Cytomegalovirus (CMV) Infections - Pipeline Assessment and Market Forecasts to 2019

Reference Code: GDHC504PRT

Publication Date: January 2013

Cytomegalovirus Infections: Key Metrics in Seven Major Pharmaceutical Markets

<table>
<thead>
<tr>
<th>2012 Epidemiology*</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalent population (CMV prevalent cases in general population)</td>
<td>462,478,028</td>
</tr>
<tr>
<td>Prevalent at-risk population (includes transplant patients, infants, and retinitis patients)</td>
<td>174,524</td>
</tr>
<tr>
<td>Diagnosed population</td>
<td>109,811</td>
</tr>
<tr>
<td>Treated population</td>
<td>68,015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2012 Market Sales</th>
<th>Prophylactic Market</th>
<th>Therapeutic Market</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$275.22m</td>
<td>$148.66m</td>
<td>$423.88m</td>
</tr>
<tr>
<td>5EU</td>
<td>$147.03m</td>
<td>$100.38m</td>
<td>$247.41m</td>
</tr>
<tr>
<td>Japan</td>
<td>$27.12m</td>
<td>$27.90m</td>
<td>$55.01m</td>
</tr>
<tr>
<td>Total</td>
<td>$449.36m</td>
<td>$276.93m</td>
<td>$726.28m</td>
</tr>
</tbody>
</table>

Pipeline Assessment

| Number of drugs in Phase I–III | 30 |
| Number of first-in-class drugs | 39 |

Key Events (2012–2019)

| Expected launch of TransVax in the US and Europe in 2016 | ↑↑↑ |
| Expected launch of Cytotect (CMV hyperimmunoglobulin) in 2015 in Europe | ↑↑ |
| Genericization of Valcyte (valganciclovir) in 2013 in the US and patent expiry in 2015 in Europe (prophylactic and therapeutic) | ↓↓↓ |
| Patent expiry of Vistide (cidofovir) in Europe in 2012 | ↓ |

2019 Market Sales

<table>
<thead>
<tr>
<th></th>
<th>Prophylactic Market</th>
<th>Therapeutic Market</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$412.37m</td>
<td>$175.11m</td>
<td>$587.48m</td>
</tr>
<tr>
<td>5EU</td>
<td>$317.86m</td>
<td>$129.91m</td>
<td>$447.77m</td>
</tr>
<tr>
<td>Japan</td>
<td>$41.77m</td>
<td>$39.96m</td>
<td>$81.73m</td>
</tr>
<tr>
<td>Total</td>
<td>$772.01m</td>
<td>$344.98m</td>
<td>$1.12bn</td>
</tr>
</tbody>
</table>

CMV Infections Market is Forecast to Witness Moderate Growth Until 2019

GlobalData estimates that the global Cytomegalovirus (CMV) infections market, comprising the markets of the US, the UK, France, Germany, Italy, Spain and Japan, was worth $685.50m in 2011 and will grow at a Compound Annual Growth Rate (CAGR) of 6.29% over the next eight years to reach $1.12 billion by 2019.

The CMV prophylactic market was estimated to be worth around $423.74m in 2011 and is forecast to grow at a CAGR of 7.79% to $772.01m in 2019. The CMV therapeutic market was estimated to be worth $261.76m in 2011 and is forecast to grow at a CAGR of 3.51% to reach $344.98m in 2019. The key events that are expected to impact the market during the forecast period are:

- The genericization of Valcyte in 2013 in the US and its patent expiry in 2015 in Europe in the prophylactic and therapeutic markets
- The expiry of Vistide's patent in Europe in 2012 in the therapeutic market
- The expected launch of Cytotect (CMV hyperimmunoglobulin) in 2015 in Europe in the therapeutic market
- The expected launch of TransVax in the US and Europe in 2016 in the prophylactic market

Additional factors that will contribute to growth are the increase of the patient pool, the expected launch of a vaccine due to its novelty and premium price and the increase in the number of Bone Marrow Transplant (BMT) and Solid Organ Transplant (SOT) patients.
Below mentioned figures show a breakdown of prophylactic and therapeutic sales by region.

### Seven Major Market Sales for Cytomegalovirus Prophylactic Market by Region, 2011–2019

<table>
<thead>
<tr>
<th>Region</th>
<th>2011</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>62%</td>
<td>53%</td>
</tr>
<tr>
<td>Germany</td>
<td>12%</td>
<td>17%</td>
</tr>
<tr>
<td>France</td>
<td>7%</td>
<td>10%</td>
</tr>
<tr>
<td>Spain</td>
<td>6%</td>
<td>8%</td>
</tr>
<tr>
<td>Italy</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Japan</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>UK</td>
<td>4%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Total: $423.74m in 2011, $772.01m in 2019

Sources: GlobalData epidemiology-based market forecasting model

### Seven Major Market Sales for Cytomegalovirus Therapeutic Market by Region, 2011–2019

<table>
<thead>
<tr>
<th>Region</th>
<th>2011</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>53%</td>
<td>50%</td>
</tr>
<tr>
<td>Japan</td>
<td>10%</td>
<td>11%</td>
</tr>
<tr>
<td>France</td>
<td>10%</td>
<td>11%</td>
</tr>
<tr>
<td>Germany</td>
<td>8%</td>
<td>9%</td>
</tr>
<tr>
<td>Italy</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Spain</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>UK</td>
<td>6%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Total: $261.76m in 2011, $344.98m in 2019

Sources: GlobalData epidemiology-based market forecasting model
New Companies Poised to Enter the CMV Prophylactic Market

Roche has a strong presence in the CMV market with Valcyte, which is the only branded product for the treatment of CMV infections. The company is likely to maintain its competitive position until the genericization of Valcyte in 2013 in the US and its patent expiry in 2015 in Europe. During the forecast period the market will experience the launch of a promising vaccine, TransVax, which has shown improved clinical safety and efficacy (Vical, press release, September 13, 2010). The CMV market will see the entrance of new companies that focus on three important strategies: first, companies focusing on novel mechanisms of action beyond DNA polymerase inhibitors; second, companies targeting transplant patients; and third, companies developing prophylactic products (40% of the pipeline products are being developed for CMV prophylaxis).

These strategies are expected to provide a distinct opportunity for pharmaceutical companies to build up their commercial presence in the CMV infections market.

Strong Pipeline Candidates with Novel Mechanisms are Expected to Intensify Future Competition

GlobalData’s analysis shows that the CMV development pipeline is strong, with 49 molecules in various stages of clinical development. The late-stage pipeline consists of one First-In-Class (FIC) vaccine, TransVax. TransVax is expected to enter the market within the forecast period and GlobalData expects TransVax to have a significant impact on the market landscape. TransVax is the first plasmid DNA vaccine being developed for CMV prophylaxis in both the US and Europe, and has also received orphan drug designation from the US Food and Drug Administration (FDA). It is expected to raise the barrier to entry for new marketed products, while providing a stiff competitive advantage over those currently on the market.

According to the Key Opinion Leaders (KOLs) interviewed for this report, the pipeline molecules have better efficacy and safety profiles than those currently used and their entrance into the market has the potential to change the current treatment algorithm by addressing existing safety and efficacy needs.

Untapped Market Opportunity with Weak Competition

GlobalData’s analysis shows that current market competition in the CMV market is weak, as Valcyte is the only branded drug for the treatment of CMV. Valcyte is a prodrug of ganciclovir with improved bioavailability, and is considered to be efficacious and safe for the treatment of CMV patients.

Aside from Valcyte, the market is completely dominated by generics, such as ganciclovir and foscarnet. Another drug, CMV-IG, is a biologic that has been available in the US since 1992. Other drugs, such as acyclovir and valacyclovir, are used off-label for CMV infections. All these drugs have low efficacy and safety profiles, leaving an untapped opportunity for companies able to provide better drugs than the existing branded products and generics.

Unmet Need Continues to Challenge the Pipeline Drugs

GlobalData’s analysis indicates that the unmet need in the CMV prophylactics and therapeutics markets is significant, as the currently used treatment options are associated with adverse events such as myelosuppression and renal toxicity. They also have black-box warnings on their labels. Therefore, safety is a major concern in both the prophylactic and therapeutic markets. Efficacy is an unmet need, primarily in the prophylactic market, and viral resistance to the current drugs is a limitation for the therapeutic markets. There remains ample opportunity for new molecules with novel mechanisms of action and new entrants targeting transplant patients as they are at a high risk of developing CMV. This analysis is represented below for the prophylactic and therapeutic markets in below mentioned figures respectively.
Unmet need in the CMV therapeutic market is moderately high

What do the physicians think?

The KOLs interviewed for this report stated that primary concerns within this market remain the need for vaccines to address the needs in the at-risk population segments, such as pregnant women and transplant recipients, a need for oral formulations with good bioavailability, and the need for new drugs for the treatment of congenital disease in neonates.

"Having a vaccine is a major need and priority in the market as currently there is no approved vaccine for CMV prevention."

US key opinion leader, September 2012

"I think the vaccines, if introduced, will be helpful either in preventing pregnant women from getting primary infection or developing immunity in transplant recipients who are most likely to relapse."

US key opinion leader, September 2012

"We need better drugs for oral treatment with good bioavailability. Products which show good concentrations in the blood are needed."

OUS key opinion leader, July 2012

"Currently, there is no drug approved for congenital CMV infection and the use of drugs which are available in the market is mainly limited by their toxicity. Thus there is a major need for developing drugs to treat congenital CMV infection."

OUS key opinion leader, July 2012

Note: Size of the bubble represents approximate cost-effectiveness of the product
Unmet need indicates the adverse events and efficacy associated with four marketed drugs including three generics

Source: Cytogam Prescribing Information, 2010; Cytovene Prescribing Information, 2010; Foscavir Prescribing Information, 2007; Valcyte Prescribing Information, 2010; Vistide Prescribing Information, 2012; Primary research interviews with key opinion leaders in the G7 countries.
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2 Introduction

2.1 Catalyst
The report has been produced to explore the existing CMV market landscape and provide an insight into the changes that may occur with the anticipated entry of TransVax, the first-ever vaccine in this area. Furthermore, Valcyte's patent expiry is expected to alter the major market players and the expected revenue within the forecast period. Moreover, the trend of companies researching and introducing novel mechanisms of action within the therapeutic space is likely to cause rapid and unprecedented change.

2.2 Related Reports
- GlobalData (2012) PharmaPoint: Seasonal Influenza Vaccines Global Market Forecast and Market Analysis. GDHC40PIDR

2.3 Upcoming Related Reports
- GlobalData (2013) PharmaPoint: HIV Therapeutics Global Market Forecast and Market Analysis. GDHC41PIDR
- GlobalData (2013) PharmaPoint: HCV Therapeutics Global Market Forecast and Market Analysis. GDHC42PIDR
11.6 About GlobalData

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