Executive Summary

Nintedanib: Key Metrics in NSCLC Markets

<table>
<thead>
<tr>
<th>2022 nintedanib Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$47.98m</td>
</tr>
<tr>
<td>5EU</td>
<td>$11.28m</td>
</tr>
<tr>
<td>Japan</td>
<td>$17.81m</td>
</tr>
<tr>
<td>China</td>
<td>$9.12m</td>
</tr>
<tr>
<td>India</td>
<td>$0.12m</td>
</tr>
<tr>
<td>Total</td>
<td>$86.31m</td>
</tr>
</tbody>
</table>

Key Events (2012–2022)

| Approval/launch of nintedanib in the US and 5EU in 2015 | ↑ |

Source: GlobalData

5EU = France, Germany, Italy, Spain, and UK; 7MM = US, 5EU, and Japan
NA: Not Available

Sales for nintedanib in the Global NSCLC Market

Nintedanib sales are expected to increase from $7.33m upon launch in 2015 to $86.31m in 2022 from sales in the seven major markets, China, and India.

Key factors affecting the uptake of nintedanib will include:

- Nintedanib’s strong OS benefit and excellent safety profile
- Nintedanib will be used in combination with docetaxel, which is already the standard of care in the second line and available as a generic in all the markets
- Nintedanib will face competition in the second line from established second line therapies Alimta and Avastin as well as from the emerging therapies ramucirumab and nivolumab.
- Nintedanib’s late entry into the second line market will encumber its uptake.

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

Nintedanib Sales for NSCLC by Region, 2022

![Nintedanib Sales by Region](image-url)
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 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 Xalkor (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
Introduction

- GlobalData (2013). Non-Small Cell Lung Cancer - Italy Drug Forecast and Market Analysis to 2022. GDHC1127CFR
- 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
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- 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). 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

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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