



GlobalData»
PharmaPoint

**IRESSA (NON-SMALL CELL LUNG CANCER) –
FORECAST AND MARKET ANALYSIS TO 2022**

Executive Summary

Iressa (gefitinib): Key Metrics in NSCLC Markets	
2012 Iressa Sales	
US	NA
5EU	\$141.88m
Japan	\$129.45m
China	\$79.29m
India	\$5.74m
Total	\$356.37m
Key Events (2012–2022)	Level of Impact
Iressa patent expiry in the 5EU & Japan (2019)	↓↓↓
Approval/launch of Iressa in the second line in 5EU & Japan, in the year 2017 and 2016 respectively	↑↑
2022 Iressa Sales	
US	NA
5EU	\$5.50m
Japan	\$111.23m
China	\$6.36m
India	\$5.93m
Total	\$129.02m
Source: GlobalData	
5EU = France, Germany, Italy, Spain, and UK; 7MM = US, 5EU, and Japan	
NA: Not Available	

Sales for Iressa (gefitinib) in the Global NSCLC Market

Global drug sales for Iressa are forecast to decline from \$356.37m in 2012 to \$129.02m in 2022 at a negative Compound Annual Growth Rate (CAGR) of 9.66%. Peak sales of \$500m are expected in 2018.

The major drivers of Iressa sales growth in the NSCLC therapeutics market will include:

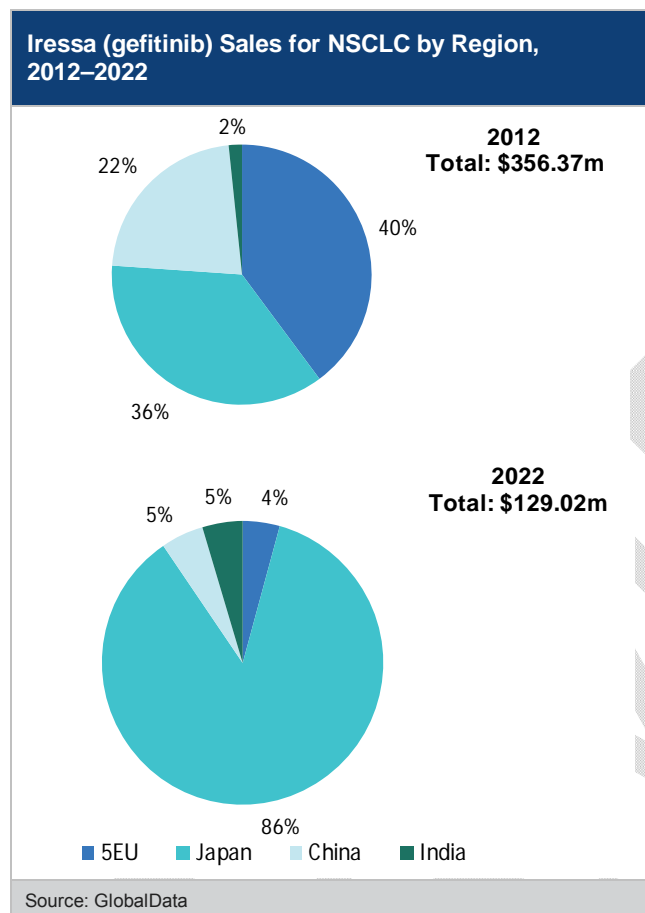
- Established in the treatment algorithm and clinical guidelines in the EU, Japan, and China
- Targeted therapy for a specific patient population
- A growing aging population and increasing NSCLC incident cases in the majority of the markets covered, especially in Japan and the emerging markets of China and India
- Iressa's use in the first line will be driven by increased rates of EGFR mutation testing in many of the markets

The major barriers responsible for the decline in Iressa sales of NSCLC therapeutics will include:

- Iressa will face competition in the first and second lines due to the launch of Gilotrif and dacomitinib in the forecast period
- Iressa is not approved for marketing in the US
- Iressa will have difficulty in acquiring patient share in the second line due to the presence of well established Tarceva in the same line

Executive Summary

The below figure illustrates the sales of Iressa for NSCLC in the seven major markets, China, and India during the forecast period.



What Do the Physicians Think?

“There are a lot of unmet medical needs for squamous [non-small cell lung cancer] because we have not so many possibilities to treat the patients. And also, we have made progress in [the] first line [for non-squamous patients] with Avastin and with TKIs, but [in the] second and third line, we have no very effective treatment [for non-squamous patients], so a lot of unmet medical needs are there.”

OUS KOL, March 2013

“[For access to new drugs,] I think it will depend on the magnitude of the benefit we will get in clinical studies. I think if there is a statistically significant difference, but it is not clinically meaningful, I think it will be difficult to have reimbursement...at this time. The drug can be approved, but the reimbursement, access to the market, will be more difficult to obtain for the company.”

OUS KOL, March 2013

“There [has] been a big backlash in the lung cancer world against Avastin most recently ... that is a drug that probably has a modest impact and one that is quite expensive and also which has a pretty good rate of complication. So I think we are looking for drugs that are effective which don't have a high rate of complication and if something meets those standards we will use it.”

US KOL, February 2013

Executive Summary

“We have the problem with the testing in some cases you don’t have so much tissue you need to re-biopsy the patients to do further testing ...It would be great to have an upfront testing for about 10 to 20 alterations, so you have the information at the beginning of the treatment with the limited tissue you have.”

OUS KOL, March 2013

SAMPLE

Table of Contents

1 Table of Contents

1	Table of Contents.....	5
1.1	List of Tables	8
2	Introduction	9
2.1	Catalyst.....	9
2.2	Related Reports.....	9
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 and Histology.....	13
3.1.3	NSCLC Biomarkers	14
3.1.4	Quality of Life.....	15
3.2	Symptoms.....	16
4	Disease Management	18
4.1	Treatment Overview.....	18
4.1.1	Diagnosis.....	20
4.1.2	Clinical Staging	20
4.1.3	Screening and Early Detection.....	23
4.1.4	Localized Procedures and Therapies.....	24
4.1.5	Systemic Chemotherapy.....	25
4.1.6	Targeted Therapy	26

Table of Contents

5	Competitive Assessment.....	29
5.1	Overview.....	29
5.2	Strategic Competitor Assessment	30
6	Iressa (gefitinib).....	33
6.1	Overview.....	33
6.2	Efficacy	35
6.3	Safety	37
6.4	SWOT Analysis.....	37
6.5	Forecast.....	38
7	Appendix.....	39
7.1	Bibliography	39
7.2	Abbreviations	44
7.3	Methodology	47
7.4	Forecasting Methodology.....	47
7.4.1	Number of NSCLC Patients Currently Seeking Treatment.....	47
7.4.2	Percent Drug-treated Patients.....	48
7.4.3	General Pricing Assumptions.....	48
7.4.4	Individual Drug Assumptions	51
7.4.5	Generic Erosion.....	51
7.5	Physicians and Specialists Included in This Study	52
7.6	Survey of Prescribing Physicians	54
7.7	About the Authors	55
7.7.1	Author.....	55

Table of Contents

7.7.2	Epidemiologist	55
7.7.3	Global Head of Healthcare.....	56
7.8	About GlobalData.....	57
7.9	Disclaimer	57

SAMPLE

Table of Contents

1.1 List of Tables

Table 1: Symptoms of Disease NSCLC	17
Table 2: Treatment Guidelines for NSCLC	19
Table 3: Stage Definitions for NSCLC	22
Table 4: Treatment Overview by Stage of Diagnosis for NSCLC.....	28
Table 5: Leading Treatments for NSCLC.....	32
Table 6: Product Profile – Iressa (gefitinib)	35
Table 7: Iressa SWOT Analysis, 2013.....	37
Table 8: Global Sales Forecasts (\$m) for Iressa, 2012-2022	38
Table 9: Five Year Prevalence	48
Table 10: Physicians Surveyed by Country	54

Introduction

2 Introduction

2.1 Catalyst

Non-small cell lung cancer (NSCLC) is the second most common cancer in both men and women. Diagnosed patients have an extremely poor prognosis, with five-year survival rates limited to approximately 2% in US patients diagnosed at stage IV of the disease. Historically, treatment options for advanced-stage NSCLC patients have been dominated by platinum-based chemotherapy. However, the launch of targeted therapies such as Iressa (gefitinib) in 2003, Tarceva (erlotinib) in 2004 and Xalkori (crizotinib) in 2011 for specific molecular subpopulations of NSCLC patients has revolutionized the treatment landscape. During the forecast period, the competitive landscape will continue to evolve as new targeted therapies are launched that address specific biomarkers or histology in the first and second lines of therapy. The NSCLC market will continue to grow during the forecast period, driven by a rising aging population and increasing incident cases of NSCLC in the US, 5EU, Japan, China and India.

"Non-small cell lung cancer (NSCLC) is the second most common cancer in both men and women. Diagnosed patients have an extremely poor prognosis, with five-year survival rates limited to approximately 2% in US patients diagnosed at stage IV of the disease."

In addition, the launch of emerging premium-priced pipeline agents will drive the uptake of new therapies and prolong the time of patients on therapy in the second line and beyond. Physicians will have several treatment options to choose from to address the high unmet needs of their NSCLC patients, including Gilotrif and LDK378 for the treatment of patients who develop resistance to first-line treatment with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) therapies, and necitumumab for the first-line treatment of squamous NSCLC patients. In addition, launch of the first-in-class PD1 immunotherapy, nivolumab, will be a significant contributor to market growth during the forecast period.

2.2 Related Reports

Introduction

- GlobalData (2013). Non-Small Cell Lung Cancer – United States Drug Forecast and Market Analysis to 2022. GDHC1124CFR
- GlobalData (2013). Non-Small Cell Lung Cancer - France Drug Forecast and Market Analysis to 2022. GDHC1125CFR
- GlobalData (2013). Non-Small Cell Lung Cancer - Germany Drug Forecast and Market Analysis to 2022. GDHC1126CFR
- GlobalData (2013). Non-Small Cell Lung Cancer - Italy Drug Forecast and Market Analysis to 2022. GDHC1127CFR
- GlobalData (2013). Non-Small Cell Lung Cancer - Spain Drug Forecast and Market Analysis to 2022. GDHC1128CFR
- GlobalData (2013). Non-Small Cell Lung Cancer – United Kingdom Drug Forecast and Market Analysis to 2022. GDHC1129CFR
- GlobalData (2013). Non-Small Cell Lung Cancer - Japan Drug Forecast and Market Analysis to 2022. GDHC1130CFR
- GlobalData (2013). Non-Small Cell Lung Cancer - China Drug Forecast and Market Analysis to 2022. GDHC1131CFR
- GlobalData (2013). Non-Small Cell Lung Cancer – India Drug Forecast and Market Analysis to 2022. GDHC1132CFR
- GlobalData (2013). Alimta (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC195DFR
- GlobalData (2013). Abraxane (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC196DFR
- GlobalData (2013). Tarceva (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC198DFR
- GlobalData (2013). Xalkori (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC199DFR

Introduction

- GlobalData (2013). Avastin (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC200DFR
- GlobalData (2013). onartuzumab (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC201DFR
- GlobalData (2013). necitumumab (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC202DFR
- GlobalData (2013). ramucirumab (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC203DFR
- GlobalData (2013). custirsen (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC204DFR
- GlobalData (2013). ganetespib (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC205DFR
- GlobalData (2013). nintedanib (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC206DFR
- GlobalData (2013). Gilotrif (afatinib) (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC207DFR
- GlobalData (2013). dacomitinib (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC208DFR
- GlobalData (2013). LDK 378 (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC209DFR
- GlobalData (2013). Yervoy (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC210DFR
- GlobalData (2013). nivolumab (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC211DFR
- GlobalData (2013). GSK1572932A (MAGE-A3) (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC212DFR

Introduction

- GlobalData (2013). Halaven (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC213DFR
- GlobalData (2013). Non-Small Cell Lung Cancer - Current and Future Players. GDHC1017FPR

2.3 Upcoming Related Reports

- GlobalData (2013). Acute Myeloid Leukemia (AML) – Opportunity Analysis and Forecasts to 2017.
- GlobalData (2013). Colorectal Cancer – Opportunity Analysis and Forecasts to 2017.

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.

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

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