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VivaVision Biotech announces positive results of phase 2 study for treatment of dry eye disease

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VVN001 demonstrating clinical and statistical superiority over vehicle in reducing total and sub-regional Corneal Fluorescein Staining scores



VivaVision Biotech, Inc. (VivaVision), an ophthalmic pharmaceutical developer focusing on discovery and development of innovative therapies for ocular diseases, announced positive topline results from a Phase 2 clinical study of VVN001 in patients with dry eye disease.

The randomized, double-masked, vehicle-controlled Phase 2 clinical study was conducted at 14 centers across the United States and evaluated the safety and efficacy of VVN001 in patients with dry eye disease. A total of 170 patients were randomized into three groups, VVN001 (5%), VVN001 (1%) or VVN001 vehicle. The patients were treated twice daily over 84 days, and were evaluated at Days 1, 14, 28, 56 and 84.

After 84 days of dosing, a treatment effect was seen in the a priori primary efficacy endpoint of inferior corneal staining. Subjects in both the 1% and 5% treatment group improved, as well as the vehicle group. The improvement in the 5% treatment group was greater than in vehicle. In total corneal staining, there was a statistically and clinically significant improvement, and a dose and treatment duration-related improvement relative to vehicle. Similar effects were seen in the sign of clinically significant improvement in Schirmer scores. In the a priori selected symptom, SANDE scores, there was a statistically and clinically significant improvement from baseline, as well as a difference from the vehicle.

Both concentrations of VVN001 were safe and well- tolerated, with no significant treatment-related safety findings observed during the study. The only treatment-related safety finding with greater than 3% of patients was instillation site pain, which was reported in 3.5% of patients treated with VVN001 compared to 3.6% of patients treated with vehicle.