PROSTATE CANCER – GLOBAL DRUG FORECAST AND MARKET ANALYSIS TO 2023
Executive Summary

Prostate Cancer: Key Metrics in the 9MM, 2013–2023

<table>
<thead>
<tr>
<th>2013 Epidemiology</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate cancer incident cases</td>
<td>813,462</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>2013 Market Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$1.6bn</td>
</tr>
<tr>
<td>5EU</td>
<td>$770m</td>
</tr>
<tr>
<td>Japan</td>
<td>N/A</td>
</tr>
<tr>
<td>Brazil</td>
<td>$167m</td>
</tr>
<tr>
<td>Canada</td>
<td>$41m</td>
</tr>
<tr>
<td>Total</td>
<td>$2.6bn</td>
</tr>
</tbody>
</table>

Pipeline Assessment

| Number of drugs in Phase III       | 9      |

Most Promising Pipeline Drugs

<table>
<thead>
<tr>
<th>Peak-Year Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yervoy (Bristol-Myers Squibb)</td>
<td>$599m</td>
</tr>
<tr>
<td>ProstAtak (Advantagene)</td>
<td>$729m</td>
</tr>
</tbody>
</table>

Key Events (2013–2023)

<table>
<thead>
<tr>
<th>2023 Market Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$3.7bn</td>
</tr>
<tr>
<td>5EU</td>
<td>$2.39bn</td>
</tr>
<tr>
<td>Japan</td>
<td>$311m</td>
</tr>
<tr>
<td>Brazil</td>
<td>$1.6bn</td>
</tr>
<tr>
<td>Canada</td>
<td>$159m</td>
</tr>
<tr>
<td>Total</td>
<td>$8.2bn</td>
</tr>
</tbody>
</table>

Source: GlobalData

5EU = France, Germany, Italy, Spain, and UK; 9MM = US, France, Germany, Italy, Spain, UK, Japan, Brazil, and Canada
mCRPC = metastatic castration-resistant prostate cancer; N/A = not applicable; nmCRPC = non-metastatic castration-resistant prostate cancer

The table above provides the key metrics for prostate cancer in the nine major pharmaceutical markets (9MM) (US, France, Germany, Italy, Spain, UK, Japan, Brazil, and Canada) covered in this report during the forecast period from 2013 to 2023.

Value of Prostate Cancer Market to Increase Three-Fold By 2023

GlobalData estimated the value of the prostate cancer market in 2013 at $2.6 billion across the 9MM. This market is defined as sales of major branded drugs commonly prescribed for prostate cancer patients across the 9MM, excluding hormonal and bone therapies. Over half of these sales, $1.6 billion (62%), were generated in the US, with the 5EU (France, Germany, Italy, Spain, and the UK) representing the next largest region by sales, estimated at $770m (30%). Japan contributed the smallest proportion of sales to the global prostate cancer market, with no sales in 2013, due to branded therapies such as Johnson and Johnson’s (J&J’s) Zytiga (abiraterone acetate), Medivation/Astellas’ Xtandi (enzalutamide), and Sanofi’s Jevtana (cabazitaxel) only launching in Japan in 2014.

By 2023, GlobalData projects that prostate cancer sales will rise to $8.2 billion in the 9MM, at a Compound Annual Growth Rate (CAGR) of 12.3%. In particular, GlobalData expects the Brazilian and Japanese prostate cancer markets to grow the most rapidly. The Brazilian market will grow to $1.6 billion by 2023, at a CAGR of 25%, while the
launch of branded drugs in Japan in 2014 will increase the value of the Japanese prostate cancer market to $311m by 2023. In contrast, the proportion of sales from the US and 5EU are forecast to decrease to 46% and 29%, respectively.

Major drivers of the growth of the prostate cancer market over the forecast period include:

- A rapidly aging population, resulting in prostate cancer incident cases increasing in the markets covered in this report. Overall, across the 9MM, the diagnosed incidence of prostate cancer is expected to increase by an Annual Growth Rate (AGR) of 3.6% from 2013−2023. This growth in the disease incidence is forecast to be most pronounced in Brazil.

- The anticipated label extension of Xtandi into chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC), non-metastatic castration-resistant prostate cancer (nmCRPC), and hormone-sensitive prostate cancer. Xtandi’s superior safety and efficacy garnered a favorable impression from key opinion leaders (KOLs) interviewed by GlobalData, and its use in multiple prostate cancer patient segments ensures that it will be the market-leading prostate cancer drug by the end of the forecast period in 2023.

- The launch of nine new premium-priced therapies for the treatment of prostate cancer by 2023. GlobalData expects the launch of eight pipeline agents for castration-resistant prostate cancer (CRPC), and one for the treatment of localized prostate cancer. In addition, it expects label extensions for both Zytiga and Xtandi in the treatment of hormone-sensitive prostate cancer.

Major barriers to the growth of the prostate cancer market over the forecast period include:

- Loss of patent protection for Zytiga, the leading drug in the prostate cancer market in 2013. Zytiga will lose patent protection in the US at the end of 2016, and in all the other markets during the forecast period. GlobalData expects that the entry of generic versions of the drug will erode Zytiga sales in the prostate cancer market.

- Further healthcare austerity measures, which will limit premium pricing opportunities for pipeline agents in the prostate cancer market. Increasing cost-consciousness across all markets will result in drug companies needing to factor in the changing reimbursement landscape when deciding on pricing strategies. GlobalData expects that tighter expenditure control will impede the reimbursement and uptake of drugs that are priced too high.
Executive Summary

The figure below illustrates the global sales for prostate cancer by region during the forecast period.

Xtandi Will Become the Leader in the Global Prostate Cancer Market

Over the forecast period, GlobalData anticipates that Xtandi will become the market leader in prostate cancer. Xtandi launched in 2012 in mCRPC as a treatment for patients who have failed docetaxel chemotherapy. In 2014, it received a label extension in the US, 5EU, and Japan into chemotherapy-naïve mCRPC as well. GlobalData expects that Xtandi will receive further label extensions into nmCRPC and hormone-sensitive prostate cancer in 2016 and 2019, respectively. Thus, by the end of the forecast period, with the exception of localized prostate cancer, Xtandi will be available in all other prostate cancer patient segments. In addition, Xtandi’s favorable safety and efficacy, combined with its ease of administration, makes it a popular choice among prostate cancer experts interviewed by GlobalData. Unlike Zytiga, Xtandi does not require co-administration with prednisone, giving it a significant advantage, as it eliminates the need to monitor patients on a monthly basis. GlobalData forecasts that Xtandi sales will represent a remarkable 46% of total global drug sales in the prostate cancer market in 2023.
Executive Summary

The figure below provides an analysis of the company portfolio gap in prostate cancer during the forecast period.

The CRPC Treatment Landscape Will Undergo Dramatic Change

Prior to 2010, the chemotherapy, docetaxel, was the gold-standard first-line treatment for mCRPC. Since 2010, five new treatments for mCRPC have become available: Jevtana, Provenge (sipuleucel-T), Zytiga, Xtandi, and Xofigo (radium 223 dichloride). Over the forecast period, GlobalData expects six new pipeline agents to launch in mCRPC. As a result, the mCRPC treatment landscape will change dramatically. With the availability of so many new therapeutic options, physicians will face the critical issue of determining how to best use and sequence the new drugs for the treatment of prostate cancer. In addition, drug developers will need to keep in mind the shifting treatment landscape in order to develop relevant clinical trials. Currently, most Phase III drugs are being evaluated in the pre- or post-docetaxel setting. However, as docetaxel is now being relegated as a later-line therapy, these settings are quickly becoming obsolete.

The treatment of nmCRPC will also undergo significant change. While there are no currently approved therapies for the treatment of nmCRPC, GlobalData expects three drugs to launch in this setting during the forecast period: J&J's ARN-509 and Bayer's ODM-201, as well as Xtandi's label extension into nmCRPC. GlobalData anticipates that Xtandi will launch first in this setting in 2016, followed by ARN-509 in 2017 and ODM-201 in 2019.

Nine New Pipeline Agents Will Launch in Prostate Cancer During the Forecast Period

The prostate cancer pipeline is robust, with nine drugs in Phase III development. The androgen-signaling pathway remains a major target of drug developers in the prostate cancer space; however, many of the pipeline candidates also have diverse mechanisms of action that target novel proteins and pathways. Among these new candidates is a checkpoint inhibitor (Bristol-Myers Squibb's [BMS'] Yervoy [ipilimumab]), a clusterin inhibitor (OncoGenex's custirsen sodium), and an anti-
Executive Summary

angiogenic agent (Active Biotech and Ipsen's tasquinimod). There are also several vaccines, both autologous and off-the-shelf, that have a strong presence in the prostate cancer pipeline, including Bavarian Nordic's ProstVac (Vaccinia-PSA-TRICOM/Fowlpox-PSA-TRICOM), Advantagene's ProstAtak, Sotio's DCVAC/PCa, and GreenPeptide's ITK1. However, GlobalData's primary research shows there is uncertainty among physicians as to how big of a role immunotherapies or vaccines will play in the future management of prostate cancer, especially given the mixed response to Dendreon's therapeutic vaccine, Provenge.

Overall, GlobalData expects that the nine new pipeline agents will represent a 37.5% share of the global prostate cancer market in 2023. As most of these pipeline agents are targeting the mCRPC population, GlobalData expects that their uptake will be slow due to the already crowded mCRPC market. In the nmCRPC setting, ARN-509 and ODM-201 are expected to launch; however, this will occur after the launch of Xtandi, which is also being developed for nmCRPC. ProstAtak is expected to be the only therapy launching in the localized prostate cancer setting during the forecast period, and will require long-term data demonstrating that it delays tumor recurrence, before its wider adoption into clinical practice by physicians.

The figure below provides a competitive assessment of the nine late-stage pipeline agents in prostate cancer during the forecast period.

Unmet Need Will Remain for Therapies That Provide a Durable Overall Survival Benefit for CRPC Patients

While the level of clinical development in the CRPC space is unprecedented, GlobalData found that there is still a high unmet need for treatments that can provide a durable overall survival (OS) benefit or cure for CRPC. All of the drugs that have launched in CRPC in the last five years, such as Zytiga, Xtandi, and Xofigo, extend OS at best only by several months over the previous standards of care. While data from clinical trials demonstrate
progression-free survival (PFS) of more than a year for Zytiga and Xtandi, in reality, physicians reported a much shorter time to progression. Even among the pipeline agents, there presently is no indication that any of them will be able to significantly extend OS or cure CRPC. Thus, physicians and patients alike remain keen for treatments that can cure or provide durable OS in CRPC.

What Do the Physicians Think?

According to KOLs interviewed by GlobalData, Zytiga and Xtandi are swiftly replacing docetaxel as the gold-standard first-line treatment for mCRPC. GlobalData found that KOLs overwhelmingly preferred Xtandi over Zytiga, due to the fact that it does not need to be used in combination with prednisone and requires less frequent patient monitoring.

“I think that most of the patients with castration-resistant prostate cancer will be treated with Zytiga or Xtandi before receiving docetaxel.”

OUS Key Opinion Leader

“Probably at the beginning, it will be 50:50 [split between patients receiving Zytiga and Xtandi], and after a while, I suspect that all of the patients will be receiving Xtandi in [the] first line, because you don’t need to use steroids [with it].”

OUS Key Opinion Leader

“Given the choice, I would prefer Xtandi to Zytiga, because the complications [with it] are somewhat fewer, the monitoring requirements are less, and that’s appealing to guys like us.”

OUS Key Opinion Leader

KOLs also anticipate that the treatment of hormone-sensitive prostate cancer will undergo significant changes during the forecast period. While androgen-deprivation therapies (ADTs) have historically been the main form of treatment for hormone-sensitive prostate cancer, KOLs are excited by new studies that demonstrate the benefit of combining chemotherapy, Zytiga, or Xtandi with ADT.

“I’m sure there’s going to be massive change over the next 10 years. There are ongoing trials testing the use of Zytiga and Xtandi at the same [time] as initiating ADT, and so, we’ll have data from those trials within the next five years, and I would expect for [the results of] those trials to be positive. I would imagine [that] within a 10-year timeframe, people will be getting ADT plus Zytiga or ADT plus Xtandi as their initial hormone treatment.”

OUS Key Opinion Leader
“It [chemohormonal therapy] is standard practice for high-volume metastatic prostate cancer, and that’s an accepted change that just happened within the last two months. The benefit of chemotherapy was actually quite extraordinary in that high-volume, newly-diagnosed metastatic disease patient population.”

US Key Opinion Leader

With an influx of new treatments that have recently launched or will launch during the forecast period, KOLs report the need for more information or studies to demonstrate how to best use the new agents and how to best sequence them in the treatment of prostate cancer.

“A significant challenge in managing CRPC is [how] to [best] order the treatment. It’s [good] to know if it’s better to start with a second-generation hormone treatment, or if it’s better to start with chemotherapy. The big question for now is how to improve the treatment of a patient with so many new drugs [being] available.”

OUS Key Opinion Leader

“I think that the main goal [in treating prostate cancer] is to define which patient will benefit from one or the other drug. But this is very difficult to decide because we don’t have any predictive factor.”

OUS Key Opinion Leader

Despite the launch of so many new therapies, KOLs are keen to find treatments that will provide a durable OS benefit or cure CRPC.

“Well, they [patients] still die from the disease; that’s the major challenge. We don’t have any therapy that is anything other than palliative and provides a modest survival benefit. So, the fact that people get very excited about a four-month survival benefit tells you that [the] expectations are fairly low. That’s not to diminish the importance of a four-month survival benefit, but what we really want is a therapy that’s potentially curative, which none of them are.”

OUS Key Opinion Leader
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2 Introduction

2.1 Catalyst

Prostate cancer is the second most common cancer in men worldwide, after skin cancer. It accounts for 15% of all the cancers diagnosed in men, and thus represents a huge burden on healthcare systems. While patients diagnosed with early-stage, localized prostate cancer can be cured, patients who are diagnosed with or progress to castration-resistant prostate cancer (CRPC) have no curative options. Since 2010, five new drugs have been approved for the treatment of CRPC: Dendreon’s Provenge (sipuleucel-T), Sanofi’s Jevtana (cabazitaxel), Johnson & Johnson’s (J&J’s) Zytiga (abiraterone acetate), Medivation/Astellas’ Xtandi (enzalutamide), and Bayer’s Xofigo (radium 223 dichloride). During the forecast period from 2013–2023, GlobalData expects that nine new late-stage pipeline agents will launch, eight of which will be for the treatment of CRPC. As a result of this unprecedented level of clinical development, GlobalData predicts there will be massive changes in the CRPC treatment paradigm. In addition, due to the influx of new therapies, the size of the prostate cancer market across the nine major pharmaceutical markets (9MM) (US, France, Germany, Italy, Spain, UK, Japan, Brazil, and Canada) will increase three-fold.

2.2 Related Reports

- GlobalData (2014). HER2-Positive Breast Cancer – Global Drug Forecast and Market Analysis to 2022, September 2014, GDHC86PIDR
Introduction


2.3 Upcoming Related Reports

- GlobalData (2015). Renal Cell Carcinoma – Global Drug Forecast and Market Analysis to 2023
- GlobalData (2015). Multiple Myeloma – Global Drug Forecast and Market Analysis to 2023
Appendix

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

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