# Microplasmin study shows promising results for two serious eye conditions

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A Phase III trial of a drug used for the treatment of vitreomacular adhesion (VMA) and macular hole (MH) revealed key findings for patients diagnosed with these severe conditions which can lead to significant vision impairment.

Dr. Matthew Benz, retinal surgeon at The Methodist Hospital in Houston, presented the data of the microplasmin trial (TG-MV-006) on behalf of ThromboGenics NV, at the World Ophthalmology Congress in Berlin yesterday.

The trial recruited 326 patients at 42 centers in the United States, and Benz is the primary investigator at Methodist. In his presentation, Benz reported that in the study, 27.7 percent of the 220 patients treated with the in-office injection of microplasmin had their VMA corrected, compared to 13.2 percent of the 106 patients who received a placebo injection. Untreated, VMA can cause distortion and blurring of central vision. Current treatment includes either observation or surgery.

The TG-MV-006 study confirmed that microplasmin was generally safe and well tolerated with no increase in the rate of retinal tear or detachment in comparison to the placebo. Study investigators also discovered that patients diagnosed with certain types of macular holes, a severe condition which can lead to irreversible vision impairment including central blindness, could benefit from the same drug.

In this group, 45.6 percent of the 52 patients with smaller macular holes

were cured with a single injection of microplasmin without the need for eye surgery in the six months after treatment. This compared with 15.6 percent of the 32 patients in the placebo group.

"The ability to cure a significant proportion of patients with a range of retinal disorders, including macular hole, with a simple injection of microplasmin is clearly an attractive alternative to the current option of surgery," said Benz.

ThromboGenics NV is a biopharmaceutical company focused on the discovery and development of innovative treatments for eye disease. The second Phase III trial in the microplasmin MIVI-TRUST program (TG-MV-007) is due to report in the third quarter of 2010.

## About the study

The microplasmin Phase III program, referred to as MIVI-TRUST (Microplasmin for IntraVitreous Injection-Traction Release without Surgical Treatment), consists of two multi-center, randomized, placebo controlled, double-masked trials. These trials are designed to evaluate 125µg of microplasmin versus placebo in the intravitreal treatment of patients with symptomatic focal vitreomacular adhesion (VMA). The MIVI-TRUST program is the largest interventional clinical program ever performed to specifically evaluate the vitreoretinal interface in patients with retinal disorders. In total, over 650 patients were enrolled in these trials, which were held across 90 centers in 7 countries.

The primary endpoint of both trials is the non-surgical resolution of focal vitreomacular adhesion one month after a single injection of microplasmin. This endpoint is being measured and recorded using optical coherence tomography (OCT), the standard method of assessment for this condition, which provides images that can clearly show the separation of the vitreous from the retina.

A Per Protocol analysis of the microplasmin treated patients showed that 54.3 percent of patients achieved FTMH closure after six months without the need for surgery. The closure of FTMH also resulted in these patients experiencing a significant improvement in their visual acuity (VA) compared to baseline. At the end of the six month follow-up period, they had achieved a 13.6 letter improvement in vision, which is in line with patients who undergo surgery to resolve their FTMH. These results show that microplasmin could represent a major breakthrough, as it has the potential to cure approximately 50 percent of patients with FTMH without the need for major eye surgery.

The trial also evaluated VA. In the case of the 27.7 percent of microplasmin patients who achieved the primary endpoint, a statistically significant improvement in VA compared to their pre-treatment levels was observed. In contrast, the 13.2 percent of placebo treated patients who met the primary endpoint did not have a statistically significant improvement in VA compared to their pre-treatment levels (p=0.18).

Provided by Methodist Hospital System

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