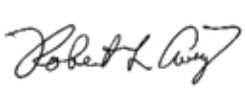
A Lost Opportunity for Chronic DME

In November 2011, The US Food and Drug Administration (FDA) stated that it was unable to approve a new drug application for Iluvien because the application did not provide sufficient data to support that Iluvien is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for Iluvien in the FAME study were significant and were not offset by the benefits demonstrated by Iluvien in these clinical trials, according to an Alimera news release. In the complete response letter, the FDA indicated that Alimera would need to conduct 2 additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. Alimera stated in a press release that 2 replicable trials of the same size would not be feasible to pursue.

Conversely, at the end of February of this year, Alimera announced the issuance of the Final Assessment Report from the Reference Member State, the Medicines and Healthcare products Regulatory Agency of the United Kingdom, and the agreement of all the Concerned Member States that Iluvien is approvable. Since that time, Austria, the United Kingdom, and most recently, Portugal have granted marketing approval to Alimera for Iluvien.

For many retina specialists, it was surprising that Iluvien was not granted an FDA label with a chronic DME restriction, because this group of patients is indeed the hardest to treat. They typically do not respond well to laser therapy, yet these patients experienced good results with the implant in the clinical trials. It is our hope that we receive more information regarding why the FDA did not feel that a restricted label would be appropriate.

It will be interesting to see how patients who receive the implant in those European Union countries that granted marketing approval do with Iluvien as compared with the results in the clinical trials. Unfortunately, however, patients in the United States with chronic DME now have 1 less option for treatment available to them. ■



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