



GlobalData»
PharmaPoint

**KADCYLA (HER2-POSITIVE BREAST CANCER) -
FORECAST AND MARKET ANALYSIS TO 2023**

Executive Summary

The table below presents the key metrics for Kadcylla for human epidermal growth factor receptor type 2 (HER2)-positive breast cancer in the eight major pharmaceutical markets (US, France, Germany, Italy, Spain, UK, Japan, and China) during the forecast period from 2013–2023.

Kadcyla: Key Metrics in the 7MM and China for HER2-Positive Breast Cancer Markets, 2013–2023	
2013 Market Sales	
US	\$236m
5EU	\$7m
Japan	-
China	-
Total	\$243m
Key Events (2013–2023)	
Launch of Kadcylla (ado-trastuzumab emtansine, T-DM1) in the adjuvant setting in 2019	↑↑
2023 Market Sales	
US	\$3484m
5EU	\$1,161m
Japan	\$86m
China	\$213m
Total	\$4,943m
Source: GlobalData	
7MM= US, France, Germany, Italy, Spain, UK and Japan	
5EU = France, Germany, Italy, Spain, and UK	

Sales for Kadcylla in the HER2-Positive Breast Cancer Market

In the 8MM in this report, GlobalData valued Kadcylla for HER2-positive breast cancer market at \$243 million in 2013, and expects the market to increase to \$4,943 million in 2023, at a Compound Annual Growth Rate (CAGR) of 35.1%. The top drivers of growth for Kadcylla in HER2-positive breast cancer market during the forecast period include:

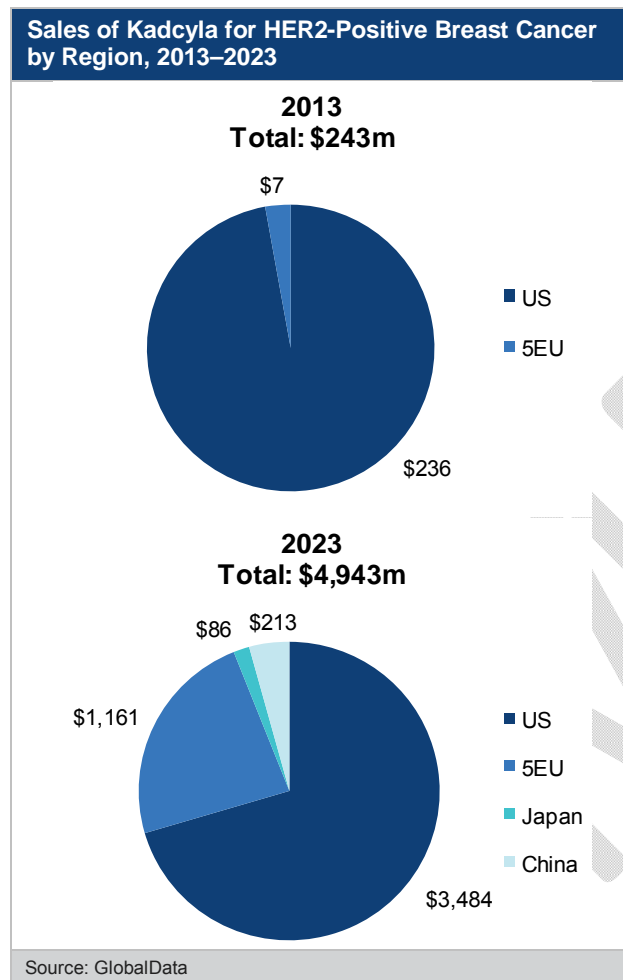
- The results of the TH3RESA trial showed Kadcylla to be effective in advanced HER2-positive metastatic breast cancer patients.
- Monotherapy.
- Excellent tolerability, with few side effects.

Major barriers to growth for Kadcylla in the HER2-positive breast cancer market include:

- IV administration is not as convenient as an oral agent.
- High cost of treatment
- Clinical trials did not compare Kadcylla to Perjeta+Herceptin, the accepted first-line treatment.

Executive Summary

The figure shown below provides the global sales of Kadcylla for HER2-positive breast cancer during the forecast period.



What Do Physicians Think?

KOLs praised the efficacy of Kadcylla for metastatic disease, and are already anticipating its use in earlier settings.

“The effectiveness with the lack of toxicity is one of the big attractions of T-DM1 [Kadcyla].”

OUS Key Opinion Leader, April 2014

“I am a big believer in TDM-1. I did lots of those first trials with TDM-1, and I think it’s a great drug. And so, we are very hopeful that it’s going to have positive results in the different adjuvant trials that are underway.”

US Key Opinion Leader, January 2014

“We are hopeful that HER2-positive disease will be essentially cured in the next decade, or shorter, by the new agents that we have, that all clearly showed a dramatic benefit in patients who had received prior trastuzumab in the case of Kadcylla, and in those who hadn’t [been treated with prior trastuzumab] in the case of Perjeta. I mean, there was clearly an improved survival. So, that suggests that by adding those agents in some form in the early-stage setting, that we will cure more patients with HER2-positive disease.”

US Key Opinion Leader, January 2014

Executive Summary

“If [Kadcyla] turned out to be an active agent in the early-stage setting, that’s where it will get used. I mean, ultimately, there is not going to be a desire to hold back on drugs — [that is,] to use better drugs later. We are going to want to use our best drugs up front. If T-DM1 is better, and we can use T-DM1 up front and have a better result in terms of efficacy, and have a lower toxicity, then that’s what will be used.”

US Key Opinion Leader, December 2013

KOLs still believe there is room for TKIs, especially after disease progression following the use of anti-HER2 mAbs. Neratinib, in particular, is a TKI under development that they are looking forward to using in the metastatic setting.

“What I tell people is, at some point, you should be using a lapatinib combination, either with Herceptin or with Xeloda [(capecitabine)], and then you should be using whatever other chemotherapies with Herceptin that you have still left — eribulin, navelbine, gemcitabine — and I don’t think the order matters.”

US Key Opinion Leader, January 2014

“In my opinion, it [Tykerb] has always been a very promising drug, but the promise...has never been held in the clinic, probably because of scheduling, which doesn’t allow the full potential of anti-tumor activity because you have to stop at a certain point because of unacceptable toxicity. The same is for neratinib or afatinib; probably playing with the schedule and ensuring optimal exposure of the tumor to optimal saturation of receptors may really reveal additional properties of these drugs in the treatment of trastuzumab-, or antibody-, in general, refractory HER2-positive tumors.”

OUS Key Opinion Leader, April 2014

“[Neratinib is] such a potent oral tyrosine kinase inhibitor [that], maybe instead of pitching themselves against Herceptin, they could look at how they are going to work in patients who don’t respond, or who have higher-risk disease, or afterwards, etcetera.”

US Key Opinion Leader, January 2014

“[Neratinib is a] drug that has a very impressive anti-tumor activity, very impressive. I remember the Phase II study in patients [who were] never treated before with anti-tumor agents, that, as a single agent it, gave a 50% response rate, which is quite remarkable.”

OUS Key Opinion Leader, April 2014

Executive Summary

“The real difficulty is that the market has moved on so much from when the trials [for neratinib and Gilotrif] have been done, and one assumes these drugs are going to be expensive, with a lot of toxicity, and without a clear data set to support them, because everyone has moved on to giving totally different treatment. I think it’s going to be much harder to get those in.”

OUS Key Opinion Leader, April 2014

Effective therapies for the treatment of brain metastases remain the biggest unmet need, and KOLs are interested to see how cyclin-dependant kinase inhibitors, which are currently in development for HER2-negative disease, can deliver in this setting.

“...HER2-positive patients very frequently get brain metastases....Radiation is a good treatment, but it doesn’t last forever, so progression in the brain after radiation is a real problem. We do not have any good treatments for that; that’s an unmet medical need.”

US Key Opinion Leader, January 2014

“Another class of drugs which has activity in HER2-positive disease, but is being pursued in ER [estrogen-receptor]-positive disease, of course, are CDK 4/6 inhibitors, and those are quite interesting....They have the potential of crossing the blood-brain barrier, and are highly effective in ER-positive disease, and I’m hopeful [that we] are going to really change the course of patients who have ER-positive breast cancer.”

US Key Opinion Leader, January 2014

Table of Contents

1 Table of Contents

1	Table of Contents	6
1.1	List of Tables	8
1.2	List of Figures	8
2	Introduction	9
2.1	Catalyst.....	9
2.2	Related Reports	9
2.3	Upcoming Related Reports	11
3	Disease Overview	12
3.1	Etiology and Pathophysiology	12
3.1.1	Etiology	12
3.1.2	Pathophysiology.....	12
3.2	Basic Breast Anatomy.....	14
3.3	Breast Cancer Staging	15
3.4	Prognosis.....	16
3.5	Quality of Life	17
3.6	Symptoms.....	19
4	Disease Management	20
4.1	Treatment Overview.....	20
4.1.1	Treatment of Early-Stage Breast Cancer (Stage 0 to Stage IB).....	20
4.1.2	Treatment of Locally-Advanced and Regional Breast Cancer (Stage IB to IIIA).....	21
4.1.3	Treatment of Metastatic HER2-Positive Breast Cancer (Stage IV)	24

Table of Contents

5	Competitive Assessment	27
5.1	Overview.....	27
6	Kadcyla (ado-trastuzumab emtansine, T-DM1).....	29
6.1	Overview.....	29
6.2	Efficacy	31
6.3	Safety	32
6.4	SWOT Analysis.....	32
6.5	Forecast.....	33
7	Appendix.....	34
7.1	Bibliography.....	34
7.2	Abbreviations	41
7.3	Methodology	44
7.4	Forecasting Methodology.....	44
7.4.1	Diagnosed HER2-Positive Breast Cancer Patients.....	44
7.4.2	Percent Drug-Treated Patients.....	45
7.4.3	General Pricing Assumptions	45
7.4.4	Individual Drug Assumptions.....	47
7.5	Primary Research – KOLs Interviewed for this Report	49
7.6	Primary Research – Prescriber Survey	51
7.7	About the Authors	52
7.7.1	Analyst.....	52
7.7.2	Therapy Area Director.....	52
7.7.3	Global Head of Healthcare	53

Table of Contents

7.8 About GlobalData.....54

7.9 Disclaimer54

1.1 List of Tables

Table 1: AJCC Stage Definitions for Breast Cancer..... 16

Table 2: Prognosis for Breast Cancer in the US 17

Table 3: Treatment Guidelines for HER2-Positive Breast Cancer26

Table 4: Product Profile – Kadcylla30

Table 5: Kadcylla SWOT Analysis, 2013.....32

Table 6: Global Sales Forecast (\$m) for Kadcylla, 2013–202333

Table 7: HER2-Positive Breast Cancer Incidence, 2013–202345

Table 8: Average Body Weight and Surface Area Across the 8MM46

Table 9: Average Annual Cost of Therapy (\$) – Kadcylla, Second Line47

Table 10: Physicians Surveyed by Country51

1.2 List of Figures

Figure 1: Basic Breast Anatomy, Including Key Lymph Nodes..... 14

Figure 2: Active Phase III Clinical Trials for Kadcylla.....30

Introduction

2 Introduction

2.1 Catalyst

HER2-positive breast cancer is the second most common cancer in the world and the most common cancer in women worldwide. When diagnosed at a very early stage, the prognosis is positive, with a five-year survival rate of nearly 100%. However, in the later stages of the disease, survival rapidly decreases. HER2-positive breast cancer is aggressive, and historically, has had a worse overall survival (OS) compared with HER2-negative disease, which is considered to be less aggressive. In 1998, the launch of the first HER2-targeted therapy, Herceptin (trastuzumab), revolutionized the treatment of the disease, bringing the OS close to that of HER2-negative breast cancer. The realization that introducing HER2-targeted therapies earlier into the disease management strategy could improve disease-free survival (DFS) has created a large market for HER2-directed therapies. Today, HER2-positive breast cancer patients are living longer with their disease, thanks to established disease management strategies using numerous combinations of chemotherapy with Herceptin and the tyrosine kinase inhibitor (TKI), Tykerb (lapatinib). During the forecast period from 2013–2023, GlobalData expects that the HER2-positive market will grow due to the aging populations in the US, 5EU, Japan, and China.

Furthermore, with the new premium-priced agents, such as Perjeta (pertuzumab) and Kadcyla (ado-trastuzumab emtansine) becoming established in the early lines of metastatic disease, physicians will have additional treatment options for patients. More therapies will be used in the neoadjuvant and adjuvant settings, and several pipeline agents are also being investigated in the non-metastatic market in this disease. A number of these agents are looking to address the greatest unmet need for HER2-positive breast cancer patients — brain metastases — which typically occur in the later lines of metastatic therapy and are caused by increasingly resistant disease.

2.2 Related Reports

- GlobalData (2014). Non-Small Cell Lung Cancer (NSCLC) – Global Drug Forecast and Market Analysis to 2022 – Event-Driven Update, April 2014, GDHC002EPIDR
- GlobalData (2014). Pancreatic Cancer – Opportunity Analysis and Forecasts to 2017, March 2014, GDHC016POA

The realization that introducing HER2-targeted therapies earlier into the disease management strategy could improve disease-free survival (DFS) has created a large market for HER2-directed therapies.

Introduction

- GlobalData (2013). Bladder Cancer – Opportunity Analysis and Forecasts to 2017, December 2013, GDHC014POA
- GlobalData (2014). HER2-Positive Breast Cancer – Global Drug Forecast and Market Analysis to 2023, September 2014, GDHC86PIDR
- GlobalData (2014). HER2-Positive Breast Cancer – US Drug Forecast and Market Analysis to 2023, September 2014, GDHC253CFR
- GlobalData (2014). HER2-Positive Breast Cancer – 5EU Drug Forecast and Market Analysis to 2023, September 2014, GDHC254CFR
- GlobalData (2014). HER2-Positive Breast Cancer – Japan Drug Forecast and Market Analysis to 2023, September 2014, GDHC255CF
- GlobalData (2014). HER2-Positive Breast Cancer – China Drug Forecast and Market Analysis to 2023, September 2014, GDHC256CF
- GlobalData (2014). Herceptin (HER2-Positive Breast Cancer) – Forecast and Market Analysis to 2023, September 2014, GDHC463DFR
- GlobalData (2014). Perjeta (HER2-Positive Breast Cancer) – Forecast and Market Analysis to 2023, September 2014, GDHC464DFR
- GlobalData (2014). Tykerb (HER2-Positive Breast Cancer) – Forecast and Market Analysis to 2023, September 2014, GDHC466DFR
- GlobalData (2014). Gilotrif (HER2-Positive Breast Cancer) – Forecast and Market Analysis to 2023, September 2014, GDHC467DFR
- GlobalData (2014). Neratinib (HER2-Positive Breast Cancer) – Forecast and Market Analysis to 2023, September 2014, GDHC468DFR
- GlobalData (2014). HER2-positive breast cancer - Current and Future Players, September 2014, GDHC1038FPR

Introduction

2.3 Upcoming Related Reports

- GlobalData (Q3 2014). HER2-Negative Breast Cancer – Global Drug Forecast and Market Analysis to 2023
- GlobalData (Q3 2014). Renal Cell Carcinoma – Global Drug Forecast and Market Analysis to 2023

SAMPLE

Appendix

7.8 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.

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