Worldwide statistics indicate that there is a high cholesterol burden despite the presence of many cholesterol-lowering drugs in the market. Out of all the available options, statins have been ubiquitously prescribed over the last 25 years. Researchers have concluded that reduction of plasma LDL cholesterol (LDLC) is the cornerstone of assessing heart risk. Irrespective of baseline cholesterol concentration, each mmol/L LDLC reduction translates to cardiovascular risk reduction by one-fifth. Although statins are well tolerated and reduce LDLC levels to the targets specified by NCEP and NICE guidelines, there is a residual cardiovascular risk. Heart diseases are the leading cause of death in the US and most of them are due to high cholesterol.

Statins, though the mainstay therapy for lowering cholesterol, have been associated with some adverse events. These have deterred their use in a subset of population termed as 'Statin Intolerant'. Furthermore, patients with some genetic conditions such as Familial Hypercholesterolemia do not respond to statin therapy. Due to the long historical use of statins and the launch of generics (providing price advantage), the novel drugs will initially target only specific subset of patients for whom statins are clearly not the best treatment option. This need in the market for drugs that work through a different mechanism of action is coupled with a huge opportunity presented by a target population of around 20 million in the US and the EU5 countries.

The ‘PCSK9 and Other Novel Hypercholesterolemia Drugs, 2014 - 2024’ report provides an extensive study of the new class of prescription drugs being evaluated for the treatment of high cholesterol levels caused both by genetic and lifestyle factors.

During the period 2012-2013 three such drugs - Juxtapid, Kynamro, and Lipaglyn - received market authorization; several more novel molecules are in clinical trials. These new drugs have different mechanism of actions: inhibiting or activating genes / proteins in cholesterol metabolism. Examples include PCSK9 inhibitors, CETP inhibitors, MTTP inhibitors, ApoB inhibitors and PPAR agonists. In addition, researchers are also evaluating gene silencing approach.

The report offers an in-depth analysis of four of the five novel classes of drugs mentioned above (PCSK9 inhibitors, MTTP inhibitors, ApoB gene silencers and CETP inhibitors). One of the key objectives is to provide readers a detailed insight into the landscape of novel prescription drugs for treatment of hypercholesterolemia. This is done by:

- Identifying drug candidates based on their mechanism of cholesterol-lowering actions
- Reviewing key efficacy and safety parameters for drugs in late-stage clinical trials
- Reviewing the technologies behind drug-development
- Understanding drivers and constraints of each drug-class
- Assessing the competitive landscape, recent market developments such as relevant investments and partnerships
- Evaluating the development and sales potential for each of the key molecules under consideration

The possibility of a drug to become blockbuster depends on various factors. In addition to safety and efficacy, other factors include cost, mode of administration, side effects and their approval and availability in various geographies. For each of these new classes of drugs, we have highlighted the key drivers and limiting factors. We have also presented our own perspective on how the acceptance and evolution of these drugs is likely to advance in the coming years. The analysis is backed by an extensive review of the hypercholesterolemia / dyslipidemia landscape and familial hypercholesterolemia (HoFH and HeFH) markets.

The base year for the report is 2013. The report provides market forecasts for the following two time horizons: 2014 - 2019 (short-midterm) and 2019 - 2024 (long term), respectively. The figures mentioned in this report are in USD, unless otherwise specified.
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