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Physician Views: What impact will the IMPROVE-IT study have on the treatment landscape?

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Abstracts

As many have speculated, final data from Merck & Co.'s long-awaited IMPROVE-IT study has implications that stretch far beyond the commercial performance of the drug assessed in the trial; ezetimide (sold by Merck as Zetia or Vytorin when combined with simvastatin).

Nine years after the 18,000-patient study began to enrol, IMPROVE-IT hit its primary endpoint by demonstrating that the addition of Zetia to simvastatin provided a statistically significant reduction in cardiovascular event (heart attack and stroke) rates compared to simvastatin alone among patients at a higher risk of such events.

The commercial impact on Merck will be limited, argue analysts, with Zetia set to lose patent exclusivity within the next two years. In a best-case scenario, erosion of franchise sales – which still amount to around $4 billion annually – may be slower once generics are able to launch.

The broader implication from IMPROVE-IT is aligned to the hypothesis that a reduction in LDL cholesterol is associated with a reduction in cardiovascular event rates. This is important for a number of cholesterol reduction therapies in development, in particular the PCSK9 inhibitors being developed by Amgen, Sanofi/Regeneron Pharmaceuticals and (further down the line) Pfizer.

The IMPROVE-IT study is similar, both in size and design, to ongoing cardiovascular outcomes studies assessing each of the most advanced products in the PCSK9 inhibitor class. A positive result thus increases the likelihood that compelling reductions in LDL-C seen with the PCSK9 inhibitors will be associated with mortality and cardiovascular outcomes benefits.

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Had IMPROVE-IT produced a negative result, the FDA may have chosen to delay approval of PCSK9 inhibitors until outcomes data were available, argue analysts. While this data, which will initially be published in and around 2017, is still viewed as critical to bolstering uptake of the class, a notable overhang has been removed. Furthermore, with IMPROVE-IT supportive of the reduced LDL-C hypothesis, adoption of the PCSK9 inhibitors prior to the publication of outcomes data may occur more rapidly. In a best-case scenario, regulators may initially approve drugs in this class across a broader patient population and not limit pre-outcomes use to those who are statin intolerant or who are predisposed with significantly higher cholesterol levels (Physician Views Poll Results: Lack of outcomes data, negative IMPROVE-IT results will limit PCSK9 inhibitor use; less frequent dosing seen as offering minimal advantage).

On the other hand, a positive IMPROVE-IT result may position the Vytorin combination as an additional line of therapy for patients who fail to achieve their cholesterol goals when treated with statin monotherapy, prior to treatment with a PCSK9 inhibitor. A now proven mortality benefit, coupled with generic availability from 2017 onwards, may prompt payers to 'step through' Vytorin before access to the more expensive PCSK9 class. In addition, IMPROVE-IT's data provides no specific insight about the cardiovascular benefit associated with LDL-C reductions below 53mg/dl, which is associated with the PCSK9 class.

In the favour of the new biologic therapies, are compelling LDL-C reductions demonstrated in Phase III studies and the likelihood that many patients with higher LDL levels will probably require more intensive therapy than that provided by Vytorin, argued Bernstein analyst Geoffrey Porges in a note to investors this week.

Poll Questions

With these factors in mind, FirstWord is polling US and EU5-based cardiologists this week with the following questions...

> Will your usage of ezetimide (branded and/or generic once available) increase following the publication of positive data from the IMPROVE-IT study?
>
> Will you be encouraged to prescribe ezetimide ahead of PCSK9 inhibitors in difficult-to-treat patients following publication of positive data from the IMPROVE-IT study?

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What level of pressure do you expect payers to exert on you to move statin-failure patients to therapy with ezetimide prior to initiation of therapy with a PCSK9 inhibitor?

Will data from the IMPROVE-IT study have a materially positive effect on your usage of PCSK9 inhibitors ahead of data from cardiovascular outcomes studies for this new class of therapy?

How would you best describe your anticipated usage levels of the PCSK9 inhibitor class prior to the publication of data from outcomes studies?

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