

Microplasmin Treatment of Vitreoretinal Disease: Update on the Phase III MIVI-TRUST Program

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Purpose: To present the current Phase III program regarding Microplasmin (ThromboGenics Ltd.) for nonsurgical resolution of focal vitreomacular adhesion.

Methods: The Phase II Microplasmin IntraVitreous Injection (MIVI) trials are presented, and the design and status of Phase III program are discussed.

Results: The two pivotal trials in the current Phase III program (MIVI-TRUST, Microplasmin IntraVitreous Injection - Traction Release without Surgical Treatment) are multi-centre, randomized, placebo controlled, double-masked trials which are evaluating 125µg of microplasmin versus placebo in the intravitreal treatment of patients with focal vitreomacular adhesion, including macular hole. The trials will enroll approximately 320 patients each across approximately 40 centres in the United States (TG-MV-006) and 40 centres in Europe and United States (TG-MV-007). The primary endpoint of both trials is the non-surgical resolution of focal vitreomacular adhesion after one month. Additional measures of efficacy and safety will also be assessed at various intervals over six months in both studies.

Discussion: In several Phase II trials, microplasmin has been well tolerated and shown evidence of intended biologic effect. Specifically, microplasmin has been associated with PVD induction, vitreomacular adhesion resolution, and also nonsurgical closure of macular holes. The Phase III MIVI-TRUST program is ongoing, and results will be available in 2010.