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Adcom vote gives Firazyr new momentum

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FDA experts are giving Firazyr its best chance at achieving the $350m peak sales that Shire executives boldly forecast three years ago. An advisory committee voted strongly in favour of the subcutaneous injection to treat hereditary angioedema (HAE) and likewise recommended the label allow self-administration of the immunosuppressant (*Event - Self administration key to Shire's Firazyr hopes, June 17, 2011*).

The strength of the endorsements, with only one no vote in each case, suggests the immunosuppressant has a good chance of being the fourth novel product to hit the market for the condition that can cause sometimes life threatening swelling. Should approval come by the regulator's August 25 PDUFA date, the British firm could begin to make up for the disappointment that Firazyr has sold only $18m in its first three years on the European market.

Responding

Firazyr received a non-approvable letter in 2008 when it was owned by the German firm Jerini. This was based on a lack of statistically significant improvement in the pivotal 64-patient Fast-1 trial and the use of tranexamic acid, unapproved in the US for HAE, as a control in the 77-patient Fast-2 trial (*Jerini notches up small win in HAE race, April 25, 2008*).

Fast-3, begun after Shire purchased Jerini in 2008 for €328m ($509m), responded effectively to the agency's objections: it used a placebo control and enrolled 98 patients with the inherited deficiency of C1-esterase characteristic of HAE. Patients taking Firazyr had significantly faster time to relief of the symptoms of HAE when compared to patients taking placebo.

The adcom's 12-1 vote in favour of Firazyr's safety and efficacy is a sign that Fast-3 addressed the agency's earlier concerns. More importantly from a commercial perspective, the panel voted 11-1 in favour of self-administration for the protein therapy's label, something only one drug in the space, ViroPharma's Cinryze, has won. European regulators have already granted Firazyr the self-administration label (*Shire needs Firazyr to stand out in HAE crowd, March 2, 2011*).

As Firazyr is intended for acute episodes, whilst Cinryze, currently viewed as the dominant product in the space with a $574m sales forecast in 2016, is prescribed for prevention, they do not strictly speaking compete. Firazyr's direct US competition would be Dyax's Kalbitor and CSL's Berinert P; in either case supervision by a medical professional is required when administering the drugs - Berinert is an IV infusion and Kalbitor has an anaphylaxis black box warning. Pharming's Rhucin is so far approved only in Europe, and also requires medical supervision.

The hope is that Firazyr will win some converts. *EvaluatePharma's*2016 forecast puts sales at $173m, a total that if achieved would start to make up for the three years of disappointing sales so far and start to justify the price Shire paid for Jerini (*EP Vantage Interview - Shire enters HAE market with Jerini buy, July 3, 2008*). A positive adcom vote was an important step toward that goal.