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Physician Views: Repatha Recommended for European Approval – How Will EU5 Cardiologists Utilise the PCSK9 Inhibitor Class?

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Abstracts

Amgen and Sanofi/Regeneron Pharmaceuticals may be locked in one of the most intriguing US drug regulatory races of recent memory, but it is the European Medicines Agency that has provided a first definitive regulatory action for the PCSK9 inhibitor class by recommending approval of Amgen's Repatha.

The EMA has recommended approval of a broad label for Repatha in Europe, which includes those patients with mixed dyslipidaemia who are unable to reach LDL-cholesterol reduction goals with statin therapy or whom are intolerant to statins. Furthermore, Phase III data for Repatha has demonstrated LDL-C reductions of 46 percent to 64 percent from baseline at week 12 in various patient populations with hyperlipidaemia.

How cardiologists utilise this drug class is, however, a very different matter. Data from ongoing outcomes studies – due to be published in 2017/18 – are expected to shape the longer-term uptake of the PCSK9 inhibitors, while other factors – such as pricing and access – will also play a prominent role on the European landscape (ViewPoints: Europe provides positive regulatory momentum for PCSK9 inhibitor class, but regional cardiologists likely to prescribe less than US counterparts).

To better ascertain sentiment towards the PCSK9 inhibitor class, FirstWord Pharma is asking cardiologists based in France, Germany, Italy, Spain and the UK the following questions...

> It has been estimated that the PCSK9 inhibitors will cost between $5000 and $10000 per patient per year in the US market; even factoring a likely price

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discount in Europe, how significant a role do you expect price to play in limiting the use of these drugs?

Prior to the availability of cardiovascular outcomes data for the PCSK9 inhibitor class (expected in 2017/18), what level of usage do you anticipate for the treatment of patients with HeFH or HoFH?

Prior to the availability of cardiovascular outcomes data for the PCSK9 inhibitor class, what level of usage do you anticipate for the treatment of patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or patients who are statin intolerant?

How significant a role do you expect an initial lack of cardiovascular outcomes data for this drug class to limit usage in statin-intolerant/LDL-C target non-achiever patients?

How much increased pressure do you expect to be under to ensure that patients have received the correct dosing/treatment with statins and/or other available therapies once the PCSK9 inhibitor class becomes available?

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