

Physician Views: The return of inhaled insulin – a paradigm shift or hard sell?

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Abstracts

Sanofi is currently in the process of launching Afrezza in the US market. Afrezza is an inhaled insulin developed by MannKind, which was in-licensed by Sanofi last year. It is the first inhaled insulin to be made available since Pfizer launched Exubera in the US in September 2006. Due to poor uptake, Exubera was withdrawn from the market in October 2007.

Both Exubera and Afrezza have demonstrated comparable, but not superior, efficacy to injectable insulin. Commercial failure of Pfizer's product was driven in part by additional cost (for the patient/payer) and the large inconvenient device that was used to administer Exubera.

MannKind and Sanofi have sought to circumvent these issues: Afrezza is delivered via a small, whistle-sized device and has a list price of between \$225 and \$280 for a 30-day supply of 90 cartridges. Assuming a typical level of rebates and discounts, analysts do not expect this price to act as a major obstacle to access.

Challenges are nevertheless expected to lie ahead. These include likely broad tier-3 formulary status at launch and the view among some analysts that endocrinologists will not proactively prescribe Afrezza, but instead wait for patients to request the drug (which in turn will increase necessary investment in promotion of the franchise).

When FirstWord polled 52 endocrinologists last April (shortly after Afrezza had gained a positive Advisory Committee recommendation), a key concern among physicians was the side-effect risk associated with inhalation. Around half of all respondents indicated that potential long-term pulmonary and cancer risks – an issue also discussed in depth during the AdCom – would act as the main reason for them not using Afrezza. Around a

third of endocrinologists suggested that a likely lack of real-world efficacy versus injectable insulin would act as the main deterrent.

Sanofi's launch strategy for Afrezza is focused on two groups of diabetes patients: Those who are potential insulin users who do not currently use insulin because of a dislike of injections and those who use basal insulin, but are naïve to short-acting insulin and require an 'intensification' of therapy at mealtimes.

Patient feedback cited by Sanofi in recent investor presentations indicates a potentially sizeable population who are discouraged to initiate insulin therapy due to injectable administration, while physician feedback sourced by FirstWord indicates that patients with needle phobia represent the obvious target for Afrezza.

While Sanofi suggests that around 40 percent of potential insulin users are not using insulin because of a dislike of injections, translating this into an 'actionable' driver for uptake of Afrezza will nevertheless be challenging. Not only does anecdotal evidence indicate that many patients who are initially cautious towards self-injection quickly become adept at the practice, but the proportion of true needle-phobic patients is much lower.

With physicians already indicating that patients who are adverse to the idea of injection are likely to act as the most prominent users of Afrezza, it also remains to be seen how much traction Sanofi can achieve in those patients who need an intensification of therapy, but whom already inject basal insulin.

To better ascertain how the initial launch of Afrezza is likely to progress, and whether Sanofi's strategy appears feasible, FirstWord is polling US and EU-5 based endocrinologists this week (Sanofi is due to submit the drug for approval in Europe shortly). Specifically we are asking them...

Versus your experience in the real-world setting, what is your assessment of the suggestion that there are a significant proportion of potential insulin users – 40 percent – who are not currently using insulin because of a dislike of injections?

This figure is very low

This figure is moderately low

This figure is marginally low

This figure is accurate

This figure is marginally high

This figure is moderately high

This figure is very high

Is it fair to suggest that the majority of patients who are initially sceptical of self-injecting insulin quickly become adept at the practice?

Completely disagree

Disagree

Somewhat disagree

Neither agree or disagree

Somewhat agree

Agree

Completely agree

Patients who already self-inject basal insulin, but who require intensification with a short-acting insulin at mealtimes, represent a significant opportunity for use of Afrezza?

Completely disagree

Disagree

Somewhat disagree

Neither agree or disagree

Somewhat agree

Agree

Completely agree

Do you plan to actively prescribe Afrezza unless a patient specifically requests it?

No – will not prescribe under any circumstances

No – would recommend against prescribing

No – would prescribe readily if patient requests

Yes – slight use

Yes – moderate use

Yes – very high use

Yes – Extremely high use

Afrezza meets a significant unmet need in the insulin market?

Completely disagree

Disagree

Somewhat disagree

Neither agree or disagree

Somewhat agree

Agree

Completely agree

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