages, Both Sexes, N (Millions), 2012.................................................................................................................................73
- **Figure 7:** Flow Chart of the Diagnosis and Management of Atopic Dermatitis ........................................................................................................80
- **Figure 8:** Atopic Dermatitis Therapeutics – Clinical Trials by Country, 2013........................................................................................................160
- **Figure 9:** Competitive Assessment of Late-Stage Pipeline Agents in Atopic Dermatitis, 2012–2022..........................................................162
- **Figure 10:** Company Portfolio Gap Analysis in Atopic Dermatitis, 2012–2022.................................................................................................187
- **Figure 11:** Global Sales for Atopic Dermatitis by Region, 2012–2022........................................................................................................203
- **Figure 12:** Sales for Atopic Dermatitis in the US by Drug Class, 2012–2022................................................................................................212
- **Figure 13:** Sales for Atopic Dermatitis in France by Drug Class, 2012–2022.................................................................................................218
- **Figure 14:** Sales for Atopic Dermatitis in Germany by Drug Class, 2012–2022.................................................................................................224
- **Figure 15:** Sales for Atopic Dermatitis in Italy by Drug Class, 2012–2022 .................................................................................................230
- **Figure 16:** Sales for Atopic Dermatitis in Spain by Drug Class, 2012–2022 .................................................................................................235
- **Figure 17:** Sales for Atopic Dermatitis in the UK by Drug Class, 2012–2022.................................................................................................240
- **Figure 18:** Sales for Atopic Dermatitis in Japan by Drug Class, 2012–2022.................................................................................................246
Table of Contents

Figure 19: Sales for Atopic Dermatitis in China by Drug Class, 2012–2022 .................................................................252
Figure 20: Sales for Atopic Dermatitis in India by Drug Class, 2012–2022 .................................................................256
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). PharmaPoint: Rheumatoid Arthritis - Global Drug Forecast and Market Analysis Event-Driven Update, July 2013, GDHC60PIDR

2.3 Upcoming Related Reports

Appendix

11.8 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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