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<td>Lynparza (olaparib [AstraZeneca])</td>
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<td>Launch of palbociclib in the second-line hormonal metastatic setting in 2016 (US, EU, and Japan)</td>
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<tr>
<td>Launch of buparlisib in the second-line hormonal metastatic setting in 2018 (US, EU, Japan, and China)</td>
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<td>Patient expiry of Afinitor (everolimus) in 2020 (US and China) and 2019 (EU and Japan)</td>
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<td>Launch of Lynparza in the adjuvant chemotherapy triple-negative breast cancer (TNBC) setting in 2021 (US, EU, Japan, and China)</td>
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<td>Japan</td>
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<td>China</td>
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<td>Total</td>
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Source: GlobalData

Above mentioned Table presents the key metrics for the human epidermal growth factor receptor type 2 (HER2)-negative breast cancer market (as defined by the branded therapies) in the eight major pharmaceutical markets (US, France, Germany, Italy, Spain, UK, Japan, and China) during the forecast period from 2013–2023.

### HER2-Negative Breast Cancer Market to Increase by Four-Fold by 2023

In the eight major markets (8MM) covered in this report, GlobalData valued the HER2-negative breast cancer market, as defined by the branded therapies, at $1.45 billion in 2013. In this market, 48% of sales in 2013 will come from drugs in the hormone receptor-positive (HR+) setting; the remaining 52% will come from the TNBC setting. GlobalData expects the HER2-negative breast cancer market to increase to $6.12 billion by 2023, at a Compound Annual Growth Rate (CAGR) of 15.5%, when HR+ sales will account for around 82% of the global market, and TNBC sales will account for around 18%. The US is expected to remain the largest market over the forecast period, rising from $763m and a 53% share of the global market in 2013 to $3.59 billion and a 59% share of the total market in 2023, at a CAGR of 16.8%. This growth will largely be driven by the launch of several premium-priced products, and the rapid acceptance and reimbursement of these agents across various settings.
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The top drivers of growth in the HER2-negative breast cancer market during the forecast period include:

- The launch of a number of innovative premium-priced products — namely, the CDK4/6, PI3K (HR+), and PARP (TNBC) inhibitors. Sales from just these drug classes are expected to account for $5.1 billion (84%) of the global HER2-negative breast cancer sales in 2023. The collective sales from CDK4/6 and PI3K inhibitors will account for $3.6 billion and 79% of the global sales in the HR+ setting in 2023. The collective sales from all of the PARP inhibitors will account for $1.02 billion and 94% of the global sales in the TNBC setting in 2023.

- The increasing worldwide aging population and incident cases of HER2-negative breast cancer.

- Older women are at a higher risk of developing breast cancer, and furthermore, the implementation of nationwide breast cancer screening programs in several countries will contribute to an increase in the diagnosis of early-stage disease. This is especially the case in urban China, where, over the forecast period, the incident cases are expected to increase faster than in any other market covered in this report, at an Annual Growth Rate (AGR) of 6.4%.

- Sales from the highly lucrative adjuvant setting. By 2023 Lynparza sales across the 8MM in TNBC are expected to reach $926m, the vast majority of which (79%) will be from sales in the adjuvant TNBC setting at $731m. NeuVax (nelipepimut-S/E75) is also set to enter the adjuvant setting (HR+) in the US and 5EU, and even with relatively low patient shares (<10%), it will score comparatively high global sales of $567m by 2023. The sheer size of the adjuvant population and the high number of treatment cycles that can be administered in this setting are the reason for its lucrative nature. GlobalData identified the adjuvant setting as a particularly financially rewarding one for companies to enter, and it will remain relatively untapped, even after the forecast period.

Major barriers to growth in the HER2-negative breast cancer market during the forecast period include:

- All of the current branded therapies are expected to go off patent in most of the 8MM by the end of the forecast period. Sales of the current branded therapies will only amount to $387m (6%) of global sales in 2023, compared with $1.45 billion in 2012.

- Tighter control of total healthcare expenditures in the 5EU will be a significant hurdle for the uptake of new premium-priced drugs. In the US, the Affordable Care Act (ACA) is creating a new cost-conscious environment that could
impacting the free-pricing system for pharmaceuticals.

- Inconsistent healthcare coverage across China continues to be a barrier to growth in the HER2-negative breast cancer market, as well as drug reimbursement issues.

Below mentioned Figure illustrates the global sales for HER2-negative breast cancer during the forecast period by region and hormone receptor status.

### Global Sales for HER2-Negative Breast Cancer by Region and HR Status, 2013–2023

#### By Region

<table>
<thead>
<tr>
<th>Region</th>
<th>2013</th>
<th>2023</th>
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<tbody>
<tr>
<td>US</td>
<td>$76</td>
<td>$127</td>
</tr>
<tr>
<td>France</td>
<td>$129</td>
<td>$41</td>
</tr>
<tr>
<td>Germany</td>
<td>$187</td>
<td>$77</td>
</tr>
<tr>
<td>Italy</td>
<td>$127</td>
<td>$49</td>
</tr>
<tr>
<td>Spain</td>
<td>$76</td>
<td>$49</td>
</tr>
<tr>
<td>UK</td>
<td>$41</td>
<td>$77</td>
</tr>
<tr>
<td>Japan</td>
<td>$129</td>
<td>$49</td>
</tr>
<tr>
<td>China</td>
<td>$187</td>
<td>$77</td>
</tr>
</tbody>
</table>

#### By Hormone Receptor Status

<table>
<thead>
<tr>
<th>Status</th>
<th>2013</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR+</td>
<td>82%</td>
<td>59%</td>
</tr>
<tr>
<td>TNBC</td>
<td>18%</td>
<td>41%</td>
</tr>
</tbody>
</table>

Source: GlobalData
HER2-Negative Breast Cancer Pipeline Focuses on CDK4/6 and PARP Inhibitors

The HER2-negative breast cancer pipeline focuses heavily on essentially two therapeutic classes: the CDK 4/6 and PARP inhibitors. In the HR+ setting, GlobalData expects the launch of three CDK 4/6 inhibitors (abemaciclib, LEE011, and palbociclib) and four PARP inhibitors in the TNBC setting (niraparib, Lynparza, talazoparib and veliparib). GlobalData believes that although the efficacy and safety profiles of these drugs will be important, they are by no means going to be the key differentiators. Certainly, in the HR+ setting, palbociclib will clearly be the market leader, largely due to the fact that it will be the first-to-market drug in its class.

In the TNBC setting, there will be fierce competition among the PARP inhibitors. However, reaching the market first will not play such a crucial role in securing a large share, as the margin will be slim, and Lynparza is expected to gain approval (in ovarian cancer) before any other PARP. AstraZeneca will be the only pharmaceutical giant that will be developing its asset (Lynparza) in this setting; the company will be able to leverage its vast material resources to ensure that Lynparza’s share of this market is maximized. Furthermore as discussed in Section 2.6, sales from the huge adjuvant setting will push up the sales of Lynparza considerably.

Pfizer and AstraZeneca Will Be the Leaders in the HR+ and TNBC Markets, Respectively

Unlike the HER2-positive breast cancer market, which is dominated by Roche, the HER2-negative market currently has no such clear-cut leaders. In the large group of HR+ patients (who account for around 75% of all newly-diagnosed cases of breast cancer), the mainstay of treatment for the vast majority of patients is hormone therapy, which now consists mostly of generics. In regard to chemotherapy for this patient group, there is a mix between the use of off-label chemotherapeutic regimens and some branded therapies. Numerous companies produce these therapies, and all of them generally hold modest patient shares across the various settings. The landscape of chemotherapy in the TNBC setting is similar in this regard. However, GlobalData expects this to change drastically, as new market leaders will emerge with the introduction of innovative agents.

We believe Pfizer will dominate the HR+ setting, largely as a result of palbociclib being the first CDK 4/6 inhibitor to market, which will be accelerated by the Food and Drug Administration’s (FDA’s) breakthrough therapy (BT) designation.

GlobalData also believes that AstraZeneca will become the market leader in TNBC with the launch of its PARP inhibitor, Lynparza. Although Lynparza will not be the first-to-market drug in this class, we believe that AstraZeneca’s position as a pharmaceutical giant, and the sales that will specifically come from the adjuvant setting
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(accounting for 79% of peak-year sales of Lynparza) will boost Lynparza sales and allow AstraZeneca to dominate this setting. Indeed, HER2-negative breast cancer as a whole is an area with which AstraZeneca is very much familiar, as a former leader with a strong portfolio of now-generic hormonal therapies (fulvestrant and anastrozole). However, it should be noted that although AstraZeneca will be the clear market leader in the TNBC setting by 2023, Lynparza will only be used in the niche population of patients with a BRCA-positive tumor.

Other companies that GlobalData believes will be in a strong position by the end of the forecast period include Novartis (in the HR+ setting), which will hold a good hand of cards in the form of a number of assets, including a CDK 4/6 inhibitor (LEE011) and a PI3K inhibitor (buparlisib). We believe that Novartis’ wealth of experience in this setting, gained from Afinitor and letrozole, will bolster the company’s position as a real future contender in HER2-negative breast cancer.

Below mentioned Figure provides an analysis of the company portfolio gap in HER-negative breast cancer during the forecast period.

**Market Shift from Post-Hormonal Therapies to Combination Therapy with Hormonal Agents in the Metastatic Setting**

Currently, the use of branded therapies in HER2-negative, HR+ breast cancer is mainly in the post-hormonal setting; all sales in 2013 across the 8MM were from chemotherapy use in the metastatic setting. By 2023, a huge shift is expected to occur, whereby the overwhelming majority of sales will come from combination targeted therapy with hormonal agents, at $4.03 billion (85% market share). GlobalData identified this as a highly appealing market because of the long duration of
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therapy with these agents. Afinitor could, in fact, be described as the market leader among such agents, as it currently boasts the highest sales across the 8MM ($506m in 2013). We also believe that the new agents, such as the CDK 4/6 and PI3K inhibitors, will completely redefine the treatment algorithm, so it will be focused on the pre-chemotherapy setting. As hormone therapy delays the time before chemotherapy needs to be administered, we believe the use of chemotherapy will slowly start to be phased out. Furthermore if the PD-1 immunotherapies enter the breast cancer setting, as GlobalData expects may eventually be the case, there will be even less emphasis on chemotherapy in the metastatic setting.

Post-Hormonal Market Set for Drastic Changes

By the end of the forecast period in 2023, the post-hormonal metastatic setting will be almost completely genericized. This, combined with the shift in the treatment landscape (see Section 2.4), is expected to have a substantial effect on the post-hormonal metastatic setting. Questions as to which drugs will be efficient after the failure of CDK 4/6 and PI3K inhibitors will also arise, providing a good opportunity for pharmaceutical companies to position new products in this setting, even more so than today. Chemotherapies will be used as salvage therapy, and the number and use of the current generic chemotherapeutic regimens is likely to decrease greatly, and to be replaced with the current branded therapies (Halaven [eribulin mesylate], Doxil/Caelyx [pegylated liposomal doxorubicin], etcetera), which will by 2023, have become generic.

Highly Lucrative Adjuvant Setting Will Become a Key Area of Interest in Both HR+ and TNBC

GlobalData believes that the adjuvant setting will be a highly lucrative market for companies to test their assets. The sheer size of the adjuvant population, and the high number of treatment cycles that can be administered in this setting, are the reasons for its lucrativeness. This is expected to be true for both the HR+ and TNBC settings. By 2023 Lynparza sales across the 8MM in TNBC are expected to reach $926m, the vast majority of which (79%) will be from sales in the adjuvant TNBC setting. Similarly, NeuVax is set to enter the adjuvant setting (HR+) in the US and 5EU; even with relatively low patient shares (<10%), it will score comparatively high global sales of $567m by 2023. Overall, sales from the adjuvant setting will account for $1.3 billion (21%) of the global sales in HER2-negative breast cancer in 2023, and will act as a substantial driver for market growth.

Greatest Unmet Needs Will Remain for TNBC Patients

The launch of the PARP inhibitors in the TNBC setting will have a phenomenal effect with regard to changing the treatment paradigms for the niche BRCA mutation population (who account for approximately 30% of TNBC patients). However, there will still be absolutely no new treatments for the vast majority of TNBC patients across the
Executive Summary

8MM. TNBC is the most aggressive of all breast cancers. Unlike the other types of breast cancer, where HER2-targeting agents or hormonal therapies can be used to specifically exploit the overproduction of certain receptors, TNBC has no such targets. This, combined with the fact that most TNBCs are high-grade and progress and recur more rapidly than non TNBCs, means there are stark unmet needs in this setting that must be filled. Although the PD-1/PD-L1 immunotherapies could be the ideal candidates to address the unmet needs in the TNBC segment, it is important to remember that this population is heterogeneous. Thus, there will be a good opportunity for companies to identify patient subpopulations that can be targeted with a similar agent, and the financial rewards could be immense.

Below mentioned Figure provides a competitive assessment of the late-stage pipeline agents in HER2-negative breast cancer during the forecast period.

What Do Physicians Think?

Key opinion leaders (KOLs) highlighted the key unmet needs in HER2-negative breast cancer — specifically, in the TNBC setting. They expressed their excitement about the new CDK 4/6 and PI3K checkpoint inhibitors, as well as the PARP inhibitors, in this setting.

“I think that there is no clear consensus for treatment in triple-negative breast cancer, and it’s an unmet need….It’s just a nightmare.”

OUS Key Opinion Leader, July 2014
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“I think [the] number-one unmet need would be a better understanding of the biological diversity within triple-negative [breast cancer]. Number two would be targeted therapies directed at subsets of triple-negative [patients].”

US Key Opinion Leader, July 2014

“We are examining a very specific subgroup of breast cancers, which is a subset of a subset, the so-called, molecular apocrine group. It accounts for around the same [number of patients] as the BRCA population in TNBC….The triple-negative group is not a group; it is heterogeneous”.

OUS Key Opinion Leader, July 2014

“We really need more sophisticated approaches other than hormone therapy alone….We need to choose drugs that can be combined with the hormone treatment. As far as I can tell, the only class of drugs I can envision here is the CDK 4/6 inhibitors. They can be used in combination with hormone treatment very well, and do not have a heavy toxicity profiles.”

OUS Key Opinion Leader, July 2014

“Palbociclib is the most promising [in the HR+ setting], as it will be [the] first to market, and that usually gets the market share.”

US Key Opinion Leader, July 2014

“I think this palbociclib is a nice compound. Let’s see the Phase III trials. But I clearly believe this trial is going to be positive, and I think that this is going to be the next standard of care in [the] first line.”

OUS Key Opinion Leader, July 2014

“I think they [CDK 4/6 inhibitors] are very active, and they will be widely used, I think. The toxicity is also very low, so [they are] very friendly drugs.”

OUS Key Opinion Leader, July 2014

“The PARP inhibitors clearly work, right now, at least only in the BRCA mutation-positive patients…They are going to be good drugs in this small percentage of the [patient] population.”

US Key Opinion Leader, April 2014

“There’s a combination of ipilimumab and nivolumab in a study called CheckMate, which is going on at the moment. There is a suggestion that there may be an opportunity [for this combination] in patients with triple-negative breast cancer.”

OUS Key Opinion Leader, July 2014
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Introduction

2 Introduction

2.1 Catalyst

Human epidermal growth factor receptor type 2 (HER2)-negative breast cancer is the second most common cancer in the world and the most common cancer in women worldwide. When diagnosed at a very early stage, the prognosis is positive, with a five-year survival rate of nearly 100%. However, in the later stages of the disease, survival rapidly decreases. HER2-negative breast cancer can generally be subdivided into two major groups: HER2-, ER+ and/or PR+ (hormone receptor-positive [HR+]), and HER2-, ER-, and PR- (triple-negative breast cancer, or TNBC). HR+ breast cancer is typically diagnosed in older patients, and is the most common type, accounting for approximately 75% of all cases. It is generally considered less aggressive, as it is usually low-grade, and the patient prognosis is relatively good. TNBC accounts for approximately 10–15% of all cases of breast cancer. These tumors have a poor prognosis, and some TNBC will be positive for BRCA mutations.

GlobalData has produced this report in light of changes that are expected to cause explosive growth in both the HER2-negative and HER2-positive breast cancer settings. We expect a total of 11 new entrants to launch over the forecast period from 2013–2023. The size of the HER2-negative breast cancer market across the eight major markets (8MM) (US, France, Germany, Italy, Spain, UK, Japan, and China) is expected to increase by four-fold. This increase will primarily be driven by the launch of the CDK 4/6 and PI3K inhibitors in the HR+ setting, and the PARP inhibitors in the TNBC setting.

2.2 Related Reports

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

- GlobalData (2015). Renal Cell Carcinoma – Global Drug Forecast and Market Analysis to 2023, to be published
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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