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Physician Views: How Do Doctors See Praluent and Repatha Stacking Up After FDA Panel Meetings?

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Abstracts

The question of whether to approve Regeneron and Sanofi's Praluent (alirocumab) and Amgen's Repatha (evolocumab) never really seemed to be in doubt at FDA's Endocrinologic and Metabolic Drugs Advisory Committee meetings on Tuesday and Wednesday, as panel members by and large expressed comfort with the safety and efficacy profiles of the respective anti-PCSK9 mAbs to treat dyslipidaemia.

Rather, the committees appeared to be more concerned about what specific groups of patients the agents should be approved for, which is an issue of high importance to physicians and patients, as well as the payers (and pharmacy benefit managers) that may ultimately serve as the gatekeeper for deciding who does and does not receive an anti-PCSK9 agent.

CVS and Express Scripts, which are in charge of making formulary decisions for millions of Americans, may have found the committee discussions rather encouraging based on the obvious anxiety articulated by a number of panellists who said it would be premature to prescribe Praluent or Repatha for patients with run-of-the-mill hypercholesterolaemia before the results from ongoing cardiovascular outcome trials (CVOT) become available in 2017 or so.

Assuming the FDA heeds the committee's advice and approves the agents for use only in patients with familiar hypercholesterolaemia (FH), and possibly also in high-risk patients not achieving LDL goals on statins – roughly in line with Repatha's label in the EU – this would remove, for the time being anyway, the possible doomsday scenario outlined by CVS in February, when the PBM warned that spending on anti-PCSK9 mAbs would hit $150 billion per year.

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But to whom exactly will physicians decide to prescribe Praluent and Repatha, and how will they decide between them?

Analysts suggest the biggest differentiating factor between the products is Regeneron and Sanofi's decision to test both a low- and high-dose versions of Praluent, which could give physicians who may not necessarily be comfortable with patients achieving very low LDL levels the added flexibility of starting with the lower, potentially cheaper dose and moving up to the higher dose only if necessary. Amgen, on the other hand, will be able to tout a once-monthly regimen of Repatha (along with a biweekly regimen), which some patients may prefer rather than Praluent, which would only be available as a biweekly injection.

To gain better understanding about how the panel discussion has shaped their views on the two products, FirstWord PLUS is polling US- and/or EU5-based cardiologists and asking them…

> Praluent's dosing flexibility (ie, the availability of a high and lose dose to allow for titration) has been highlighted as a potential differentiating factor between it and fellow anti-PCSK9 mAb, Repatha, particularly for doctors who are not comfortable with patients having "very low" LDL levels. Might this make you any more likely to prescribe Praluent rather than Repatha?
>
> It has been suggested that the manufacturers of Praluent may seek to take advantage of having a two-dose levels by pricing the low-dose option well below both the high-dose and ostensibly Repatha. If this turns out to be the case, how important would it be in deciding which anti-PCSK9 mAb to prescribe?
>
> FDA panel members were slightly more critical about the safety profile of Repatha due to Amgen's shorter clinical trials (12 weeks). How concerned are you that the agent's safety may be meaningfully different than Praluent?
>
> What factors will be most important when it comes time to decide between prescribing Praluent or Repatha?
>
> Assuming the FDA approves both agents with labels that allow for use in high-risk (non-FH) patients not achieving LDL goal on statin therapy, to what percentage of these patients would you expect to prescribe an anti-PCSK9 mAb within one year of launch?

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