March 21, 2025

Opus Genetics Announces Presentation on Phentolamine Ophthalmic Solution 0.75% in Dim Light Disturbances at World Cornea Congress IX

RESEARCH TRIANGLE PARK, N.C., March 21, 2025 (GLOBE NEWSWIRE) -- Opus Genetics, Inc. (Nasdaq: IRD), a clinical-stage ophthalmic biotechnology company developing gene therapies for the treatment of inherited retinal diseases (IRDs) and therapies for other ophthalmic disorders, today announced that a presentation featuring the LYNX-1 Phase 3 study of Phentolamine Ophthalmic Solution 0.75% in patients with dim light disturbances will be delivered this week at World Cornea Congress IX, taking place March 20-22, 2025 in Washington, D.C.

Key highlights from the presentation

- As previously reported, the LYNX-1 Phase 3 study met its primary endpoint, with a statistically significant greater percentage of Phentolamine Ophthalmic Solution 0.75%-treated participants gaining 15 or more letters of mesopic low contrast distance visual acuity (mLCVA) at Day 8, compared to placebo (13% vs. 3%; $p<0.05$).
- The effect of Phentolamine Ophthalmic Solution 0.75% increased at Day 15, with 21% of participants gaining 15 or more letters of mLCVA compared to 3% of participants given the placebo ($p<0.01$).
- Patient reported outcomes for glare, halos, and starbursts were significantly lower for the Phentolamine Ophthalmic Solution 0.75% group compared to placebo at Day 15 ($p<0.01$).
- A subset analysis of post-LASIK participants demonstrated clinically meaningful results at Day 8, with 29% of Phentolamine Ophthalmic Solution 0.75% participants gaining 15 or more letters of mLCVA compared to 9% of participants given the placebo.
- The effect of Phentolamine Ophthalmic Solution 0.75% was sustained at Day 15 in post-LASIK participants, with 21% of participants gaining 15 or more letters of mLCVA compared to 0% of participants given the placebo.
- The positive LYNX-1 Phase 3 data support the rational of the ongoing Phase 3 LYNX-2 trial of Phentolamine Ophthalmic Solution 0.75% for keratorefractive patients with reduced mLCVA with photic phenomena. LYNX-2 is fully enrolled, with topline results expected mid 2025.
- The full abstract can be accessed at the World Cornea Congress IX websitehere.

“We are pleased to present the results from the LYNX-1 Phase 3 trial of Phentolamine Ophthalmic Solution 0.75%, including a subset analysis highlighting results from participants who underwent some form of keratorefractive surgery, including LASIK,” said Jay Pepose,

M.D., PhD., Chief Medical Advisor at Opus Genetics. “Some patients who underwent keratorefractive surgery have experienced debilitating reduced mesopic vision and are more likely to be involved in motor vehicle collisions. Phentolamine Ophthalmic Solution 0.75% has the potential to be the first treatment for keratorefractive patients suffering from these debilitating symptoms.”

Presentation details

Title:	**Randomized, Placebo-Controlled, Double-Masked Phase 3 Studies of Phentolamine Solution in Keratorefractive Patients with Dim Light Disturbances and Decreased Mesopic Vision**
Presenter:	Jay Pepose, M.D., Ph.D. (Chief Medical Advisor, Opus Genetics)
Session:	Paper Session 2
Date/time:	Friday, March 21, 2025 at 2:10 – 2:16 PM ET
Location:	Rock Creek C, Ballroom Level, Westin Washington DC Downtown

About Opus Genetics

Opus Genetics is a clinical-stage ophthalmic biotechnology company developing gene therapies to treat patients with inherited retinal diseases (IRDs) and other treatments for ophthalmic disorders. The pipeline includes adeno-associated virus (AAV)-based investigational gene therapies that address mutations in genes that cause different forms of bestrophinopathy, Leber congenital amaurosis (LCA) and retinitis pigmentosa. Our most advanced investigational gene therapy program is designed to address mutations in the LCA5 gene, which encodes the lebercilin protein and is currently being evaluated in a Phase 1/2 open-label, dose-escalation trial, with encouraging early data. BEST1 investigational gene therapy is designed to address mutations in the BEST1 gene, which is associated with retinal degeneration; we expect that a Phase 1/2 study will be initiated in 2025. The pipeline also includes Phentolamine Ophthalmic Solution 0.75%, a non-selective alpha-1 and alpha-2 adrenergic antagonist being investigated to reduce pupil size, and APX3330, a novel small-molecule inhibitor of Ref-1, being investigated to slow the progression of non-proliferative diabetic retinopathy. Phentolamine Ophthalmic Solution 0.75% is currently being evaluated in Phase 3 trials for treatment of presbyopia and reduced dim (mesopic) light low contrast vision following keratorefractive surgery. We have reached agreement with the FDA on a SPA for a Phase 3 trial to evaluate oral APX3330 for the treatment of DR. For more information, please visit www.opusgtx.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning data from and future enrollment for our clinical trials and our pipeline of additional indications.

These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under

the heading “Risk Factors” included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and in our other filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. In some cases, you can identify forward-looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “aim,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise.

These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation:

- Our ability to successfully integrate the business of former Opus Genetics Inc. and manage our expanded combined product pipeline;
- Our ability to develop and obtain regulatory approval for newly acquired gene therapies to treat inherited retinal diseases;
- Our ability to obtain and maintain orphan drug designation or rare pediatric disease designation for our current and future product candidates;
- The success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts;
- Regulatory requirements or developments;
- Changes to or unanticipated events in connection with clinical trial designs and regulatory pathways;
- Delays or difficulties in the enrollment of patients in clinical trials;
- Substantial competition, including from generic versions of our product candidates;
- Rapid technological change;
- Our development of sales and marketing infrastructure;
- Future revenue losses and profitability;
- Changes in capital resource requirements;
- Risks related to our inability to obtain sufficient additional capital to continue to advance our product candidates and our preclinical programs;
- Domestic and worldwide legislative, regulatory, political and economic developments;
- Our dependency on key personnel;
- Changes in market opportunities and acceptance;
- Reliance on third parties to conduct our clinical trials and supply and manufacture drug supplies;
- Future, potential product liability and securities litigation;
- System failures, unplanned events, or cyber incidents;

- The substantial number of shares subject to potential issuance associated with our equity line of credit arrangement;
- Risks that our licensing or partnership arrangements may not facilitate the commercialization or market acceptance of our product candidates;
- Future fluctuations in the market price of our common stock;
- Actions by activist stockholders;
- The success and timing of commercialization of any of our product candidates;
- Obtaining and maintaining our intellectual property rights; and
- The success of mergers and acquisitions.

The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission that advise interested parties of the risks and factors that may affect our business. All forward-looking statements contained in this press release speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Source: Opus Genetics, Inc.