

Physician Views: Life beyond statins – what opportunity for PCSK9 inhibitors?

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Abstracts

With Sanofi and Regeneron Pharmaceuticals set to unveil the first Phase III data for their experimental PCSK9 inhibitor alirocumab imminently, expectation for this class of therapies is set to rise even further over the coming months. Shaped by positive Phase II results, analysts expect the peak market opportunity for PCSK9 inhibitors to be worth between \$5 billion and \$10 billion.

Amgen is poised to deliver Phase III data for its own PCSK9 inhibitor – AMG 145 – along similar timelines to Sanofi and Regeneron, with data from large studies of both drugs set to be published in 2014 (Pfizer, Roche, Eli Lilly and Alnylam are also active in the PCSK9 development space).

However, it is data from a small 100-patient study (ODESSEY Mono), which compares alirocumab (75/150mg injected every two weeks) to Merck & Co.'s orally dosed Zetia in patients with high cholesterol that is due to be published imminently.

The ODESSEY Mono study represents a small proportion of total Phase III patient exposure (100 patients from approximately 22,000 patients in late-stage testing), but nevertheless could help to further de-risk the outlook for the PCSK9 class note analysts.

Anticipation levels are building given the efficacy demonstrated by both Sanofi/Regeneron and Amgen's products in Phase II studies, where reductions in LDL-cholesterol of between 40 percent and 70 percent have been demonstrated when administered in combination with statin therapy.

Given the entrenchment (and genericisation) of most statin therapies, coupled with the subcutaneous administration and cost of PCSK9 inhibitors, three key market

opportunities would appear to exist for PCSK9 inhibitors: high-risk coronary heart disease patients who are intolerant to high-dose statins, coronary heart disease patients who are deemed refractory to statin therapy and patients with genetically high LDL-cholesterol (those diagnosed with Heterozygous familial hypercholesterolemia). Nevertheless, given the size of the overall market (the peak statin market was worth approximately \$20 billion per annum), analysts are confident of blockbuster potential for the emergent PCSK9 inhibitor class.

This week's Physician Views poll asks US and 5EU-based cardiologists and general practitioners:

To rate their awareness of the PCSK9 inhibitor class

How significant a barrier to uptake the subcutaneous administration of PCSK9 inhibitors will be?

To what percentage of high-risk coronary heart disease patients who are intolerant to high-dose statins they would expect to prescribe PCSK9 inhibitors?

To what percentage of coronary heart disease patients deemed refractory to statin therapy they would expect to prescribe PCSK9 inhibitors?

To what percentage of diagnosed Heterozygous familial hypercholesterolemia (HeFH) patients with uncontrolled LDL-C they would expect to prescribe PCSK9 inhibitors?

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