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Pharma**Point**

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

Executive Summary

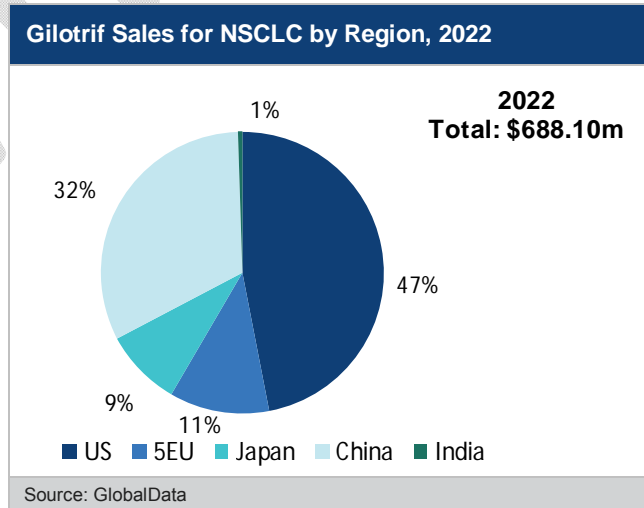| Gilotrif: Key Metrics in NSCLC Markets	
2022 Gilotrif Sales	
US	$323.14m
5EU	$78.87m
Japan	$61.19m
China	$221.45m
India	$3.47m
Total	**$688.10m**
Key Events (2012–2022)	**Level of Impact**
Approval/launch of Gilotrif in the US and 5EU in 2013	↑↑↑
Approval/launch of Gilotrif in the Japan & India in 2014 and China in 2015	↑↑↑
Source: GlobalData	
5EU = France, Germany, Italy, Spain, and UK; 7MM = US, 5EU, and Japan	
NA: Not Available	

Sales for Gilotrif in the Global NSCLC Market

Gilotrif sales are expected to increase from $53.28m upon launch in 2013 to $688.10m in 2022 from sales in the seven major markets, China, and India.

Key factors affecting the uptake of Gilotrif will include:

- Gilotrif will expand into the second-line treatment of EGFR-mutant patients in 2014 where it may gain patient shares of TKI-resistant patients

- Significantly extends PFS over chemotherapy in the first-line treatment of EGFR-positive patients

- Gilotrif's convenient daily oral dosing schedule and less price will give advantage over onartuzumab and Tarceva therapy

- Gilotrif will face intense competition with well-established drugs like Tarceva and Iressa in the first line patient segment.

- Gilotrif's comparatively poor safety profile then it's major competitors

- In the second-line, Gilotrif will compete against Roche's combination of onartuzumab and Tarceva to delay or prevent TKI resistance as well as Pfizer's dacomitinib

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

Gilotrif Sales for NSCLC by Region, 2022

2022 Total: $688.10m

US 47%, China 32%, 5EU 11%, Japan 9%, India 1%

Legend: US, 5EU, Japan, China, India

Source: GlobalData

Executive Summary

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

"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

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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.

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

"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."

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). Iressa (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC197DFR

- GlobalData (2013). Tarceva (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC198DFR

Introduction

- GlobalData (2013). Xalkori (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC199DFR

- 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

Introduction

- GlobalData (2013). GSK1572932A (MAGE-A3) (Non-Small Cell Lung Cancer) - Forecast and Market Analysis to 2022. GDHC212DFR

- 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

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.

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