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GlobalData
PharmaPoint

EMPAGLIFLOZIN (TYPE 2 DIABETES) - FORECAST AND MARKET ANALYSIS TO 2022

Executive Summary

Below table provides a summary of Empagliflozin for Type 2 diabetes in the 10 major pharmaceutical markets during the forecast period from 2012 – 2022.

Empagliflozin: Key Metrics in 10 Major Pharmaceutical Markets	
2022 Market Sales	
US	$287m
5EU	$50m
Japan	$17m
China	$0m
India	$0m
Brazil	$0m
Total	**$354m**

Source: GlobalData.
5EU: France, Germany, Italy, Spain, UK.

Sales for Empagliflozin in the Global Type 2 Diabetes Market

Empagliflozin sales are expected to increase from $20m upon launch in 2014 to $354m in 2022 at a Compound Annual Growth Rate (CAGR) of 33%.

Key factors affecting the uptake of Empagliflozin sales growth in the Type 2 Diabetes therapeutics market will include:

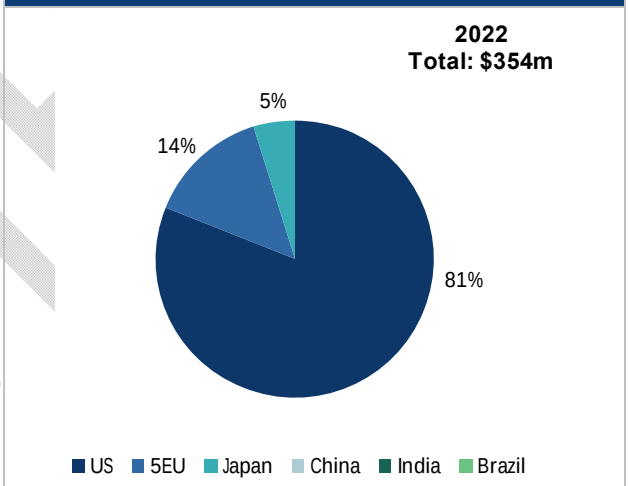
- Well tolerated and has no hypoglycaemic effect
- Available in convenient oral dosage form
- Presence of blood pressure lowering and insulin-independent effects

The major hurdles for Empagliflozin sales of the Type 2 Diabetes therapeutics market will include:

- Presence of side effects such as dehydration, genital and urinary tract infection effects
- Unknown long-term cardiovascular effects produced by inhibition of SGLT-2

The below figure illustrates the sales of Empagliflozin for Type 2 Diabetes therapeutics in the 10 major markets during the forecast period.

Sales of Empagliflozin by Region, 2022



Source: GlobalData.

Executive Summary

What Do the Physicians Think?

"I think that [the number of] people needing a second and third drug is going to increase dramatically in the next 10 years and that we will just see those numbers go up, up, up. Two things are going to drive that up. One is the expectation that we'll treat these people fairly aggressively to get their A1c down to around 7 to 7.5. The target appears to be moving based on a few of the studies, but we are not going to tolerate people after 8.5 and 9 like we used to. That's going to drive it, and second is that most people are not going to have a control over lifestyle, they are going to continue to overeat and under-exercise and they are going to see their weight continue to go up and therefore their need for more medications will go up with it. So I think [in this] the market, the sky is the limit on how much the market is going to be."

Key Opinion Leader, April 2013

"I think over the next 10 years the long-acting GLP-1 receptor agonist therapies will increase the most, because now you know the companies will be developing once-a-week treatments… Longer-acting preparations, if they are proved to be effective and safe, will be used more and more because they really do have a benefit in weight loss."

Key Opinion Leader, April 2013

"Weight change direction or level and the risk of hypoglycemia, these are strong determinants for the choice of the drug today or in the future even more."

Key Opinion Leader, April 2013

"*My biggest challenge [with type 2 diabetes] has been the lack of long-term efficacy; that the disease is complicated, the disease is resilient, and most of the agents are not potent enough to get everybody under control long enough. So, lack of efficacy and having therefore to combine medications has been my biggest challenge."*

Key Opinion Leader, April 2013

"We have SGLT-2 inhibitors, we have the long-acting GLP-1 receptor agonists, DPP-4 inhibitors, and this will be quite a choice now for physicians to find the right drugs or right combination of drugs."

Key Opinion Leader, April 2013

"The SGLT-2s and the dual PPARs are probably going to have a better impact long-term… the things that increase insulin secretion, somewhat are similar to the sulfonylureas, they are going to have hypoglycemic events, or they are going to cause people to gain weight, or they are going to burn the pancreas out… I am much less impressed with them than I am with the SGLT-2s and the dual PPARs."

Key Opinion Leader, April 2013

Executive Summary

"The whole concept of individualization of therapy is very important; it is something that we practiced for a long time. Each patient is different. We have to give quite a combination of drugs to each patient depending on various factors."

Key Opinion Leader, April 2013

"I think the use of metformin [first-line therapy] will not change. I think it will continue, but the use of sulfonylureas will decline… I think they will be gradually replaced by newer therapies, some available now, some will be available later in the future."

Key Opinion Leader, April 2013

"The endocrinologist recognized that being overly conservative can hurt the patients, so in other words if you say that there is no long-term data for new drug that can prevent complications, you can't wait. I am not going to wait for 10 years for randomized controlled trials to show me that injection will dispel. If I know that it prevents complications, I am happy. We are not going to have 300 randomized controlled trials checking all possible combinations because now it's so many combinations of drugs you could test. So, me and other colleagues, what we have been doing really for years is that we know what works and we know what doesn't work … we know that we don't have data but we really need to prescribe certain therapies without data, knowing what the advantages are. I think that the newer guidelines fully acknowledge the reality, that's what endocrinologists are doing, I think the guidelines didn't set up anything new, they are just catching up with what physicians are doing already."

Key Opinion Leader, April 2013

Table of Contents

1 Table of Contents

Table of Contents

Table of Contents

Table of Contents

1.1 List of Tables

1.2 List of Figures

2 Introduction

2.1 Catalyst

The American Diabetes Association's 73rd Scientific Sessions, held in June 2013, represented an opportunity for the major industry players with a stake in the type 2 diabetes market to showcase their diabetes drugs' latest results. In particular, Eli Lilly presented new data on its investigational drugs, dulaglutide and empagliflozin, as well as confirmed its development and regulatory timescale for biosimilar insulin products, including a version of Sanofi's Lantus. Another key takeaway from the ADA sessions was Sanofi's encouraging data on its Lantus follow-on product, aimed at protecting its Lantus franchise.

While the global type 2 diabetes markets is crowded with inexpensive generics and marked by a pipeline filled with me-too drugs, GlobalData expects this market to undergo substantial growth between 2012 and 2022, more than doubling over this period. The main driver of this enormous expansion will be the dramatic increase in disease prevalence, which is attributable to increased life expectancy and an increasingly sedentary and stressful lifestyle. The second largest driver will be the physicians' efforts to delay disease progression and reduce the costly burden of diabetic complications through the use of combination therapies and novel branded drugs. In the emerging markets in particular, uptake of branded drugs will increase due to rapid economic growth.

Despite the high number of marketed therapies, this market is still experiencing large unmet needs and it has a significant growth opportunity for new patent-protected products. Metformin will remain the first-line therapy for type 2 diabetes due to physicians' familiarity with it and the availability of long-term data, but the usage of sulfonylureas, another front-line therapy, will gradually be replaced over the next 10 years by novel therapies with improved side-effect profiles. The battle for second- or third-line therapy will involve DPP-4 inhibitors, GLP-1 receptor agonists, SGLT-2 inhibitors and other upcoming novel therapies. Of all currently marketed classes, GLP-1 receptor agonists will experience the fastest growth due to their weight-loss effects and the skyrocketing epidemic of obesity. With the recent therapeutic guidelines putting emphasis on a patient-tailored approach in treating type 2 diabetes, pharmaceutical companies will achieve considerable success with their me-too drugs. In the future, companies may choose to focus not on blockbuster medicines, but rather on niche drugs that are aimed at smaller groups.

Introduction

2.2 Related Reports

- GlobalData (2013). Actos (Type 2 Diabetes) –Forecast and Market Analysis to 2022, July, 2013, GDHC214DFR.
- GlobalData (2013). Byetta (Type 2 Diabetes) –Forecast and Market Analysis to 2022, July, 2013, GDHC215DFR.
- GlobalData (2013). Victoza (Type 2 Diabetes) –Forecast and Market Analysis to 2022, July, 2013, GDHC216DFR.
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Introduction

- GlobalData (2013). Invokana (Type 2 Diabetes) –Forecast and Market Analysis to 2022, July, 2013, GDHC226DFR.
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Introduction

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Introduction

- GlobalData (2013). Type 2 Diabetes – Brazil Drug Forecast and Market Analysis to 2022. GDHC142CFR.
- GlobalData (2013). Type 2 Diabetes – Current and Future Players. GDHC1018FPR.

Appendix

9.7 About GlobalData

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

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

9.8 Disclaimer