



PanOptica Doses First Patient with New Formulation of PAN-90806, a Novel, Topical Anti-VEGF Eye Drop, in Phase 1/2 Clinical Trial

Next-generation Suspension Formulation Designed to Improve Tolerability and Treatment Response in Patients with Wet AMD

IND Amendment in US and CTAs Filed in EU for Phase 1/2 Trial

BERNARDSVILLE, N.J — May 22, 2018 — [PanOptica, Inc.](#), a private biopharmaceutical company focused on developing innovative ophthalmology therapies, today announced that the Company has dosed the first patient in a Phase 1/2 dose-ranging clinical trial of PAN-90806, a once-daily topical eye drop formulation of a small-molecule anti-vascular endothelial growth factor (anti-VEGF) for the treatment of neovascular eye diseases. The Company is investigating its new suspension formulation of PAN-90806 as monotherapy, for up to three months, in a masked study involving 60 newly diagnosed patients with neovascular age-related macular degeneration (wet AMD) randomized to one of three dose strengths at sites in the US and the European Union (EU).

PanOptica announced that it had filed an Investigational New Drug Application (IND) amendment in the US, and Clinical Trial Applications (CTAs) in the EU in April 2018 to enable the new study.

“This Phase 1/2 trial builds on research completed to date and advances PAN-90806 as a potentially safe and effective topical eye drop treatment for back-of-the-eye diseases such as wet AMD and diabetic retinopathy,” said Paul G. Chaney, President and Chief Executive Officer of PanOptica. “Our new formulation of PAN-90806 has the potential to improve upon the safety and tolerability seen in our previous Phase 1 study in patients with wet AMD and may enhance the response rate and treatment effect across a higher, broader dose-range.”

In pre-clinical pharmacokinetic and toxicology studies, the new suspension formulation of PAN-90806 was associated with a reduced risk of dose-related corneal findings and maintained or improved dose-dependent target tissue distribution to the central choroid and central retina across a higher dose range than possible with the previous solution formulation. In a prior Phase 1 neovascular AMD study with the solution formulation, higher doses were associated with corneal adverse events, most frequently punctate keratopathy and occasional cornea edema, which were reversible upon discontinuation of dosing.

Currently available treatments are effective at slowing vision loss and may improve vision for some patients, but require careful follow-up and frequent, chronic monthly or bi-monthly intraocular injections for many patients in order to optimize vision outcomes. Topically applied PAN-90806 eye drops have the potential to reduce patients’ injection burden, a benefit that may help reduce treatment discontinuation rates and improve outcomes through improved patient comfort, safety, acceptance, and adherence, especially in the chronic maintenance phase of treatment.

PanOptica designed the Phase 1/2 clinical trial of the new, advanced-generation formulation with the objective of demonstrating tolerability, a broader safe dose range, and a more robust response rate and effect size in treatment-naïve patients with wet AMD.

About PAN-90806

PAN-90806 is a potent and selective inhibitor of VEGF receptor signaling. VEGF is a protein that plays a critical role in angiogenesis (the formation of new blood vessels) and increased permeability (leakage from blood vessels), two pathological processes that contribute to the vision loss associated with wet AMD. In pre-clinical research using validated ocular angiogenesis models, topically administered PAN-90806 in the form of an eye drop suppressed the formation of new blood vessels. In non-clinical pharmacokinetic studies, topical administration of PAN-90806 achieved significant and sustained levels in the retina and choroid of multiple species, supporting further investigation of PAN-90806.

About PanOptica

PanOptica, Inc., is a private biopharmaceutical company focused on developing innovative ophthalmology therapies. Investors include Third Rock Ventures, and SV Health Investors. The company was co-founded by Paul Chaney, past President of OSI-Eyetech, and Martin Wax, MD, formerly Vice President of Research and Development and Head of Ophthalmology Discovery and Pre-Clinical development at Alcon Labs, Inc. The company seeks early-stage assets translated from other diseases and develops select candidates through human clinical proof of concept. For more information, please visit www.panoptica.com.

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