



GlobalData»
PharmaPoint

**ATOPIC DERMATITIS –
US DRUG FORECAST AND MARKET ANALYSIS TO
2022**

Executive Summary

Sales for Atopic Dermatitis 2012–2022 in US

The US Atopic dermatitis market was worth approximately \$1.35 billion in 2012, with a projected compound annual growth rate (CAGR) of 4.37% due to increase in total sales to \$2.70 billion in 2022.

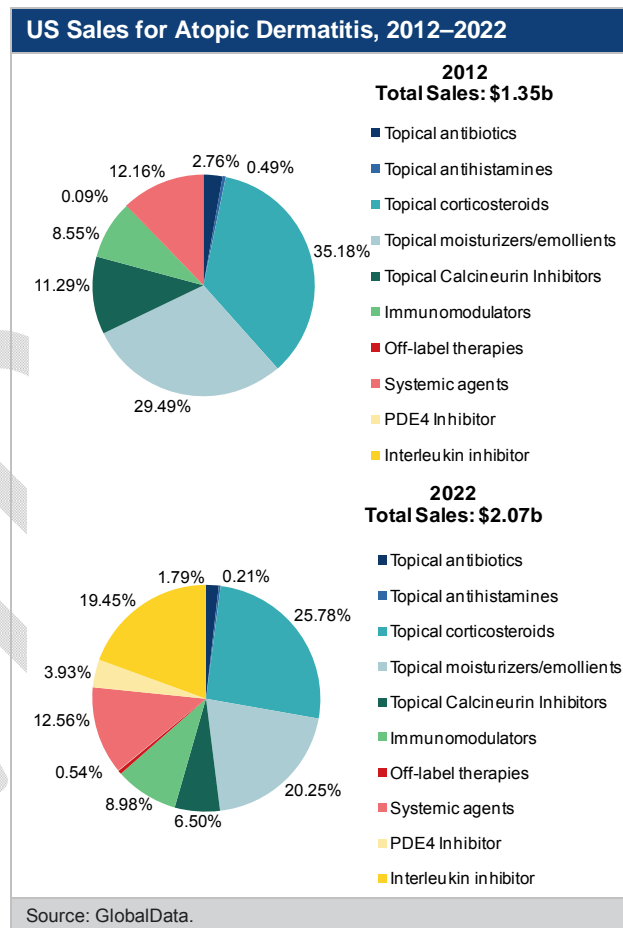
Major drivers of market growth over this forecast period are:

- Drugs that currently require high to intermediate co-pay and/or prior authorization may benefit from healthcare reforms.
- Publication of new clinical practice parameters in January 2013 associated with the anticipated rise in systemic immunomodulators uptake over the forecast period.

Major barriers to the growth of the Atopic dermatitis market are:

- Increasing emphasis on lowering healthcare expenditure may prove a hurdle for developers hoping to command premium prices.
- The saturated, highly genericized nature of this atopic dermatitis market may deter developers.

The figure below illustrates the US atopic dermatitis 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

Table of Contents

1 Table of Contents

1 Table of Contents	5
1.1 List of Tables	9
1.2 List of Figures	10
2 Introduction	11
2.1 Catalyst	11
2.2 Related Reports	11
2.3 Upcoming Related Reports	12
3 Disease Overview	13
3.1 Etiology and Pathophysiology	13
3.1.1 Etiology	13
3.1.2 Pathophysiology	14
3.2 Symptoms	18
4 Disease Management	20
4.1 Diagnosis	20
4.2 Treatment Overview	22
4.3 US	28
4.3.1 Diagnosis	28
4.3.2 Clinical Practice	30
5 Competitive Assessment	33
5.1 Overview	33
5.2 Strategic Competitor Assessment	34

Table of Contents

5.3	Product Profiles – Major Brands	35
5.3.1	Protopic (tacrolimus).....	35
5.3.2	Elidel.....	42
5.3.3	Cyclosporine (numerous generic names).....	47
5.3.4	Other Therapeutic Drug Classes Used in Atopic Dermatitis	50
5.4	Product Profiles – Off-Label Therapies	52
5.4.1	Actimmune (interferon gamma-1b)	52
6	Opportunity and Unmet Need	56
6.1	Overview	56
6.2	Unmet Needs	57
6.2.1	A Systemic Drug for Severe Recalcitrant Patients	57
6.2.2	Tests that Stratify Patients and Allow for a Tailored Treatment Approach	59
6.2.3	A Drug that Effectively Controls Patients' Pruritus.....	60
6.2.4	Further Research into the Pathophysiology of Atopic Dermatitis	61
6.2.5	A Drug that Induces Disease Remission.....	62
6.2.6	Improved Quality of Life for Both Patients and their Carers.....	63
6.3	Unmet Needs Gap Analysis.....	63
6.4	Opportunities.....	65
6.4.1	Increase Treatment Armamentarium for Severe Recalcitrant Patients	65
6.4.2	Predictive Tests for Patient Stratification.....	65
6.4.3	More Therapeutic Options that Address Patients' Pruritus.....	66
7	Pipeline Assessment	67
7.1	Overview	67

Table of Contents

7.2 Promising Drugs in Clinical Development	69
7.2.1 Dupilumab (SAR231893/ REGN668)	70
7.2.2 AN2728	80
7.2.3 Phase II Pipeline Products	88
8 Market Outlook	89
8.1 Global Drivers and Barriers	89
8.1.1 Driver: Anticipated launch of the first biologic for the treatment of moderate to severe disease	89
8.1.2 Driver: The underserved severe refractory patient segment presents an untapped market opportunity	90
8.1.3 Driver: A drug that is able to target two or more atopic diseases would gain a foothold in these markets	90
8.1.4 Driver: Atopic dermatitis presents an attractive patient population for drug developers ...	90
8.1.5 Driver: Restoring skin barrier function remains a key goal of disease management, meaning a continued need for moisturizers and topical agents	91
8.1.6 Barrier: First to second line of therapy is dominated by cheap, genericized topical drugs which create significant obstacles for novel drugs hoping to penetrate the market	92
8.1.7 Barrier: The largest atopic dermatitis patient segment – mild disease – can be well-controlled on most forms of topical therapy	92
8.1.8 Barrier: Pediatric sufferers are the largest patient group and pose a high bar in terms of safety for new products	92
8.1.9 Barrier: The complexity of the multiple etiologies that lead to atopic dermatitis means that treatment outcomes with existing drugs are not universal across all patient groups	93
8.1.10 Barrier: A significant proportion of patients experience disease remission in their early adolescent years and this may occur without drug therapy	94

Table of Contents

8.2	US	94
8.2.1	Forecast	94
8.2.2	Key Events	97
8.2.3	Drivers and Barriers	98
9	Appendix	101
9.1	Bibliography	101
9.2	Abbreviations	107
9.3	Methodology	109
9.4	Forecasting Methodology	109
9.4.1	Diagnosed Atopic Dermatitis Patients	109
9.4.2	Percent Drug-treated Patients	110
9.4.3	Drugs Included in Each Therapeutic Class	110
9.4.4	Launch and Patent Expiry Dates	110
9.4.5	General Pricing Assumptions	111
9.4.6	Individual Drug Assumptions	112
9.4.7	Generic Erosion	114
9.4.8	Pricing of Pipeline Agents	114
9.5	Physicians and Specialists Included in this Study	115
9.6	Primary Research – Prescriber Survey	116
9.7	About the Authors	117
9.7.1	Author	117
9.7.2	Global Head of Healthcare	118
9.8	About GlobalData	119

Table of Contents

9.9 Disclaimer	119
----------------------	-----

1.1 List of Tables

Table 1: Symptoms of Atopic Dermatitis.....	19
Table 2: Treatment Guidelines for Atopic Dermatitis.....	25
Table 3: Most Prescribed Drugs for Atopic Dermatitis by Severity in the Global Markets, 2013	27
Table 4: Referral Rates to a US Dermatologist, Split by Severity and Specialist Type, 2013.....	29
Table 5: Key Metrics Relating to the Diagnosis, Relapse and Remission Rates of Atopic Dermatitis in the US, 2013	30
Table 6: Leading Treatments for Atopic Dermatitis, 2013	35
Table 7: Product Profile – Protopic.....	37
Table 8: 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.....	38
Table 9: Protopic SWOT Analysis, 2013	41
Table 10: Product Profile – Elidel.....	43
Table 11: Combined Clinical Efficacy Results of Elidel versus Vehicle Cream at Week 6 from Two Phase III Studies	44
Table 12: Elidel SWOT Analysis, 2013.....	46
Table 13: Product Profile – Cyclosporine	48
Table 14: Cyclosporine SWOT Analysis, 2013	50
Table 15: Summary of Other Therapeutic Classes for Atopic Dermatitis, 2013	51
Table 16: Product Profile – Actimmune	53
Table 17: Actimmune SWOT Analysis, 2013.....	55
Table 18: Overall Unmet Needs in Atopic Dermatitis – Current Level of Attainment.....	57
Table 19: Clinical Unmet Needs in Atopic Dermatitis – Gap Analysis, 2013.....	64

Table of Contents

Table 20: Late-Stage Atopic Dermatitis Pipeline, 2013	69
Table 21: Comparison of Therapeutic Classes in Development for Atopic Dermatitis, 2013	70
Table 22: Product Profile – Dupilumab	72
Table 23: Ongoing Clinical Trials of Dupilumab in Atopic Dermatitis Patients, as of September 2013	74
Table 24: Dupilumab SWOT Analysis, 2013	79
Table 25: Product Profile – AN2728	81
Table 26: Efficacy Results for AN2728 in Mild to Moderate Adolescent Atopic Dermatitis Patients (Day 29) ...	82
Table 27: AN2728 SWOT Analysis, 2013	87
Table 28: Phase II and Phase I Atopic Dermatitis Pipeline, 2013	88
Table 29: Global Atopic Dermatitis Market – Drivers and Barriers, 2012–2022	89
Table 30: Sales Forecasts (\$m) for Atopic Dermatitis in the US, 2012–2022	96
Table 31: Key Events Impacting Sales for Atopic Dermatitis in the US, 2012–2022	97
Table 32: Atopic Dermatitis Market in the US – Drivers and Barriers, 2012–2022	98
Table 33: Key Launch Dates	110
Table 34: Key Patent Expiries	110
Table 35: Physicians Surveyed, By Country	116

1.2 List of Figures

Figure 1: Immunologic Pathway Involved in Healthy, Acute Atopic Dermatitis, and Chronic Atopic Dermatitis Skin	16
Figure 2: Flow Chart of the Diagnosis and Management of Atopic Dermatitis	23
Figure 3: Competitive Assessment of Late-Stage Pipeline Agents in Atopic Dermatitis, 2012–2022	69
Figure 4: Sales for Atopic Dermatitis in the US by Drug Class, 2012–2022	97

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 market place; 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
- GlobalData (2013). Atopic Dermatitis - Germany Drug Forecast and Market Analysis to 2022, November 2013, GDHC185CFR

Introduction

- GlobalData (2013). Atopic Dermatitis - Italy Drug Forecast and Market Analysis to 2022, November 2013, GDHC186CFR
- GlobalData (2013). Atopic Dermatitis - Spain Drug Forecast and Market Analysis to 2022, November 2013, GDHC187CFR
- GlobalData (2013). Atopic Dermatitis - UK Drug Forecast and Market Analysis to 2022, November 2013, GDHC188CFR
- GlobalData (2013). Atopic Dermatitis - Japan Drug Forecast and Market Analysis to 2022, November 2013, GDHC189CFR
- 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). Dupilumab (Atopic Dermatitis) - Forecast and Market Analysis to 2022, November 2013, GDHC296DFR.
- GlobalData (2013). AN2728 (Atopic Dermatitis) - Forecast and Market Analysis to 2022, November 2013, GDHC297DFR
- GlobalData (2013). Atopic Dermatitis - Current and Future Players. GDHC1024FPR

2.3 Upcoming Related Reports

- GlobalData (2013). OpportunityAnalyzer: Acne - Opportunity Analysis and Forecasts to 2017, GDHC011POA

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.

9.9 Disclaimer

All Rights Reserved.

No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photocopying, recording or otherwise, without the prior permission of the publisher, GlobalData.