The table below presents the key metrics for bladder cancer in the six major pharmaceutical markets (6MM) covered in this report (US, France, Germany, Italy, Spain, UK) during the forecast period from 2012–2017.


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<tr>
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<th>2012 Patient Population</th>
<th>2012 Market Sales</th>
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<tr>
<td><strong>Incident Population</strong></td>
<td>183,116</td>
<td>US $139.4m</td>
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<tr>
<td><strong>Treated Population</strong></td>
<td>180,993</td>
<td>5EU $99.8m</td>
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<tr>
<td><strong>Total</strong></td>
<td></td>
<td>Total $239.3m</td>
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**Key Events (2012–2017)**

- EOquin launch US and EU – 2016  

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<td>5EU</td>
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Despite the Launch of Spectrum Pharmaceuticals’ EOquin, Nominal Growth in US and EU Bladder Cancer Market Is Expected from 2012 to 2017

GlobalData estimates the bladder cancer market in the US and 5EU (France, Germany, Italy, Spain, and UK) in 2012 to be valued at $239.3m. This market is defined as the sales of branded drugs, including Valstar (US only) and Javlor (Europe only), and major generics regimens across both markets. Predominantly due to the higher price of drugs, the majority of sales were generated in the US market, $139.4m (58%), with EU sales estimated to be $99.8m (42%).

By the end of the study period in 2017, GlobalData forecasts global sales in the bladder cancer market to increase to $297.5m, at a compound annual growth rate (CAGR) of 4%. The majority of sales at this point will still come from the US, with $181.1m (61%), with its market share increasing marginally from 58% in 2012 to 61% by the end of the forecast period. Overall, GlobalData expects an increase in market size primarily due to a forecast increase in number of incident cases across the study period in the 6MM and the entrance of EOquin into the market during the forecast period.
Executive Summary

The emergence of Spectrum Pharmaceuticals’ EOquin, the only product in the pipeline to enter the market during the forecast period, will also have a small incremental effect on the bladder cancer market. Global sales for EOquin will account for $13.2m in its launch year, 2016, and $26.1m in 2017, accounting for 8.8% of sales in that year.

There are several major drivers of the bladder cancer market in the US and 5EU.

- The forecast increase in number of incident cases of bladder cancer will be the single greatest driver for growth across the study period.
- The launch of EOquin into the market in 2016 will drive growth of the market towards the end of the forecast period. However, GlobalData also anticipates that the EOquin’s most profound impact on the market will not occur until after the forecast period ends in 2017. GlobalData estimates global sales for EOquin in 2016 to be $13.2m and peak-year sales during the forecast in 2017 to reach $26.1m, accounting for 8.8% of global bladder cancer sales.
- The 2009 re-launch of branded therapy Valstar (2009) into the US market and subsequent gradual increase in patient share is driving modest growth of this market.
- GlobalData has identified a lack of late-stage company-sponsored pipeline developments in the bladder cancer setting by large pharmaceutical and biotech companies. This lack of interest will result in fewer pipeline products entering the market, in turn stagnating growth.
- The highly generic nature of the bladder cancer setting will inhibit growth as pricing, sales and marketing, and competition will all be truncated.
- The majority of bladder cancer patients are over the age of 60; this means a large portion of them in the US will receive insurance coverage through Medicare. The pending Medicare Prescription Drug Price Negotiation Act legislation would allow Medicare to negotiate lower drug prices; this lowers the reimbursement of drugs in this setting and is expected to act as a barrier for growth.
- In Europe, meanwhile, the economic crisis has meant that healthcare systems have heightened their focus on providing cost-effective healthcare. Reimbursement decision-makers like the UK’s NICE have rejected drugs in bladder cancer in the past, such as Javelor, on this basis of this, which means new entrants will need to demonstrate significant improvements in efficacy to substantiate any premium price claims.
Executive Summary

High Unmet Needs Exist across the Different Patient Populations

Interviewed experts report the level of unmet need in the bladder cancer market to be high, both in the early-stage, non-muscle invasive bladder cancer (NMIBC) and the late-stage muscle-invasive and metastatic settings. Little progress has been made over the past 10 years that has significantly changed the treatment algorithm for patients or provided more efficacious treatment options. GlobalData has identified better cure rates for NMIBC patients to be one of the key unmet needs.

NMIBC is the largest patient population in bladder cancer, accounting for 70% of all newly diagnosed cases. Long-established treatments such as BCG and mitomycin c are the mainstay in this setting. However, approximately 70% of patients will relapse after treatment. Patients with advanced or metastatic disease are not better served either: first-line therapy consists of a gemcitabine-cisplatin regimen, as there are no targeted therapies that have been approved in this setting.

Concomitantly, KOLs call for the identification of predictive biomarkers that would allow improved identification of NMIBC patients who are the most likely to relapse, or to inform on different treatment strategies.

A Clear Lack of Clinical Developments for Bladder Cancer

Late-stage clinical development in bladder cancer is poorly served. Only one drug is being investigated in a full-fledged Phase III program (EOquin, NMIBC setting) and only a handful of drugs are being evaluated in Phase II company-sponsored trials. In the metastatic setting, most of the developments are being conducted by independent investigators and are therefore not designed to gain regulatory approval. However, if conclusive, they are likely to contribute to the off-label use of commercially available drugs, especially if they are targeting a segment where large unmet needs remain, such as metastatic bladder cancer.
Additionally, these independent trials are likely to be scrutinized for early signals of efficacy that can then be pursued through more solid, large-scale, company-sponsored trials. This “back seat” methodology provides a strategic position to maximize rewards while minimizing risks.

**Pipeline Agents Will Offer Marginal Improvements over Current Therapies**

Based on interviewed expert insight, GlobalData expects the current pipeline agents to only deliver marginal clinical benefit to patients compared with existing therapies. Spectrum Pharmaceuticals’ EOquin is the only pipeline agent expected to launch over the forecast period (2012–2017). This drug should have a significant commercial edge over its benchmark comparator mitomycin c; however, it is expected to only demonstrate minimal clinical superiority. Other pipeline agents being developed in company-sponsored trials include Cold Genesys’ CG-0070 and OncoGenex’s apatansen. GlobalData believes CG-0070 should be able to demonstrate clinical benefit over Valstar in the BCG-refractory cystectomy-ineligible setting and could take a significant market share away from Valstar in the US as the mainstay for patients in this setting.

In the metastatic setting, GlobalData expects the addition of OncoGenex’s apatansen to improve clinical outcomes for patients treated with the gemcitabine-cisplatin regimen alone, although the benefit may be minor.

**Significant Opportunity Remains for Effective Therapies in Bladder Cancer**

With the launch of only one new agent over the forecast period, the high unmet needs in the bladder cancer setting will remain underserved. Based on interviewed expert opinion, GlobalData expects there to remain lucrative opportunities for developers of novel efficacious treatments for both the NMIBC and metastatic settings in the future. In particular, GlobalData anticipates that upon launch, developers of efficacious biomarker-driven targeted treatments could attain rapid uptake and command premium pricing. Overall, GlobalData believes the most commercially profitable setting is the low-grade Ta setting, specifically, as these patients make up the majority of all bladder cancer cases (approximately 50%). However, interviewed KOLs have also compared the metastatic setting to a low-hanging fruit in regards to gaining approval.
Executive Summary

Experts believe that drugs that demonstrate even marginal efficacy have gained regulatory approval with relative ease in the past, and will continue to do so in the near future.

Because of the substantial market size, the small number of treatment options, the lack of drugs currently being developed, and the clear regulatory path for drug approval, GlobalData believes that the bladder cancer market provides a unique opportunity for companies to make gains from developing and marketing their drugs.

What Do the Physicians Think?

“In regards to bladder cancer development, it has been 20 years since we have made any real progress.”

US Key Opinion Leader, August 2013

Interviewed KOLs have not been impressed with what the pipeline has to offer; GlobalData expects the unmet needs in the bladder cancer setting to remain over the forecast period.

“There is room for a drug that can reduce relapse rates in the NMIBC setting; this is a concern for me because the benefit of adjuvant treatment for relapse rates is not high. We lack drugs that can give us good results here.”

European Key Opinion Leader, August 2013

“BCG-intolerant or refractory patients are an important unmet need in NMIBC; this group specifically includes patients with high-grade tumors.”

US Key Opinion Leader, August 2013

“There is a very high unmet need for preventing NMIBC progression. We need to find more effective ways of preventing the disease becoming metastatic.”

European Key Opinion Leader, August 2013

“The biggest unmet need in the metastatic setting is that not all patients are sensitive to cisplatin.”

European Key Opinion Leader, August 2013

“I think that the post-first-line metastatic disease is a good opportunity because it is a low-lying fruit, the track record of drug development in this arena is not great. Vinflunine, that [would be] your control arm for the trial, is a low hurdle to beat.”

European Key Opinion Leader, August 2013

Unmet needs and opportunities have been identified by interviewed KOLs in both early-stage NMIBC and metastatic bladder cancer settings.
Interviewed KOLs have highlighted that identifying biomarkers for bladder cancer is an important challenge for the future, a direction which research and development should be focused on, and one that could facilitate the development of novel targeted treatments that could provide major clinical benefit compared to currently available treatments.

“The use of biomarkers in the NMIBC setting could help recognize high-risk patients... I think that research of biomarkers could be very important also in regards to drugs in the adjuvant setting.”

*European Key Opinion Leader, August 2013*

“What bladder cancer is really crying out for are predictive markers... I would really encourage pharma to pursue this more than any other area in this disease; I’m sure there will be a crizotinib for bladder cancer.”

*European Key Opinion Leader, August 2013*
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Introduction

2 Introduction

2.1 Catalyst

Bladder cancer has historically been a setting with a lack of interest from the pharmaceutical industry, with no major treatment or market-altering drug launches in this highly generic market for over a decade. Considering the fact that bladder cancer has one of the higher incidence rates in oncology, a lack of indicated therapies and great unmet needs, this absence of interest is surprising.

GlobalData does not expect the global bladder cancer market to change significantly by 2017, with only one new drug entering the markets covered in this report (the US, France, Germany, Italy, Spain, and the UK) However, this will have a nominal impact on market growth, which will continue to primarily be driven by a forecast increase in number of incident cases over the study period. Based on interviewed expert insight, GlobalData finds high remaining unmet needs in this highly underserved market. GlobalData expects there to be great commercial opportunities in the bladder cancer market for companies that can develop efficacious and well-tolerated drugs for both early and advanced disease settings.

2.2 Related Reports

2.3 Upcoming Related Reports

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, Boston, London, India and Singapore.

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