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Physician Views: With Januvia Data looming, What Impact Will FDA AdComm Have on Use of DPP-IV Inhibitors?

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Abstracts

Lingering concerns have been hanging over AstraZeneca's Onglyza and Takeda's Nesina since 2013 when detailed analyses from respective cardiovascular (CV) outcomes studies suggested the DPP-IV inhibitors may be associated with an increased risk of heart failure.

On April 14, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee finally provided some semblance of closure to the matter when it voted overwhelmingly in favour of changing the labels of both drugs to include new warning information about the possible heart failure risk.

Rather than be hurt by the recommendation though, Takeda and (especially) AstraZeneca were able to let out small sighs of relief that the worst case scenario – however improbable – of market withdrawals had been avoided, along with the slightly more possible scenario where use of the drugs would be restricted to certain patients. (See ViewPoints: Handicapping potential outcomes from Tuesday's FDA meeting to discuss safety of DPP-IV inhibitors.)

One wildcard looming over the proceedings is the ongoing CV outcomes study (TECOS) evaluating Merck & Co.'s Januvia, the market-leading DPP-IV inhibitor, which will play a key role in determining whether the heart failure signal is deemed to be a class effect and, more importantly, what impact it will have on use of the three medicines – and each individually.

Waiting in the wings for any possible fallout from the increased scrutiny on DPP-IV inhibitors are agents in classes like the SGLT2 inhibitors, which analysts suggest could

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gain an increased share of the market should physicians shy away from Januvia, Onglyza and/or Nesina.

To gain better understanding about the impact of the FDA panel's discussion and recommendations, FirstWord PLUS is polling US- and EU5-based endocrinologists and asking them…

> An FDA panel voted to add safety information about the risk of heart failure to labels for Onglyza and Nesina. With data from a cardiovascular (CV) outcomes trial of Januvia still to come (expected in June), what impact will the panel vote have on your overall use of DPP-IV inhibitors?
>
> Januvia is by far the most prescribed DPP-IV inhibitor, followed by Onglyza and Nesina a distant third. The FDA briefing documents and panel discussion seemed to suggest Nesina's CV profile might be slightly more benign than that of Onglyza. Will this have any impact on your use of individual DPP-IV inhibitors?
>
> Assuming Januvia's cardiovascular safety profile looks roughly in-line with Onglyza/Nesina, how will that impact your overall use of DPP-IV inhibitors?
>
> If, on the other hand, Januvia's cardiovascular safety profile looks better than that of Onglyza/Nesina, how would that impact your prescribing of Januvia ?
>
> Given the increased scrutiny of DPP-IV safety, might you be more likely to reach for another therapeutic modality rather than a DPP-IV inhibitor?

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