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Physician Views: As MannKind's Afrezza nears approval, what opportunity for an inhaled insulin?

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Abstracts

MannKind's confirmation that the FDA has extended the PDUFA date for its inhaled insulin Afrezza to July suggests that the diabetes treatment has a better chance of gaining approval. The most likely alternative scenario, postulated analysts, was receipt of a third complete response letter (CRL) from the FDA.

Despite some residual concerns from FDA staff – primarily focusing on the long-term effects of using an inhaled insulin product and a debatable hypoglycaemic benefit for Afrezza – MannKind received an overwhelmingly positive vote from members of an advisory committee last week.

Assuming the standard three month PDUFA delay has been driven mainly by logistical factors – the AdCom occurred just 10 days ahead of its original PDUFA date – and approval is secured later this summer, attentions will rapidly turn to the commercial opportunity for Afrezza – see ViewPoints: Focus switches to commercial outlook for MannKind's inhaled insulin Afrezza.

On the face of it, an effective inhaled insulin product would be a welcome addition to the diabetes armatorium, a view shared by last week's AdCom panel. However, Pfizer's Exubera – which was launched in the US in September 2006, but withdrawn due to lack of commercial success just 13 months later – casts a shadow over the market.

Despite what the AdCom considered to the modest efficacy of Afrezza versus subcutaneous short-acting insulins, it suggested approval should be granted for both type 1 and 2 diabetes patients on the basis of its inhaled delivery providing a useful benefit in certain patient sub-groups. Discussion also focused on the need for post-marketing studies and lack of sufficient data relating to potential pulmonary and cancer

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risks.

To ascertain how Afrezza may perform if it is approved by the FDA in July, FirstWord polled US-based endocrinologists this week in order to gauge their opinion towards the drug. Specifically, we asked them

How familiar they are with the development of Afrezza?

Based on available Phase III data, to what percentage of type 1 diabetes patients they would anticipate prescribing Afrezza to 12 months after launch?

Based on available Phase III data, to what percentage of type 2 diabetes patients they would anticipate prescribing Afrezza to 12 months after launch?

To what patient sub-group the availability of an inhaled insulin product would provide the most benefit?

What will act as their primary reason for non-use of Afrezza, assuming FDA approval is granted

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