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GlobalData
OpportunityAnalyzer

ACNE VULGARIS – OPPORTUNITY ANALYSIS AND FORECASTS TO 2018

Executive Summary

Below Table presents the key metrics for acne in the six major pharmaceutical markets (US, France, Germany, Italy, Spain, UK) covered in this report during the forecast period from 2012–2018.

Key Metrics in Six Major Pharmaceutical Markets for Acne, 2012–2018	
2012 Epidemiology	
Prevalent Population (6MM)	103.9 million
*Treated Population (6MM)	11.3 million
2012 Market Sales	
US	$2,075.4m
5EU	$207.0m
Total	**$2,282.4m**
Key Events (2012–2018)	**Level of Impact**
Label expansion of Epiduo in pediatric population	↑↑
TAP Epiduo program	↑↑
Launch of ASC-J9	↑↑
Launch of Visonac	↑
2018 Market Sales	
US	$2,643.5m
5EU	$224.5m
Total	**$2,868.0m**

Source: GlobalData.

For the purposes of this report, the six major pharmaceutical markets = US and 5EU (France, Germany, Italy, Spain, and the UK).

*Treated patients include those who seek treatment from a physician, typically a dermatologist, and receive prescription medication. Those treated with over-the-counter (OTC) products were not included in GlobalData's assessment of the acne market.

Steady and Sustained Growth in the US and EU Acne Markets Expected Between 2012–2018

GlobalData estimates the 2012 pharmacological therapy sales for acne to total approximately $2.3 billion across the six major pharmaceutical markets (6MM) covered within this report: the US, France, Germany, Italy, Spain, and the UK. The US contributes 91% of these sales, generating an estimated $2.1 billion in 2012. With $207.0m in sales from the 5EU, Germany was the largest market with an estimated $54.3m in sales in 2012.

By the end of the forecast period in 2018, acne sales are forecast to reach over $2.8 billion, growing at a compound annual growth rate (CAGR) of 3.9% over the six-year forecast period. The majority of sales will come from the US, which will maintain its 2012 lead and command 93% of the market in 2018. A substantial amount of growth in that market is attributed to the rapid uptake of Galderma's Epiduo (benzoyl peroxide and adapalene) for moderate patients and the continued success of isotretinoin. The anticipated launch of AndroScience's androgen receptor degradation enhancer, ASC-J9, in 2017 will add a new molecular entity to the market for acne for the first time in approximately 30 years. Photocure's Visonac is also expected to launch in 2017, adding photodynamic therapies to the treatment options for acne patients. Together, these products are expected to add approximately $200m in sales to the acne market in 2018.

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Major drivers of growth in the acne market over the forecast period include:

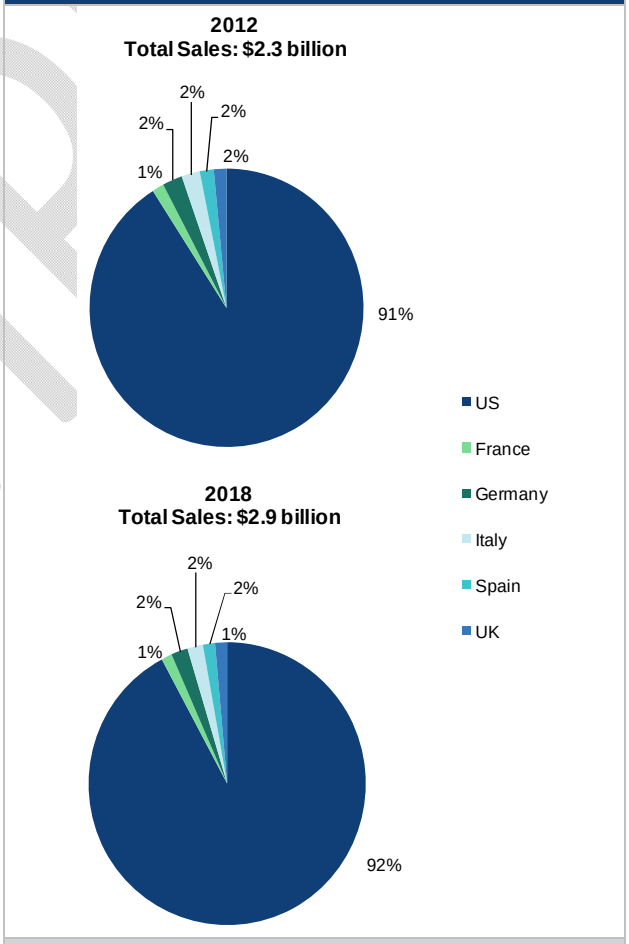
- Launch of AndroScience's ASC-J9 in 2017, a therapeutic that is highly anticipated in the previously stagnant acne market and will make hormonal therapies available to males with acne. GlobalData expects that ASC-J9 will be subject to rapid uptake.
- Continued success and uptake of Galderma's Epiduo, with label expansion into the pediatric population and launch of the Epiduo TAP program to improve patient compliance.
- Launch of Photocure's Visonac in 2017; potentially the first photodynamic therapy for use in acne.

Major barriers to the growth of the acne market during the forecast period include:

- Increasing emphasis for acne therapies to demonstrate cost-effectiveness, particularly in a number of 5EU countries. Austerity measures in Europe will pose a challenge for pharmaceutical companies trying to justify high prices of novel therapies and reformulations when compared with the cost-effective generic drugs that have a long history of use in acne.
- Pharmaceutical companies are not inclined to invest in acne research, viewing R&D in this area as a poor return on investment. This is especially true when compared with therapies such as biologic agents that are used in other dermatology indications such as psoriasis and garner lucrative sales. Increased regulatory rigidness has put pressure on the need for longer clinical trials to reflect the chronic nature of acne.

Below Figure illustrates acne sales for the six major markets (US and 5EU) during the six-year forecast period from 2012–2018.

Global Sales for Acne by Region, 2012–2018



Source: GlobalData.

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Pharmaceutical Giants Revisiting the Acne Arena, Deploying Notable R&D Strategies to Attain Market Share

Despite its considerable patient population (estimated at 103.9 million in 2012 across the US and 5EU), the acne market has often been overlooked and has remained stagnant for the past few decades, with no novel drugs entering the arena. The lack of dedicated research programs has been attributed to pharmaceutical companies viewing topicals, the mainstay of acne therapy, as being inexpensive with a poor return on investment. Instead, the market has shifted towards reformulations of existing products and/or fixed-dose combination therapies. Examples of the latter include combination products by key dermatology players, such as Galderma's Epiduo (adapalene and benzoyl peroxide), GlaxoSmithKline's (GSK) Duac (benzoyl peroxide and clindamycin phosphate), and Astellas' Zineryt (zinc acetate and erythromycin). By simplifying treatment, studies have demonstrated that compliance, and therefore efficacy, can be improved by the synergistic effect of combining two active ingredients. Meanwhile, novel formulations include microsponges, liposomes, nanoemulsions, aerosol foams, subantimicrobial-dose doxycycline and extended-release minocycline. Reformulations are a low-risk strategy for Big Pharma, compared with investments into new molecular entities for acne.

Label expansions in acne have also been explored as a lifecycle management strategy, as exhibited by Galderma's entry into the large and untapped pediatric market. In February 2013, Galderma obtained a label expansion for children under 12 years of age for its lead product, Epiduo. The need for an acne treatment for children younger than 12 years of age had previously been overlooked due to safety concerns, the sensitive nature of skin in young individuals, and the rarity of the condition in children. However, recent evidence suggests that acne is more prevalent in younger individuals than it once was, potentially due to the decreasing age of onset for puberty. Targeting the previously untapped pediatric market is a strategy that GlobalData expects will be followed by other dermatology companies during the coming decade.

Another corporate trend is the strategic acquisition of key dermatology products by Big Pharma. A notable event in 2009 involved the acquisition of Stiefel, a leading dermatology company, by GSK for $3.6 billion.

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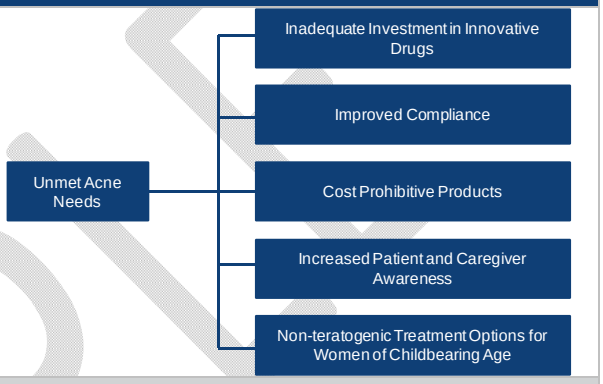
Innovative Products in Acne Should Focus on Cost-Effectiveness, Potential to Improve Compliance

The biggest unmet needs in acne include the need for new and innovative products, for improved compliance, and for less expensive products relative to existing therapies. Historically, pharmaceutical companies have been reluctant to enter the acne market due to the poor return on investment in this competitive landscape. This attitude has inhibited progress toward developing disease-modifying agents, and agents with more long-lasting effects. However, the acne landscape is expected to change in the near- to long-term, with the launch of AndroScience's ASC-J9 and Photocure's Visonac, and additional companies involved in research for innovative acne products.

Although low-cost products are available for acne, these typically contain a single active ingredient that is not very effective for acne, especially in more severe cases. Use of two or more topical treatment options for acne is challenging and adherence to these treatments is often very poor. This is more pronounced in adolescent sufferers, who often struggle to incorporate the various treatment regimens into their daily routine, viewing them as time-consuming, inconvenient and messy. Pharmaceutical companies have responded by combining two active ingredients into specially formulated combination products; however, the costs of these treatments are prohibitive. As such, there remains a need for a cost-effective combination product that will allow better patient compliance.

Below Figure provides an overview of the existing unmet needs for acne.

Overview of Unmet Acne Needs



Source: GlobalData.

Acne Market to Experience a Period of Investment in Research

A continued unmet need for acne is the need for new and innovative products to treat the underlying condition. Also necessary is further investment of time and resources into understanding the disease pathophysiology. The goal of these investigations would be to develop molecules that can specifically target critical pathways in the acne pathophysiology. There is a move in the acne field towards treatment with biologics, particularly in targeted monoclonal antibodies (mAbs), with two mAbs under development, XBiotech's Phase II mAb against interleukin (IL)-1α, and Xoma's Phase II mAb against IL-1β. The targeted approach offered by biologics could allow superior specificity

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for the treatment of acne compared with other therapy options.

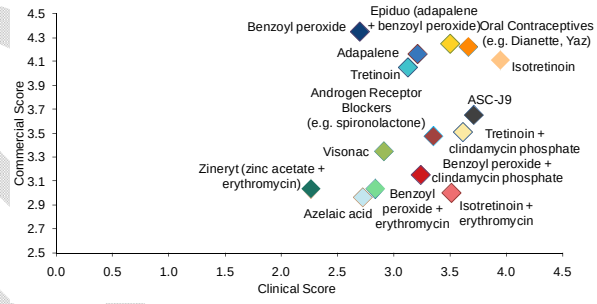
Focusing on small molecules, hormonal antagonists such as androgen- and estrogen-based molecules are also being investigated. Given the acne market's substantial patient pool and increasing understanding of the disease's pathophysiology, GlobalData expects continued interest in the acne market from biotechs and pharmaceutical companies over the coming decade.

AndroScience's ASC-J9 to Renew Hope for More Disease-Modifying Therapies That Can Further Challenge the Established Acne Landscape

There is considerable excitement around the potential of AndroScience's ASC-J9 in the acne market. ASC-J9 not only represents a novel mechanism of action, but also its entry to the market will be a much-needed addition to a stagnant market. ASC-J9 functions to target the principal hormone receptor associated with acne, the androgen receptor, a cause of acne in both men and women. In addition to use in female patients with moderate to severe acne, ASC-J9 will allow penetration into the male acne market, something not achieved with currently available hormonal treatments. Furthermore, due to its topical formulation, systemic side effects are likely to be reduced, if not altogether ameliorated. When compared with isotretinoin, the current standard for patients with severe acne, ASC-J9 has a better safety profile and is not teratogenic, which poses a major barrier for isotretinoin. ASC-J9 is expected to become a major product for the treatment of patients with severe acne and is forecast to experience rapid uptake.

A competitive assessment of AndroScience's ASC-J9 and Photocure's Visonac is provided in the Figure below.

Competitive Assessment of Acne Therapies and Late-Stage Pipeline Agents in Acne, 2012–2018



Source: GlobalData.

What Do the Physicians Think?

Inadequate patient compliance is the greatest unmet need for acne, which was highlighted by key opinion leaders (KOLs) interviewed by GlobalData. This single factor has hindered the ability for patients to achieve maximum treatment benefit, given the therapeutic options currently available, and resulted in multiple failed treatment attempts.

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"Adherence is a problem in life, people just do not do what they are supposed to, and gosh, teenagers definitely do not. There are a lot of reasons people do not use their [acne] medicines. They may want to use them and just forget, they may be more bothered by the treatment than the disease. They may [chose] not use it because their parents are telling them to use it… people do not even take short-term medicine, but long-term is even harder. Putting creams on is harder than taking a pill. Systemically [treated] patients are better, not good, but better."

[US] Key Opinion Leader

Frustration was voiced at the stagnant and neglected acne market, which has suffered from pharmaceutical companies viewing it as a poor return on investment.

"It is cheaper and quicker for them [pharmaceutical companies] to come out with a reformulation and say it is a new drug. It is the same story. The last new drug for acne was isotretinoin, Accutane [in 1982]."

[EU] Key Opinion Leader

"The problem is Pharma companies are focusing on other diseases and blockbuster [drugs], they are not going to look at acne, and this is the problem with acne; there is a lot of fear about innovation."

[EU] Key Opinion Leader

KOLs highlighted the fact that acne is a chronic condition that requires patient education as a complement to drug therapy. This requires an understanding of the benefits and limitations to treatment options and a discussion between the physician and patient about realistic treatment outcomes.

"It's not just about the drug; it's the whole system of educating a patient. This is actually more important than a drug. You need to inform the patients what to [expect] and what not to expect."

[EU] Key Opinion Leader

Furthermore, KOLs highlighted that the perception of a lack of return on investment is likely the primary reason that the acne market has been neglected. That said, many were convinced that the market is beginning to change.

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"Sometime[s] the awareness in some companies is lacking, they are searching [for] heart, circulation, diabetes, cancer, [small molecules] and [for] biologics. Dermatology is not something that companies were interested in [historically]. But with big companies like Novartis coming back to acne, GSK looking carefully at it, and Sanofi going for [a] vaccine, there is a turn in the market that people realize you can make some money from [the acne market]. The world's population is increasing [and] the market is there for acne, so there is money to earn. There was a time when they didn't spend enough [time and money investigating the acne market] but I think that is changing."

[EU] Key Opinion Leader

"Dermatologists are some of the most conservative doctors ever. When the FDA decide[s] to approve [a drug], they do not think of acne as like a heart attack. You have to convince them of a very high level of safety before they are approved. Something potentially teratogenic that you want to give to teenage girls, I think they are going to have their concerns about it."

[US] Key Opinion Leader

There is considerable excitement among KOLs interviewed by GlobalData regarding AndroScience's ASC-J9 and its game-changing potential.

"In terms of mode of action, it [ASC-J9] is exactly what is needed and would be expected [of an acne drug]. There is nothing like this available at the moment for acne, [and therefore] it has to be considered novel."

[EU] Key Opinion Leader

"[An] anti-androgen topical [drug] would be a breakthrough [therapy in acne]."

[EU] Key Opinion Leader

"I see a great potential of ASC-J9 for females with late-type acne. Because those females that are not going to take anti-androgen pills, for whatever reasons, medical or physiological, they are ideal [candidates] for ASC-J9."

[EU] Key Opinion Leader

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2 Introduction

Acne vulgaris is currently the most common dermatology condition, affecting over 90% of the world's population at some point in their lifetime. As a chronic and inflammatory dermatology condition of the pilosebaceous gland, it has a multifactorial pathogenesis. Acne is typically initiated during puberty by hormonal changes and further exacerbated by genetic factors.

2.1 Catalyst

Despite its considerable patient population, the acne market has been overlooked and remained stagnant for the last decade. There has been a lack of research efforts due to the perception of a poor return on investment for topical treatments, the mainstay of acne therapy. There is an array of treatment options for acne, though with the exception of isotretinoin, most only provide symptomatic relief as opposed to a curative or disease-modifying solution. However, isotretinoin is unable to serve a significant proportion of the acne market owed to its teratogenic nature, making its prescription for women of child-bearing age problematic.

In the past decade, there has been a shift in the acne market, with greater appreciation of its patient pool and potential for a lucrative payoff. Furthermore, there has been greater stress put on the social and psychological implications of the disease, which impact patients' quality of life. As a result, R&D investments have been initiated by key pharmaceutical players.

Key strategies underway in the acne market include:

- Drive for combination therapies, for example, Galderma's Epiduo (adapalene and benzoyl peroxide), which continues to experience rapid uptake.
- Expansion of the market into the pediatric population and for late-onset acne in women.
- A push towards disease-modifying therapies; for example, launch of AndroScience's ASC-J9 androgen receptor degradation enhancer is anticipated to be a game-changer and is expected to rival isotretinoin, the current market leader for severe acne.

Introduction

2.2 Related Reports

- GlobalData (2013). EpiCast Report: Acne Vulgaris – Epidemiology Forecast to 2022, GDHCER034-13
- GlobalData (2013). PharmaPoint: Psoriasis – Global Drug Forecast and Market Analysis to 2022, May 2013, GDHC48PIDR
- GlobalData (2013). PharmaPoint: Atopic Dermatitis – Global Drug Forecast and Market Analysis to 2022, GDHC66PIDR

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, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

10.8 Disclaimer