FDA NEWS RELEASE

For Immediate Release: Oct. 18, 2012
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FDA approves Jetrea for symptomatic vitreomacular adhesion in the eyes

On Oct. 17, the U.S. Food and Drug Administration approved Jetrea (ocriplasmin), the first drug approved to treat an eye condition called symptomatic vitreomacular adhesion (VMA).

VMA can contribute to eye problems if the vitreous (jelly in the center of the eye) starts to move away from the macula (a part of the retina responsible for reading vision). This movement can lead to damage of the macula due to pulling or tugging on the macula.

Jetrea is an enzyme that breaks down proteins in the eye responsible for VMA. The breakdown of these proteins allows a better separation between the vitreous and macula and can reduce the chances that tugging will occur. The alternative treatment for this condition is a surgical procedure called a vitrectomy.

"Today's approval represents a significant advancement in treatment for patients with symptomatic VMA," said Edward Cox, M.D., M.P.H., director of the Office of Antimicrobial Products in FDA's Center for Drug Evaluation and Research. "Those with this sight-threatening disease now have a non-surgical treatment option."

The safety and effectiveness of Jetrea were established in two clinical studies involving 652 patients with symptomatic VMA. Patients were randomly assigned to receive a single injection of Jetrea into the eye or a substance without the active ingredient.

Patients were evaluated over the next 28 days and for any side effects over the next six months. The studies found that VMA resolved in 26 percent of patients treated with Jetrea compared with 10 percent of those treated with the inactive product.

The most common side effects reported in patients treated with Jetrea include eye floaters; bleeding of the conjunctiva, the tissue that lines the inside of the eyelids and covers the white part of the eye; eye pain; flashes of light (photopsia); blurred vision; unclear vision; vision loss; retinal edema (swelling); and macular edema.

Jetrea is manufactured by Iselin, N.J.-based ThromboGenics Inc.