Table below presents the key metrics for dyslipidemia in the eight major pharmaceutical markets (8MM) (US, France, Germany, Italy, Spain, UK, Japan, and China).

<table>
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<td><strong>2013 Epidemiology</strong></td>
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</tr>
<tr>
<td>Treated dyslipidemia population</td>
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<tr>
<td><strong>2013 Market Sales</strong></td>
</tr>
<tr>
<td>US</td>
</tr>
<tr>
<td>5EU</td>
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<tr>
<td>Japan</td>
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<tr>
<td>China</td>
</tr>
<tr>
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<tr>
<td>Number of drugs in Phase I–II</td>
</tr>
<tr>
<td>Number of first-in-class drugs (Phase III+)</td>
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<tr>
<td>Evolocumab (Amgen)</td>
</tr>
<tr>
<td>Alirocumab (Sanofi/Regeneron)</td>
</tr>
<tr>
<td>Evacetrapib (Eli Lilly)</td>
</tr>
<tr>
<td>ETC-1002 (Esperion Therapeutics, Inc.)</td>
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<tr>
<td>IMPROVE-IT Phase III clinical trial demonstrates that Merck’s Zetia (ezetimibe) can help prevent events related to cardiovascular disease (CVD) as a result of low density lipoprotein (LDL)-lowering when added to Zocor (simvastatin) – November 2014</td>
</tr>
<tr>
<td>Amgen launches the first proprotein convertase subtilisin/kexin type 9 (PCSK9) monoclonal antibody (mAb), evolocumab – Q2 2015</td>
</tr>
<tr>
<td>AstraZeneca’s Crestor (rosuvastatin) loses patent protection in the US in 2016</td>
</tr>
<tr>
<td>Eli Lilly launches the first cholesteryl ester transfer protein (CETP) inhibitor, evacetrapib – 2017</td>
</tr>
<tr>
<td>Esperion launches the novel lipid modulating drug, ETC-1002 – 2020</td>
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**2023 Market Sales**

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<tr>
<th>Region</th>
<th>Sales</th>
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<tr>
<td>US</td>
<td>$23.4bn</td>
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<tr>
<td>5EU</td>
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<tr>
<td>Japan</td>
<td>$2.1bn</td>
</tr>
<tr>
<td>China</td>
<td>$6.9bn</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$37.9bn</strong></td>
</tr>
</tbody>
</table>

Source: GlobalData

SEU = France, Germany, Italy, Spain, and UK; IMPROVE-IT = IMProved Reduction of Outcomes: Vytorin Efficacy International Trial

### Sales for Dyslipidemia by Region, 2013–2023

This report focuses on the dyslipidemia pharmaceutical market from 2013–2023 in the 8MM. Throughout this report, these eight markets will be referred to as the “global market.” In the 2013 base year, the global dyslipidemia market was worth $15.4 billion, including both branded and generic drugs. Branded drug sales contributed 72% to the 2013 market, with sales valued at $11.0 billion. Generic drug sales comprised the remaining 28% of the market in 2013, with sales valued at $4.4 billion. The US dominated the dyslipidemia market in 2013, with sales reaching $10.1 billion, or roughly 65% of all global dyslipidemia sales. The outsized impact of the US on the global market is attributable to its large prevalent population of dyslipidemia patients and the dramatically higher cost of pharmaceuticals relative to the other major pharmaceutical markets.
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By 2023, GlobalData expects that the global dyslipidemia market will more than double in size, with a total value at $37.9 billion. Of this, 71%, or $26.9 billion of the 2023 market will be attributable to branded drug sales. The remaining 29%, or $11.0 billion, will come from generic drug sales. The market shares, by nation, will remain roughly steady between the base year and 2023. The US will continue to contribute the vast majority of sales to the dyslipidemia market – roughly 62% – in 2023. The dramatic increase in overall global market value is attributable to the launch of several drugs with definite blockbuster potential, which are currently in the late-stage development pipeline. These include three proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors (human monoclonal antibodies [mAbs] to PCSK9) that have the potential to reshape the dyslipidemia landscape. Additionally, the launch of the cholesteryl ester transfer protein (CETP) inhibitors and novel agents, such as Esperion’s ETC-1002 and Cerenis’ CER-001, will add new weapons to the dyslipidemia armamentarium, providing more options to high-risk patients who cannot tolerate, or do not sufficiently respond to, statin therapy.

The following figure shows the market share for the 8MM covered in this forecast in both the 2013 base year and the final forecast year, 2023. Although the overall global market value will increase significantly, the relative market share for each of the 8MM covered here will remain roughly stable, with the largest fluctuations derived from a slight drop in US market share and an increase in China’s market share.

The Launch of the PCSK9 mAbs and the CETP Inhibitors Will Drive Revenue Growth in the Dyslipidemia Market

Entering the 2013 base year, the dyslipidemia market was already mature, with a battery of therapies – the statins, ezetimibe, bile acid sequestrants, fibrates, niacin, omega-3 fish oils,
and emerging familial hypercholesterolemia agents – already available to serve the broad swath of patients and morbidities that comprise the dyslipidemia treatment space. Over the course of the forecast period, a proverbial “changing of the guard” will befall the dyslipidemia space, at least with regard to drug sales. In 2016, the last major branded statin, AstraZeneca’s Crestor (rosuvastatin), is expected to face generic competition for the first time, joining the ranks of the historical statin blockbusters, Merck’s Zocor (simvastatin) and Pfizer’s Lipitor (atorvastatin). On the whole, GlobalData expects that statins will remain the undisputed first-line treatment for almost all forms of dyslipidemia. However, the genericization of the statin class will serve to upend the sales landscape.

Two major revenue-generating events are expected to drive the change from the emerging pipeline: (1) the launch of the PCSK9 mAbs and (2) the launch of the CETP inhibitors. Both drug classes will serve niche patient subpopulations within the low-density lipoprotein cholesterol (LDL-C)-reducing dyslipidemia treatment space. They will be forced to compete not only with each other, but with established therapies. Their exploitation of novel mechanisms of action will give them an edge in achieving success towards this end. Ultimately, however, these drugs will need to perform successfully in major Phase III cardiovascular (CV) outcomes trials if they hope to gain acceptance into the broader dyslipidemia treatment space.

GlobalData expects that the major players in the PCSK9 space will be Amgen, Sanofi, Regeneron, and Pfizer. In the CETP inhibitor market, Eli Lilly and Merck will be the major players. However, the small company, Dezima Pharma, is making a play in the CETP space as well, with the promising agent, TA-8995, which has performed well through Phase II studies.

Atherosclerotic Plaque Regression, Improved Side Effect Profiles, and Rare Disease Treatments Remain the Greatest Unmet Needs in Dyslipidemia

To date, the statins and ezetimibe are the only lipid-modulating agents that have been proven to reduce CV events in major Phase III outcomes.
Executive Summary

For ezetimibe, this was only revealed recently in the groundbreaking IMPROVE-IT study (IMPproved Reduction of Outcomes: Vytorin Efficacy International Trial). Specifically, the long-term use of these drugs have demonstrated that reducing levels of LDL-C with drug therapy can produce measurable reductions in CV outcomes such as heart attack, stroke, and CV-death, with the so-called pleiotropic effects of statins notwithstanding. Despite the widespread use of these demonstrably successful classes of LDL-C lowering drugs, the incident and recurrent CV event rates for patients with dyslipidemia is astoundingly high. This is largely a result of the inability of current therapies to fully reverse the effects of established atherosclerosis.

As a result, there remains a major unmet need for drug treatments that can not only reduce LDL-C, but that can afford atherosclerotic plaque regression. This is a tall order, in that to regress a plaque – to effectively “clean” a diseased artery – atherothrombotic events must be avoided in the process. Thus, new therapies are needed that can reduce the fat and cholesterol content of established plaques as well as prevent inflammatory processes that lead to thrombosis, all while safely effecting the structural changes that can return a diseased artery back to a healthy state. Thus, it is entirely reasonable to suggest that entire suites of new drugs will be required to achieve this end. Furthermore, new drugs will likely require the simultaneous use of antithrombotic therapies such as antiplatelet and anticoagulatory agents to ensure safe and stable plaque regression.

In the more immediate future, it will be important for drug makers to develop agents that can reduce LDL-C without causing the adverse muscular side effects that are associated with statin use. Statin-related myopathies, myalgias, and, at worst, statin-induced rhabdomyolysis, are all causes for the terrible compliance issues associated with statin use. It is widely accepted that, because of these adverse effects, roughly 50% of patients will terminate their statin use following one year of therapy. The PCSK9s, the CETPs, and drugs like Esperion’s ETC-1002, are all likely candidates to fulfill this key unmet need.

In the dyslipidemia field, homozygous familial hypercholesterolemia (HoFH) is the most severe form of hypercholesterolemia, with stubbornly drug-refractory LDL-C levels that can be well into the hundreds of milligrams per deciliter. There are currently only a few novel therapies, Isis/Genzyme’s Kynamro (mipomersen) and Aegerion’s Juxtapid (lomitapide), that specifically and effectively treat patients with HoFH, and both are associated with potentially severe adverse effects associated with hepatic toxicity. The PCSK9s are expected to address some of this unmet need, but there is a lot of space for improvement in this field. As HoFH is a rare disease, potentially only impacting one in a million...
Executive Summary

people, a safe and effective therapy could command particularly high prices.

**Leading Pipeline Agents in Dyslipidemia**

During the forecast period, Amgen, Sanofi/Regeneron, and Pfizer are all expected to launch a PCSK9 mAb. Both Amgen and Sanofi are expected to launch their PCSK9s, evolocumab and alirocumab, respectively, in 2015. GlobalData expects Pfizer to launch its PCSK9, bococizumab, in 2018. At least initially, GlobalData expects that these novel agents will target a narrow population of patients: the roughly 5% that are intolerant or completely refractory to statin therapy. GlobalData’s forecast demonstrates that, even when restricted to this niche subpopulation, the PCSK9s have the potential to easily break the blockbuster threshold, both in the US and globally, due to the biologic-level pricing they will demand. All three PCSK9s are currently enrolled in major Phase III cardiovascular outcomes studies, which are not expected to have a major impact on sales until later in the forecast period, when they are scheduled to conclude.

Two major CETP inhibitor programs are currently being undertaken by Eli Lilly and Merck. GlobalData expects Eli Lilly’s evacetrapib to be the first-to-market CETP, with a launch anticipated in 2017. Merck is expected to launch its CETP, anacetrapib, the following year. Additionally, Dezima Pharma is expected to enter its CETP candidate, TA-8995 (DEZ-001), into Phase III studies in 2015. CETP inhibitors not only lower LDL-C, but they have been shown to dramatically raise high-density lipoprotein cholesterol (HDL-C). With recent clinical trials failing to show a benefit associated with raising HDL-C (such as the HPS2-THRIVE study of niacin), the importance of successful cardiovascular outcomes studies with the CETP inhibitors cannot be understated; HPS2-THRIVE: Heart Protection Study 2 – Treatment of HDL to Reduce the Incidence of Vascular Events. Indeed, GlobalData expects that their success at the regulatory level will depend upon their success in these trials. Assuming the CETPs can establish a cardiovascular benefit, they could become an important tool for favorably modulating pathogenic levels of LDL-C and HDL-C.

In keeping with the theme of serving niche patient segments within the dyslipidemia space, both Esperion Therapeutics, Inc., and Cerenis Therapeutics, Inc., are developing novel agents for the dyslipidemia space. GlobalData expects that Esperion will raise its novel LDL-C reducing agent, ETC-1002, into Phase III studies in 2015. ETC-1002’s unique mechanism of action may be able to serve patients with elevations of both LDL-C and triglycerides while avoiding the muscle-related side effects associated with statins. Cerenis recently received orphan designations for its HDL-C mimetic, CER-001, in the European Union (EU). This novel agent has the potential to serve several unmet needs in the dyslipidemia rare disease space.
In general, the drugs in the dyslipidemia pipeline will exploit novel mechanisms of action to better serve unmet needs within the space. Primarily, this means demonstrating the ability to reduce LDL-C and prevent cardiovascular events in patients who cannot tolerate statins or for whom statin therapy is insufficient to reduce LDL-C or cardiovascular risk. The genericization of the statins and the premium pricing (or biologic pricing, as with the PCSK9s and CER-001) of the emerging pipeline agents will spur the drastic changes that can be seen in the sales forecast presented herein, all while the statins remain the first-line drug therapy in the space overall.

**What Do the Physicians Think?**

The size of the drug-treated population of patients with dyslipidemia is expected to increase throughout the forecast period. At the most basic level, the overall prevalence of the disease will track with population growth in the 8MM. Interestingly, however, GlobalData Key Opinion Leaders (KOLs) from the US and the other seven major pharmaceutical markets (7MM) (France, Germany, Italy, Spain, UK, Japan, and China) believe that drug treatment rates will increase for different reasons. In the US, it is expected that the increasing number of individuals with health insurance coverage who are affected by the implementation of the Affordable Care Act (ACA), will cause the diagnosis rates and thus the drug treatment rates of dyslipidemia to increase. In all markets, it is believed that an increase in disease awareness will help increase diagnosis and treatment rates. In non-US markets, especially in China and Japan, KOLs attribute, at least in part, an increase in the prevalence of dyslipidemia to the increasing westernization of the culture.
“I think that the [diagnosis] rates will go up as awareness grows. I don't think it will necessarily be due to better diagnostic tools. I think it may be more relevant to more people having insurance coverage. And diagnosis and treatment of hyperlipidemia become things that are considered important in reimbursement panels. Hopefully, [diagnosis] will be up from 50% of people with any dyslipidemia to maybe 60 to 70%.”

US Key Opinion Leader

“But due to the westernization of lifestyles, not the diagnostic tool, the prevalence of dyslipidemia will increase in the future. The total cholesterol is increasing in the last 40 or 50 years, and triglyceride is also increasing in the last 20 or 30 years only in men. So, generally speaking, the prevalence of dyslipidemia is – will increase in the future. It’s irrespective of the diagnostic tool.”

Asia-Pacific Key Opinion Leader

“There are patient advocacy groups who are very active in supporting families with these diagnoses and will push screening of family members, etcetera. There are general health education programs, both from the government and medical charities. We will do opportunistic screening when cases appear to us. There’s a whole spectrum of those. And the lipid clinic will do exactly the same sort of thing.”

European Key Opinion Leader

Across all 8MM, KOLs agree that statins are the first-line drug treatment for dyslipidemia. Furthermore, they agree that ezetimibe is the standard second-line therapy. GlobalData found this to be the case, even when all other established lipid therapies were considered.

“Statin first, no question [for managing atherosclerotic cardiovascular disease (ASCVD)].”

US Key Opinion Leader

“First-line therapy is a statin. Depending on the problem, I would typically go with a potent statin. If they have very high LDL [low-density lipoprotein], as in familial hypercholesterolemia, and the LDL doesn’t go down enough, I will typically add a second drug, and my usual choice for that would be ezetimibe [Zetia].”

US Key Opinion Leader

“Dealing with secondary prevention, at the moment, what we’re doing is patients who are presenting with an ACS [acute coronary syndrome] – whether that’s an ST-elevation infarct or a non-ST elevation infarct – on getting atorvastatin 80 milligrams for 12 months and then going down to simvastatin 40 [milligrams] at the end of those 12 months, assuming that they have no further events. If there are particular reasons why we want to be more aggressive – for instance, they’ve had a second event despite high-dose statin – then they will often not down-titrate the drug. We will just continue at high-dose statin. In terms of primary prevention, again, we’re tending to go for pretty
Executive Summary

high-dose statins at an early stage. What we’re then doing is looking at those patients and if they’ve had a further event or if they’ve got a particularly high cholesterol to start with, then we are going for the highest-dose statin we can get to start with and often adding in something like ezetimibe [Zetia] on top of it.”

European Key Opinion Leader

“That would account for, if one looks at the data – and we have had the data from the pharmacy – probably 80 to 90% of patients will be on simvastatin and then another 10% will be on either rosuvastatin or atorvastatin. If they don’t reach the goal on that, we add in ezetimibe. Often, when we add ezetimibe, we would put the patient back on the simvastatin, because the ezetimibe is relatively expensive, and in the combination of simvastatin, that can usually reach the [LDL-C] goal in most patients.”

Asia-Pacific Key Opinion Leader

GlobalData KOLs agreed that the major pipeline drugs – the PCSK9s and the CETPs – are likely to be utilized as adjunctive therapies for patients with severe hyperlipidemias, or for patients who cannot tolerate statins. Furthermore, KOLs interviewed by GlobalData want to see positive results from major CV outcomes trials before they consider using these new drugs in the general dyslipidemic population.

“I’m expecting the outcomes [for PCSK9s] are going to be very positive, because I believe in the cholesterol hypothesis. Whether lowering LDL to 30 [milligrams per deciliter] as opposed to putting it down to 80 or 90 will make any difference, I remain to be convinced. We’ll see. It might – hypothetically, it makes sense. But as you know, there are lots of hypotheses that turn out to [be]… what do we say? – ‘A beautiful theory slain by an ugly fact.’ You really want to see the proof.”

US Key Opinion Leader

“It [whom it would be prescribed to] depends on the population studied in the [CETP inhibitor] outcomes trial. I would be unlikely to switch somebody off a statin. I would consider adding it [to a statin] or using it in patients who did not tolerate statins.”

US Key Opinion Leader
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“We don’t have surrogate outcome data [for PCSK9] from intracoronary imaging, for instance. We’re not going to have major MACE [major adverse cardiovascular event] type studies for two years, three years at least. Where do I see them [PCSK9s] being used? I see them being used probably firstly in the familial hypercholesterolemia [FH] patients who can’t take statins, or for the high-risk secondary prevention patients who can’t take statins. If you like, in that group of patients where we don’t have any other options – a patient can’t tolerate statins, you’ve got nothing else left – then we would be likely to use those drugs whilst we wait for the outcome of the Phase III trials. Or, as I say, in the FH group of patients.”

OUS Key Opinion Leader

“Of course, the preclinical data suggest the mechanism [of the CETP inhibitors] is effective and reduces atherosclerosis, but all the clinical data that we have so far is not really very supportive. It’s a bit worrying to think what the result will be with the two ongoing [CV outcomes trials of the] CETP inhibitors [evacetrapib and anacetrapib]. On balance, I would not be too hopeful that they will come out positive. I think it would depend very much on what patients are being treated and the choice of individual patients, and I suspect that hasn’t been selected to such an extent that it will come out strongly positive. If you think about the other studies like HPS2-THRIVE and the fibrate studies like ACCORD, because they selected such a wide group of patients, in the end, the result came out negative. If they’d selected a more specific group who might more clearly benefit, it could’ve been a positive result, and I think that might well be the same with the CETP inhibitors and the patient groups they’ve selected. They may not get a positive result.”

OUS Key Opinion Leader
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Dyslipidemia is a generalized term that encompasses a wide range of metabolic lipid disorders that affects a staggeringly large number of people worldwide. For example, it is thought that roughly one-third of all citizens in the United States suffer from some form of dyslipidemia. Commonly, dyslipidemia is associated with elevated blood levels of atherogenic low-density lipoprotein cholesterol (LDL-C), but dyslipidemia also encompasses pathogenic levels of high-density lipoprotein cholesterol (HDL-C), triglycerides (TGs), and a host of genetic disorders related to lipid processing and biosynthesis. The unifying theme behind all of these morbidities is their link to cardiovascular disease (CVD), including life threatening conditions such as acute coronary syndrome (ACS), stroke, and even cardiovascular (CV) death. The link between CVD and dyslipidemia is most readily seen in the slow but dangerous development of atherosclerotic cardiovascular disease (ASCVD), which refers to the buildup of atherosclerotic plaques that, in the worst case, can precipitate the aforementioned acute thrombotic CV events. Furthermore, dyslipidemias are a defining feature of major chronic diseases such as type 2 diabetes (T2D), metabolic syndrome, and obesity. Despite the plethora of current lipid-modulating therapies, the rates of CV morbidity and mortality remain the single largest cause of death worldwide. As the world’s population continues to grow, age, and become increasingly “westernized,” the prevalence of dyslipidemia is expected to rise, thereby necessitating more effective, safe, and specialized drug therapies to, at best, keep the disease in check.

In this report and forecast, the dyslipidemia market is analyzed over the course of a ten year period, from 2013–2023 in eight major pharmaceutical markets (8MM) (US, France, Germany, Italy, Spain, UK, Japan, and China). The drivers and barriers of the past and present dyslipidemia market are explored in depth as a means to set the stage for an analysis of the 10-year forecast. The role and prospects of both marketed and pipeline therapies will be analyzed, and GlobalData’s primary research will shed light on current physician insight into this large and lucrative market. The following key questions will be answered:
Introduction

- How will major clinical trials of currently marketed therapies impact the future of the dyslipidemia market? Particular attention will be given to the HPS2-THRIVE (Heart Protection Study 2 – Treatment of HDL to Reduce the Incidence of Vascular Events) and IMPROVE-IT (IMProved Reduction of Outcomes: Vytorin Efficacy International Trial) Phase III studies.

- What role will statins play in the future of the dyslipidemia market?

- How will Merck’s Zetia (ezetimibe) fit into the dyslipidemia treatment paradigm following the positive results of the ground-breaking IMPROVE-IT study?

- What are the clinical, regulatory, and commercial prospects of the proprotein convertase subtilisin/kexin type 9 (PCSK9) monoclonal antibodies (mAbs) from Amgen, Sanofi/Regeneron, and Pfizer?

- What are the clinical, regulatory, and commercial prospects of the cholesteryl ester transfer protein (CETP) inhibitors from the established players, Eli Lilly and Merck, and from the industry newcomer, Dezima Pharma?

- How will novel lipid-modulating agents, such as Esperion Therapeutics’ ETC-1002 and Cerenis Therapeutics’ CER-001, impact the dynamics of the dyslipidemia market?

- What are the key market drivers, barriers, and unmet needs that remain unaddressed by currently marketed therapies? What will remain unaddressed by the current dyslipidemia pipeline?

2.2 Related Reports


- GlobalData (2014). Type 2 Diabetes – Global Drug Forecast and Market Analysis to 2022, January 2014, PHARMADPP37964


Introduction

- GlobalData (2013). Obesity – Global Drug Forecast and Market Analysis to 2022, October 2013, PHARMADPP36385
- GlobalData (2013). Chronic Heart Failure – Global Drug Forecast and Market Analysis to 2022, June 2013, PHARMADPP34543

2.3 Upcoming Related Reports

11.7 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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