When regulatory bodies first approved PCSK9 inhibitors in 2015 for a relatively broad proportion of dyslipidemia patients, payers reacted by placing strict requirements on who is eligible. So far, PCSK9 inhibitors have largely been limited to patients who are unable to lower low-density lipoprotein cholesterol (LDL-C) levels with conventional lipid-lowering therapies. The major barrier to adoption has been the high price of PCSK9 inhibitors, observes GlobalData a leading data and analytics company

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Dyslipidemia is a condition characterized by abnormal levels of plasma cholesterol or triglycerides (TGs) with a prevalence of more than 136 million across the *7MM. Abnormal lipid levels can greatly increase a person's risk of experiencing a cardiovascular (CV) event, thus it is essential to diagnose and treat patients who present with abnormal lipid levels. Elevated low density lipoprotein cholesterol (LDL-C) levels are most commonly implicated in dyslipidemia; however, hypertriglyceridemia and low high density lipoprotein cholesterol (HDL-C) levels are also prevalent amongst patients with dyslipidemia.

Pavan Kottamasu, Healthcare & Pharmaceutical Analyst at GlobalData , commented "Of all of the dyslipidemia drugs currently available, the statins have achieved the highest level of clinical and commercial success. These drugs are universally considered as first-line therapies for the treatment of elevated LDL-C, especially in patients at high CV risk."

Merck's Zetia (ezetimibe) reduces LDL-C by inhibiting the uptake of dietary and biliary cholesterol in the gastrointestinal (GI) tract and stands as the only marketed drug to do so. Zetia is generally used as an adjunct to statin therapy when treatment with a statin alone is insufficient to reduce LDL-C to desired levels, and may be used as a first-line therapy in cases where statins cannot be tolerated.

Zetia faces strong competition from two PCSK9 inhibitors, Sanofi and Regeneron's Praluent and Amgen's Repatha. PCSK9 inhibitors are prescribed to patients with high LDL-C or to patients with familial hypercholesterolemia.

During 2017, marketed PCSK9 inhibitors continued to gain slow uptake, hampered by high costs and extensive payer restrictions. Repatha and Praluent achieved 2017 global sales of $336M and $207M, respectively. This is compared to 2016 global sales of $141M and $116M,

respectively. Although efficacious and cost-effective lipid-lowering statins are available, a large proportion of patients with dyslipidemia cannot reach recommended levels of LDL-C. Improved drug administration and filing for new indications such as once-monthly dosing for Sanofi/Regeneron's Praluent [alirocumab] and label expansion for Amgen's Repatha (evolocumab) to prevent CV events in adults with established CV disease) will accelerate the use PCSK9 inhibitors in high-risk dyslipidemia patients.

Kottamasu continued, ''Looking forward to 2018 and beyond, results are expected from the ODYSSEY OUTCOMES study. This study will determine the efficacy of the combination therapy of Praluent with statin therapy for the reduction of CV events in high-risk patients.''

Additionally, the Medicines Company and Alnylam Pharmaceuticals have a novel PCSK9 targeting therapy, inclisiran, a small interfering ribonucleic acid (siRNA) in Phase III clinical trials.

Kottamasu added, ''We expect inclisiran to launch in either 2020 or 2021 and predict that the Medicines Company and Alnylam's inclisiran will capture as much as 12% of the total PCSK9 inhibitor global market share by the year 2022. Indeed The Medicines Company and Alnylam Pharmaceuticals could learn from the struggles of Repatha and Praluent: a key strategy would be to undercut the price of the currently available PCSK9 inhibitors, in order to bolster inclisiran's initial uptake.''

* 7MM: USA, 5EU (France, Italy, Germany, Spain, UK), and Japan

Related Reports

GlobalData (2017). PharmaPoint: Dyslipidemia – Global Drug Forecast and Market Analysis to 2025, December 2016, GDHC138PIDR