

FDA recommends ocriplasmin for treating VMA

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Singapore: The US FDA dermatologic and ophthalmic drugs advisory committee recommended that the FDA grant ThromboGenics' ocriplasmin approval for the treatment of symptomatic vitreomacular adhesion (VMA). The Committee voted unanimously (10-to-0) at its meeting based on the fact that the benefits of administering ocriplasmin for the treatment of vitreomacular adhesions outweighs the potential risks.

The recommendation of the advisory committee will form part of the FDA's overall assessment of the ocriplasmin biologics license application (BLA). The FDA has assigned the ocriplasmin BLA a prescription drug user fee act (PDUFA) goal date of 17 October, 2012.

Dr Patrik De Haes, CEO, ThromboGenics, said that, "We are pleased that the advisory committee has made a positive recommendation supporting the approval of ocriplasmin for the treatment of symptomatic VMA. We will continue to work with the FDA as it completes its assessment of the ocriplasmin BLA. Symptomatic VMA is an area of unmet medical need and ThromboGenics is looking forward to making this novel treatment option available to the many patients who could benefit."

Symptomatic VMA is a progressive condition that if left untreated frequently leads to retinal distortion, further deterioration in vision and has the potential to cause irreversible damage and complications. If approved, ocriplasmin will be the first pharmacological treatment for symptomatic VMA.