PANCREATIC CANCER - OPPORTUNITY ANALYSIS AND FORECASTS TO 2017
Executive Summary

The table below presents the key metrics for pancreatic cancer in the six major pharmaceutical markets covered in this report (the US, France, Germany, Italy, Spain, and the UK) during the forecast period from 2012–2017.

| Pancreatic Cancer: Key Metrics in the Six Major Pharmaceutical Markets*, 2012–2017 |
|-----------------------------------------------|----------------------------------|-----------------------------------------------|
| **2012 Patient Population**                  |                                  | **2012 Market Sales**                         |
| Incident Population                          | 96,072                           | US                                            | $275m |
| Treatment Opportunities                      | 133,018                          | 5EU                                           | $254m |
| **Total**                                     |                                  | **Total**                                     | $529m |
| **Key Events (2012–2017)**                   | **Level of Impact**              |                                              |      |
| Abraxane (nab-paclitaxel) launch in the US and EU – 2013/2014 | ↑↑↑                              |                                              |      |
| Xeloda (capecitabine) patent expiry in the US and EU – 2013       | ↓↓                                |                                              |      |
| Algenpantucel-L launch in the US – 2015      | ↑↑                               |                                              |      |
| MM-398 launch in the US and EU – 2015        | ↑↑                               |                                              |      |
| TH-302 launch in the US and EU – 2016        | ↑↑                              |                                              |      |
| 90Y-clivatuzumab tetraxetan launch in the US – 2016   | ↑↑                               |                                              |      |
| **2017 Market Sales**                        |                                  |                                              |      |
| US                                            | $1.17bn                           |                                              |      |
| 5EU                                           | $463m                            |                                              |      |
| **Total**                                     | $1.63bn                          |                                              |      |

*For the purposes of this report, the six major pharmaceutical markets = US and 5EU (France, Germany, Italy, Spain, and UK).

New Drug Launches Will Drive Rapid Growth in the US and EU Pancreatic Cancer Market from 2012–2017

GlobalData estimates that the value of the pancreatic cancer market in the US and 5EU (France, Germany, Italy, Spain, and the UK) in 2012 was $529m. This market is defined as sales of branded drugs and major generic regimens commonly prescribed for pancreatic cancer patients across the six major markets (6MM). Just over half of these sales, $275m (52%), were generated in the US, while sales in the 5EU were estimated at $254m (48%).

By 2017, the end of the forecast period, GlobalData projects pancreatic cancer sales to rise to $1.63 billion in the US and 5EU, at a high Compound Annual Growth Rate (CAGR) of 25.2%. GlobalData expects the proportion of sales from the US to increase to 72%, with market share in the 5EU decreasing to 28% by 2017. The overall rapid increase in the market size across the 6MM is attributed to the launch of Celgene’s Abraxane in 2013 in the US and 2014 in Europe, and the incorporation of five pipeline agents into US clinical practice by the end of the forecast period.

GlobalData forecasts sales of Abraxane to rise significantly, from $21m in 2012 to $954m in 2017, at a CAGR of 115%; sales of Abraxane will represent nearly 60% of the pancreatic cancer market by the end of the forecast period.
Executive Summary

Major drivers of the pancreatic cancer market in the US and 5EU during the forecast period include the following:

- The greatest driver of the pancreatic cancer market across the 6MM will be the strong and rapid adoption of premium-priced Abraxane in place of generic chemotherapy regimens, such as FOLFIRINOX (5-flourouracil [5-FU]/leucovorin/irinotecan/oxaliplatin) and gemcitabine monotherapy. GlobalData forecasts particularly strong growth in the US, the largest market for pancreatic cancer therapeutics, and the market where Abraxane is priced the highest.

- Of the five new pipeline agents that will be launched during the forecast period, NewLink Genetics Corporation’s algenpantucel-L is expected to garner the highest sales, and is expected to launch in both the resectable and unresectable locally-advanced settings. Other drugs with significant forecast sales by 2017 include Threshold Pharmaceuticals/Merck’s TH-302, and Merrimack Pharmaceuticals’ MM-398.

- The incidence of pancreatic cancer is increasing across the 6MM, resulting in further treatment opportunities for premium-priced therapeutics.

Barriers to the growth of the pancreatic cancer market in the US and 5EU during the forecast period include the following:

- The patent expiry of Roche’s Xeloda will be a barrier to growth for the pancreatic cancer market. Xeloda is prescribed off-label across the 6MM as an oral alternative to 5-FU. Due to cost-containment pressure, GlobalData expects rapid generic erosion of the brand’s market share following its patent expiry.

- In the 5EU, GlobalData expects it to become increasingly challenging for companies to successfully gain reimbursement for premium-priced therapies for pancreatic cancer unless they offer major efficacy advantages over the current standards of care. Without reimbursement coverage by national health services, the uptake of branded therapies could be significantly depressed.

- Cost-consciousness in the EU due to the economic crisis will limit the pricing of newly-launched therapies for pancreatic cancer. Even the US market, which historically has had few constraints in terms of pricing, is facing pressure from healthcare authorities, physicians, and patients for the improved cost-effectiveness of drugs that are approved by the Food and Drug Administration (FDA).
Executive Summary

The following figure illustrates the breakdown of sales in the global pancreatic cancer market, consisting of the US and the 5EU, during the forecast period.

Celgene’s Abraxane Will Become the Dominant Brand Across the Pancreatic Cancer Market

Celgene’s Abraxane was approved in the US and Europe in 2013 and 2014, respectively, for the first-line treatment of metastatic pancreatic cancer in combination with gemcitabine. The first-line metastatic setting is the most commercially lucrative due to the high proportion of pancreatic cancer patients diagnosed with advanced disease. Key opinion leaders (KOLs interviewed by GlobalData reported the rapid adoption of Abraxane into clinical practice and expect the drug to also be prescribed off-label for unresectable, locally-advanced patients and for second-line metastatic patients who have not received the drug in the first line. As the new standard of care for the widest range of metastatic patients — namely, patients with good or average performance status — GlobalData expects GemAbrax (gemcitabine/Abraxane) to become a backbone regimen for future clinical trials of targeted agents, ensuring that Abraxane sales will be maintained, even if future pipeline agents demonstrate an efficacy benefit. Finally, with a Phase III trial of GemAbrax having been initiated in the resectable setting, GlobalData anticipates that Abraxane will become fully-entrenched throughout the major segments in the pancreatic cancer market well beyond the forecast period of this report.
Executive Summary

**High Unmet Need in Pancreatic Cancer Will Remain Unfulfilled Without Predictive Biomarker-Driven Targeted Therapies**

Due to the poor survival outcomes of patients across the pancreatic cancer spectrum, this indication has historically always been identified as one with some of the highest unmet need in oncology. Despite the approval of Abraxane, KOLs noted that this high unmet need is still prominent. Based on KOL insight, GlobalData has identified a high unmet need for efficacious treatment options for patients across the disease spectrum, including drugs that can improve cure rates in the adjuvant setting, and novel treatments that can provide a major improvement in efficacy to extend survival well over a year in the metastatic setting. Although the approval of Abraxane in combination with gemcitabine has been welcomed by KOLs, they are not satisfied with the overall survival (OS) benefit of two months compared with gemcitabine monotherapy, and called for novel, predictive, biomarker-driven targeted therapies in order to substantially extend survival. The pancreatic cancer setting is playing catch-up with other oncology indications in regards to such strategies; it is apparent that pancreatic cancer is awaiting its own Zelboraf (vemurafenib) or Xalkori (crizotinib) — namely, a drug that can be used to treat carefully selected patient populations and personalize treatment options for these patients.

Without any of the late-stage pipeline agents being developed with such a strategy in mind, GlobalData expects these unmet needs to remain unfulfilled by the end of the forecast period.

**Pipeline Agents for First-Line Metastatic Disease Will Struggle to Compete with Abraxane**

With the launch of Abraxane, the first-line metastatic setting has become more competitive. This is particularly the case for patients with good performance status, a setting where FOLFIRINOX or GemAbrax is primarily utilized. KOLs see Threshold Pharmaceuticals/Merck’s hypoxia-targeted chemotherapy, TH-302, as the most exciting pipeline drug in the first-line setting; however, the drug is being investigated in combination with gemcitabine, a backbone that has now been superseded by GemAbrax. Even if a survival improvement is obtained with TH-302/gemcitabine over gemcitabine alone, KOLs contend that TH-302 will struggle to gain uptake without head-to-head studies compared with GemAbrax. Overall, as illustrated in the figure below, based on the insight of oncologists interviewed by GlobalData and the available secondary data, GlobalData expects Abraxane to have superior clinical and commercial attributes in comparison with all late-stage pipeline agents across the metastatic setting.
Executive Summary

The figure below provides a competitive assessment of the marketed therapies and the promising late-stage pipeline drugs in development for pancreatic cancer, based on their clinical and commercial attributes.

The lack of treatment options for pancreatic cancer patients is, however, expected to facilitate the rapid uptake of this immunotherapy. Other niche settings in pancreatic cancer include the second- and third-line gemcitabine pretreated patient populations. GlobalData anticipates these segments to be the settings in which the pipeline drugs could demonstrate the greatest impact on efficacy, as there are no standard-of-care regimens for these patient populations. Therefore, if a stellar efficacy benefit is observed, pipeline agents such as Merrimack Pharmaceuticals’ MM-398 and Immunomedics’ 90Y-clivatuzumab tetraxetan have the potential to gain rapid uptake for the treatment of GemAbrax-refractory pancreatic cancer.

Strong Early-Stage Pipeline is Indicative of Remaining High Commercial Opportunities in Pancreatic Cancer

GlobalData has identified a strong early-stage pipeline for pancreatic cancer. Innovative strategies include immunotherapies, janus kinase/signal transducer and activator of transcription (JAK/STAT) inhibition, mitogen-activated protein kinase/ phosphatidylinositol-4,5-bisphosphate 3-kinase (MAPK/PI3K) pathway inhibitors, cancer stem cell-targeting agents, and poly (ADP-ribose) polymerase (PARP) inhibitors. Strikingly, in comparison with the late-stage setting, Big Pharma is playing a much stronger role in the investigation of these strategies.

Pipeline Drugs for Niche Patient Populations Are Expected to Garner Rapid Uptake

The late-stage pipeline for pancreatic cancer consists of six agents that are in Phase III of development. Of these, only NewLink Genetics’ algenpantucel-L is being investigated in the early-stage resectable setting. Based on KOL insight and clinical data, GlobalData expects algenpantucel-L/gemcitabine to demonstrate an OS advantage over gemcitabine alone, although the efficacy advantage is not anticipated to be a drastic improvement.
Executive Summary

Companies such as GlaxoSmithKline (GSK), Novartis, Roche, AbbVie, and AstraZeneca are involved in investigating drugs in early-stage clinical studies in pancreatic cancer patients. GlobalData anticipates a high commercial reward for the developers of drugs that are able to fulfill some of the remaining high unmet need across the patient segments in pancreatic cancer. In particular, GlobalData expects the developers of efficacious immunotherapies or novel, predictive, biomarker-driven targeted therapies to be able to command premium prices in the US.

What Do Physicians Think?

KOLs interviewed by GlobalData expect Abraxane to gain rapid uptake across the 6MM, particularly in the US.

“I think GemAbrax will eat into [the patient shares of] gemcitabine monotherapy, it will eat into gemcitabine plus Tarceva, and it will eat into FOLFIRINOX. Overall, I think more than half of patients will…somehow, somewhere, sometime in their natural history, [end up] being exposed to Abraxane.”

US Key Opinion Leader

“Community oncologists are using GemAbrax over FOLFIRINOX. [Due to toxicity,] they are little skittish to use FOLFIRINOX, whereas in the academic settings, it is the exact opposite….”

US Key Opinion Leader

Due to the minimal overall efficacy benefit of combination Tarceva (erlotinib) and gemcitabine compared with gemcitabine alone, KOLs reported modest prescribing of the epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI).

“Do I prescribe erlotinib? No. I think [my country] has not really warmed [up] to erlotinib. The median survival advantage of erlotinib is in the days, so we do not really consider erlotinib as an option.”

European Key Opinion Leader

KOLs reported high unmet need for efficacious treatments across the patient segments in pancreatic cancer, including in both the early-stage resectable and metastatic settings.

“We need to have better therapies in the metastatic setting with longer survivals; every aspect of pancreatic cancer needs therapies….”

US Key Opinion Leader

“Clearly, we need a better drug in the pre-operative setting to get people into surgery. We [also] need better adjuvant therapies to keep the relapse rate lower than it is [at present].”

US Key Opinion Leader

KOLs interviewed by GlobalData lamented the lack of biomarkers to guide treatment decisions in pancreatic cancer, and called for predictive biomarker-driven targeted treatments.
Executive Summary

“In the pancreatic cancer setting, there is a clear lack of therapeutic biomarkers, [in contrast to] melanoma and other cancers. There are just no predictive biomarkers at this point.”

US Key Opinion Leader

“One of the most important problems is that we do not have [predictive] biomarkers. If we had a biomarker, it will make things a bit easier. At this time, even if a drug is theoretically a great drug, when it comes to using it and expecting a benefit, it is very much limited.”

US Key Opinion Leader

KOLs are optimistic that regimens of GemAbrax in combination with a targeted therapy would be tolerable in the majority of advanced pancreatic cancer patients.

“I think there is definitely space, especially in terms of toxicity, to add [a] targeted therapy on top of GemAbrax. This is something promising because GemAbrax is pretty well tolerated, and so I think that would be interesting — to add something else to it that may [make the regimen] more effective, with slightly greater toxicity.”

US Key Opinion Leader

KOLs called for GemAbrax to become the backbone chemotherapy and the active comparator for clinical trials in pancreatic cancer, instead of gemoitabine monotherapy.

“I understand the industry[’s] [point of view], but they should understand that times are changing, and a trial that was designed five years ago probably by now it is not well-designed. If the first-line [standard-of-care] therapy has changed, in the case of these trials being positive, I think they will have a problem [with adoption] due to using the old standard of care.”

European Key Opinion Leader

Overall, oncologists interviewed by GlobalData were not particularly enthusiastic about the late-stage Phase III pancreatic cancer pipeline. In contrast, the early-stage pipeline is exciting the KOLs.

“I mean these [late-stage pipeline] drugs may produce some marginal benefits, but I am not aware of any drug that is destined to produce a major difference in this disease.”

US Key Opinion Leader

“The one really exciting thing that came out of the 2014 ASCO-GI [American Society of Oncology-Gastrointestinal Cancers Symposium] was the demonstration of a survival benefit compared to [the] historical control of an immunotherapy and a vaccine-based approach for pancreatic cancer [CRS-207/GVAX]. This was a Phase II study, so even with all the caveats of an early study, it is seen as very promising.”

US Key Opinion Leader
Table of Contents

1 Table of Contents

1 Table of Contents ................................................................................................................. 9
  1.1 List of Tables ....................................................................................................................... 14
  1.2 List of Figures ...................................................................................................................... 17

2 Introduction .............................................................................................................................. 18

  2.1 Catalyst ............................................................................................................................ 18
  2.2 Related Reports ................................................................................................................ 19
  2.3 Upcoming Related Reports ............................................................................................... 19

3 Disease Overview .................................................................................................................... 20

  3.1 Etiology and Pathophysiology ......................................................................................... 21
    3.1.1 Etiology ...................................................................................................................... 21
    3.1.2 Pathophysiology ........................................................................................................ 22
  3.2 Prognosis .......................................................................................................................... 23
  3.3 Clinical Staging .................................................................................................................. 23
  3.4 Symptoms .......................................................................................................................... 27

4 Epidemiology ........................................................................................................................ 28

  4.1 Disease Overview ............................................................................................................. 28
  4.2 Risk Factors and Comorbidities ....................................................................................... 28
    4.2.1 The risk of developing pancreatic cancer increases with age .................................... 29
    4.2.2 Tobacco smokers have a two-fold increased risk of pancreatic cancer .................... 29
    4.2.3 Diabetes and obesity increase the risk of developing pancreatic cancer .................. 29
    4.2.4 At least 10% of pancreatic cancer cases result from a hereditary predisposition ........ 30
Table of Contents

4.3 Global Trends ........................................................................................................................................31

4.3.1 United States ...................................................................................................................................31

4.3.2 France ...............................................................................................................................................32

4.3.3 Germany ..........................................................................................................................................33

4.3.4 Italy ................................................................................................................................................34

4.3.5 Spain ...............................................................................................................................................35

4.3.6 United Kingdom ..............................................................................................................................36

4.4 Forecast Methodology ..........................................................................................................................37

4.4.1 Sources Used ....................................................................................................................................38

4.4.2 Forecast Assumptions and Methods .................................................................................................40

4.4.3 Sources Not Used ............................................................................................................................42

4.5 Epidemiology Forecast ..........................................................................................................................42

4.5.1 Incident Cases of Pancreatic Cancer .................................................................................................42

4.5.2 Total Five-Year Prevalent Cases of Pancreatic Cancer .....................................................................49

4.6 Discussion ...........................................................................................................................................51

4.6.1 Conclusions on Epidemiological Trends ..........................................................................................51

4.6.2 Limitations of the Analysis ...............................................................................................................52

4.6.3 Strengths of the Analysis .................................................................................................................52

5 Current Treatment Options .......................................................................................................................54

5.1 Overview .............................................................................................................................................54

5.2 Product Profiles — Major Brands .........................................................................................................57

5.2.1 Abraxane.........................................................................................................................................57

5.2.2 Gemcitabine ....................................................................................................................................61
# Table of Contents

5.2.3 Tarceva ............................................................................................................... 65

6 Unmet Needs Assessment and Opportunity Analysis ............................................ 69

6.1 Overview ................................................................................................................ 69

6.2 Unmet Needs Analysis ............................................................................................ 71

6.2.1 Therapies That Improve Overall Survival Outcomes for Advanced Patients ........ 71

6.2.2 Effective Adjuvant Treatments That Prevent Recurrence of Disease ................. 72

6.2.3 Earlier Diagnosis of Disease ............................................................................ 73

6.2.4 Discovery of Predictive Biomarkers and Understanding of Underlying Causes of Disease ........................................................................................................... 73

6.2.5 Treatment Options for Gemcitabine-Refractory Metastatic Patients ............... 74

6.3 Opportunity Analysis ............................................................................................. 75

6.3.1 Predictive Biomarker-Driven Targeted Therapies in Combination with Chemotherapy Regimens ........................................................................................................... 75

6.3.2 Treatment for Patients with Early-Stage, Localized Pancreatic Cancer .............. 76

6.3.3 Target Patients with Poor Performance Status .................................................... 77

6.3.4 Effective Drug Delivery .................................................................................... 78

6.3.5 Establish New Chemotherapy to be Standard-of-Care Cytotoxic ....................... 79

6.3.6 Development of New Standard of Care for Gemcitabine-Refractory Advanced Patients.................................................................................................................. 80

7 Research and Development Strategies ................................................................. 81

7.1 Overview .................................................................................................................. 81

7.1.1 Reformulation strategies .................................................................................... 81

7.1.2 Small/Medium-Sized Pharmaceutical Companies Driving R&D ...................... 82

7.1.3 Large Pharmaceutical Companies Betting On Targeted Drug Approaches .......... 83
Table of Contents

7.2 Clinical Trial Design ............................................................................................................................. 84
  7.2.1 Overview ........................................................................................................................................ 84
  7.2.2 Overall Survival is the Primary Endpoint of Choice in Both Adjuvant and Metastatic Trials .................................................................................................................................................. 87
  7.2.3 The Majority of Metastatic Trials Are in Second-Line and Later Patients ........................................ 88
  7.2.4 Gemcitabine: Backbone Therapy and Standard Active Comparator for First-Line Metastatic Trials .................................................................................................................................................. 89

8 Pipeline Assessment .................................................................................................................................. 91
  8.1 Overview ............................................................................................................................................ 91
  8.2 Promising Drugs in Clinical Development .......................................................................................... 93
    8.2.1 Algenpantucel-L .......................................................................................................................... 94
    8.2.2 TH-302 .......................................................................................................................................... 98
    8.2.3 Lipoplatin ...................................................................................................................................... 103
    8.2.4 MM-398 ....................................................................................................................................... 106
    8.2.5 Glufosfamide ............................................................................................................................... 111
    8.2.6 90Y-Clivatuzumab Tetraxetan ................................................................................................. 114
  8.3 Innovative Early-Stage Approaches ...................................................................................................... 118
    8.3.1 Vaccine and Immunotherapy Combination ................................................................................ 120
    8.3.2 JAK Inhibition ............................................................................................................................. 121
    8.3.3 Dual MEK/PI3K inhibition ......................................................................................................... 122
    8.3.4 Cancer Stem Cell Targeting ...................................................................................................... 125
    8.3.5 Poly (ADP-Ribose) Polymerase Inhibitors ................................................................................ 127
    8.3.6 Drug Delivery Mechanisms ....................................................................................................... 128
### Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.3.7</td>
<td>Hedgehog Pathway</td>
<td>129</td>
</tr>
<tr>
<td>9</td>
<td>Pipeline Valuation Analysis</td>
<td>132</td>
</tr>
<tr>
<td>9.1</td>
<td>Clinical Benchmarking of Key Pipeline Drugs</td>
<td>133</td>
</tr>
<tr>
<td>9.2</td>
<td>Commercial Benchmarking of Key Pipeline Drugs</td>
<td>136</td>
</tr>
<tr>
<td>9.3</td>
<td>Competitive Assessment</td>
<td>139</td>
</tr>
<tr>
<td>9.4</td>
<td>Top-Line Five-Year Forecast</td>
<td>140</td>
</tr>
<tr>
<td>9.5</td>
<td>US</td>
<td>143</td>
</tr>
<tr>
<td>9.6</td>
<td>Europe</td>
<td>145</td>
</tr>
<tr>
<td>10</td>
<td>Appendix</td>
<td>147</td>
</tr>
<tr>
<td>10.1</td>
<td>Bibliography</td>
<td>147</td>
</tr>
<tr>
<td>10.2</td>
<td>Abbreviations</td>
<td>165</td>
</tr>
<tr>
<td>10.3</td>
<td>Methodology</td>
<td>169</td>
</tr>
<tr>
<td>10.4</td>
<td>Forecasting Methodology</td>
<td>169</td>
</tr>
<tr>
<td>10.4.1</td>
<td>Diagnosed Pancreatic Cancer Patients</td>
<td>169</td>
</tr>
<tr>
<td>10.4.2</td>
<td>Percent Drug-Treated</td>
<td>170</td>
</tr>
<tr>
<td>10.4.3</td>
<td>Drugs Included in Each Therapeutic Class</td>
<td>170</td>
</tr>
<tr>
<td>10.4.4</td>
<td>Launch and Patent Expiry Dates</td>
<td>170</td>
</tr>
<tr>
<td>10.4.5</td>
<td>General Pricing Assumptions</td>
<td>171</td>
</tr>
<tr>
<td>10.4.6</td>
<td>Individual Drug Assumptions</td>
<td>172</td>
</tr>
<tr>
<td>10.4.7</td>
<td>Generic Erosion</td>
<td>176</td>
</tr>
<tr>
<td>10.5</td>
<td>Physicians and Specialists Included in this Study</td>
<td>177</td>
</tr>
<tr>
<td>10.6</td>
<td>About the Authors</td>
<td>178</td>
</tr>
<tr>
<td>10.6.1</td>
<td>Authors</td>
<td>178</td>
</tr>
</tbody>
</table>
## Table of Contents

10.6.2 Epidemiologists........................................................................................................................................... 179
10.6.3 Global Head of Healthcare......................................................................................................................... 179
10.7 About GlobalData............................................................................................................................................ 180
10.8 Disclaimer.................................................................................................................................................. 180
**Table of Contents**

1.1 List of Tables

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>AJCC TNM Classification System for Pancreatic Cancer</td>
<td>24</td>
</tr>
<tr>
<td>Table 2</td>
<td>AJCC TNM Staging System for Pancreatic Cancer</td>
<td>25</td>
</tr>
<tr>
<td>Table 3</td>
<td>Common Pancreatic Cancer Symptoms</td>
<td>27</td>
</tr>
<tr>
<td>Table 4</td>
<td>Risk Factors for Pancreatic Cancer</td>
<td>28</td>
</tr>
<tr>
<td>Table 5</td>
<td>6MM, Sources of Pancreatic Cancer Incidence Data</td>
<td>38</td>
</tr>
<tr>
<td>Table 6</td>
<td>6MM, Incident Cases of Pancreatic Cancer, Ages ≥15 Years, Men and Women, Select Years, 2012–2022</td>
<td>43</td>
</tr>
<tr>
<td>Table 7</td>
<td>6MM, Incident Cases of Pancreatic Cancer, by Age, Men and Women, N, 2012</td>
<td>44</td>
</tr>
<tr>
<td>Table 8</td>
<td>6MM, Incident Cases of Pancreatic Cancer, by Sex, Ages ≥15 Years, N (Row %), 2012</td>
<td>46</td>
</tr>
<tr>
<td>Table 9</td>
<td>6MM, Five-Year Prevalent Cases of Pancreatic Cancer, Ages ≥15 Years, Men and Women, Select Years, 2012–2022</td>
<td>50</td>
</tr>
<tr>
<td>Table 10</td>
<td>Leading Treatments for Pancreatic Cancer in the US and 5EU</td>
<td>56</td>
</tr>
<tr>
<td>Table 11</td>
<td>Product Profile – Abraxane</td>
<td>59</td>
</tr>
<tr>
<td>Table 12</td>
<td>Abraxane SWOT Analysis</td>
<td>61</td>
</tr>
<tr>
<td>Table 13</td>
<td>Gemcitabine SWOT Analysis</td>
<td>64</td>
</tr>
<tr>
<td>Table 14</td>
<td>Product Profile – Tarceva</td>
<td>66</td>
</tr>
<tr>
<td>Table 15</td>
<td>Tarceva SWOT Analysis</td>
<td>68</td>
</tr>
<tr>
<td>Table 16</td>
<td>Overall Unmet Needs – Current Level of Attainment</td>
<td>69</td>
</tr>
<tr>
<td>Table 17</td>
<td>Design of Pipeline Phase III Trials in Pancreatic Cancer</td>
<td>86</td>
</tr>
<tr>
<td>Table 18</td>
<td>Pancreatic Cancer – Late Stage Pipeline</td>
<td>93</td>
</tr>
<tr>
<td>Table 19</td>
<td>Product Profile – Algenpantucel-L</td>
<td>96</td>
</tr>
<tr>
<td>Table 20</td>
<td>Algenpantucel-L SWOT Analysis</td>
<td>98</td>
</tr>
<tr>
<td>Table 21</td>
<td>Product Profile – TH-302</td>
<td>101</td>
</tr>
<tr>
<td>Table 22</td>
<td>TH-302 SWOT Analysis</td>
<td>103</td>
</tr>
</tbody>
</table>
### Table of Contents

Table 23: Product Profile – Lipoplatin .......................................................................................................................... 105  
Table 24: Lipoplatin SWOT Analysis ............................................................................................................................. 106  
Table 25: Product Profile – MM-398 ............................................................................................................................ 109  
Table 26: MM-398 SWOT Analysis ............................................................................................................................... 110  
Table 27: Product Profile – Glufosfamide ........................................................................................................................ 112  
Table 28: Glufosfamide SWOT Analysis .......................................................................................................................... 113  
Table 29: Product Profile – 90Y-Clivatuzumab Tetraxetan ............................................................................................... 116  
Table 30: 90Y-Clivatuzumab Tetraxetan SWOT Analysis ................................................................................................. 117  
Table 31: Early-Stage Pipeline Products in Pancreatic Cancer ............................................................................................ 119  
Table 32: Clinical Benchmarking of Key Pipeline Drugs – Pancreatic Cancer ................................................................. 133  
Table 33: Commercial Benchmarking of Key Pipeline Drugs – Pancreatic Cancer .......................................................... 136  
Table 34: Top-Line Sales Forecast ($m) for Pancreatic Cancer, 2012–2017 ........................................................................ 141  
Table 35: Key Events Impacting Sales for Pancreatic Cancer, 2012–2017 ...................................................................... 144  
Table 36: Pancreatic Cancer Market – Drivers and Barriers, 2013 .................................................................................. 144  
Table 37: Key Launch Dates 2012–2017 .......................................................................................................................... 170  
Table 38: Key Patent Expiries 2012–2017 ........................................................................................................................ 171
# Table of Contents

## 1.2 List of Figures

| Figure 1:        | Pancreatic Cancer Staging According to the AJCC TNM System                          | 26 |
| Figure 2:        | US, Incidence and Mortality Rates of Pancreatic Cancer, All Ages, Men and Women, 2008 | 31 |
| Figure 3:        | France, Incidence and Mortality Rates of Pancreatic Cancer, All Ages, Men and Women, 2008 | 32 |
| Figure 4:        | Germany, Incidence and Mortality Rates of Pancreatic Cancer, All Ages, Men and Women, 2008 | 33 |
| Figure 5:        | Italy, Incidence and Mortality Rates of Pancreatic Cancer, All Ages, Men and Women, 2008 | 34 |
| Figure 6:        | Spain, Incidence and Mortality Rates of Pancreatic Cancer, All Ages, Men and Women, 2008 | 35 |
| Figure 7:        | UK, Incidence and Mortality Rates of Pancreatic Cancer, All Ages, Men and Women, 2008 | 36 |
| Figure 8:        | 6MM, Incident Cases of Pancreatic Cancer, Ages ≥15 Years, Men and Women, Select Years, 2012–2022 | 43 |
| Figure 9:        | 6MM, Incident Cases of Pancreatic Cancer, by Age, Men and Women, N, 2012              | 45 |
| Figure 10:       | 6MM, Incident Cases of Pancreatic Cancer by Sex, Ages ≥15 Years, 2012                | 46 |
| Figure 11:       | 6MM, Age-Standardized Pancreatic Cancer Incidence, 2012                                | 47 |
| Figure 12:       | 6MM, Incident Cases of Pancreatic Cancer by Stage at Diagnosis, Ages ≥15 Years, Men and Women, 2012 | 48 |
| Figure 13:       | 6MM, Total Incident Biomarker Cases of Pancreatic Cancer, Ages ≥15 Years, Men and Women, 2012 | 49 |
| Figure 14:       | 6MM, Total Five-Year Prevalent Cases of Pancreatic Cancer, Ages ≥15 Years, Men and Women, Select Years, 2012–2022 | 50 |
| Figure 15:       | Competitive Assessment of Late-Stage Pipeline Agents in Pancreatic Cancer, 2012–2017 | 139 |
| Figure 16:       | Global Sales for Pancreatic Cancer by Region, 2012–2017                             | 142 |
Introduction

2 Introduction

2.1 Catalyst

Pancreatic cancer is characterized as a disease with some of the highest unmet need in oncology. The overall five-year survival for the disease is only approximately 5%, representing one of the poorest prognoses across the gastrointestinal (GI) cancers. Celgene’s Abraxane (nab-paclitaxel) was launched in the US and Europe in 2013 and 2014, respectively, and was the first drug approved in this disease in nearly a decade. GlobalData expects the launch of Abraxane to initiate a significant change in the pancreatic cancer market over the next five years across the six major markets (6MM) covered in this report (the US, France, Germany, Italy, Spain, and the UK). Due to the high unmet need in this disease, GlobalData forecasts the rapid uptake of Abraxane, particularly for patients with average to poor performance status who are ineligible for the efficacious, yet toxic, FOLRIFINOX (5-flourouracil [5-FU]/leucovorin/irinotecan/oxaliplatin) regimen. Abraxane sales are expected to drive the overall pancreatic cancer market and are forecast to represent greater than 50% of the total sales in 2017.

GlobalData also forecasts the launch of five new pipeline agents into the pancreatic cancer market. These are anticipated to launch across a number of settings, including the adjuvant, first-line, and second-line of therapy, and beyond. Of these pipeline drugs, GlobalData anticipates the immunotherapy, algenpantucel-L, to garner the most sales by the end of the forecast period in 2017. Algenpantucel-L is expected to be launched as an adjuvant therapy in combination with gemcitabine for early-stage resectable pancreatic cancer patients, a setting that has not advanced clinically since the development of gemcitabine monotherapy in the last decade.

Despite the launch of these new products, GlobalData expects that there will still be significant clinical and commercial interest in the development of treatments to improve the poor survival outcomes in pancreatic cancer. Based on KOL interviews, GlobalData finds a very high level of unmet need remaining for patients in this increasingly-diagnosed disease. Despite the launch of new agents, GlobalData expects significant opportunities to remain for developers of drugs with predictive biomarker-driven strategies. The challenge for new entrants will be to design adequate clinical studies that assess pipeline drugs in carefully selected patient populations and incorporate the current standard-of-care chemotherapies, such as GemAbrax, as backbone regimens. With Big Pharma being actively involved in early-stage innovative projects, GlobalData expects clinical development in pancreatic cancer to accelerate at the end of the forecast period and beyond.
2.2 Related Reports

- GlobalData (2013). Non-Small Cell Lung Cancer (NSCLC) – Global Drug Forecast and Market Analysis to 2022, July 2013, GDHC52PIDR

2.3 Upcoming Related Reports

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

10.7 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, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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