ONL Therapeutics Completes Enrollment in Global Phase 2 GALAXY Trial of Xelafaslatide in Patients with Geographic Atrophy Associated with Dry AMD

Rapid enrollment underscores strong physician and patient demand for new treatment options

ANN ARBOR, Mich., **Nov. 17, 2026** — ONL Therapeutics, Inc., a clinical-stage biopharmaceutical company developing novel therapies for protecting the vision of patients with retinal disease, today announced it completed enrollment in its global GALAXY trial, with over 324 patients enrolled across sites in the U.S., Canada and Europe. GALAXY is a global Phase 2 clinical trial evaluating the efficacy and safety of xelafaslatide (formerly ONL1204) in patients with geographic atrophy (GA) associated with dry age-related macular degeneration (AMD).

“Enrolling a large global trial with this many participants tells us that physicians and patients want a new approach to GA that significantly reduces treatment burden,” said David N. Zacks, M.D., Ph.D., chief scientific officer at ONL Therapeutics. “GA is a relentless, irreversible disease with few approved treatments, particularly in Europe. With the potential for dosing every three to six months, xelafaslatide brings a unique and differentiated mechanism of action designed to protect key retinal cells from Fas-mediated cell death to preserve vision.”

“Completing enrollment in the GALAXY trial is a tremendous milestone that reflects the dedication of many working to advance the science, from the investigators and their study teams to the patients who volunteered and the caregivers who support them,” said Lindsay Puscas, M.S., COA, CCRP, vice president of clinical operations at ONL Therapeutics. “Our focus now turns to supporting every participant through study completion to deliver the data patients and the retinal community are counting on.”

GALAXY (NCT06659445) enrolled participants across sites in the U.S., Canada and Europe, with a target of approximately 324 patients. The trial builds on data from a Phase 1b study that demonstrated xelafaslatide to be generally safe and well tolerated with encouraging efficacy signals observed after six months. Xelafaslatide, which is delivered via intravitreal injection, is being studied across three experimental arms, including two dose levels and two treatment frequencies (every 12 weeks or every 24 weeks). The primary endpoint is the rate of growth of the GA lesion area in patients treated with

xelafaslatide versus sham as assessed by fundus autofluorescence (FAF) measured at 48 weeks. Additional timepoints will be measured out to 72 weeks, and an active reference arm is applicable to patients at U.S. sites only.

“With enrollment now complete, we anticipate the release of topline data on our 48-week primary endpoint in Q4 2027,” said David Esposito, chief executive officer of ONL Therapeutics. “Every milestone in this program moves us toward our vision of helping patients see the future.”

About Xelafaslatide (ONL1204 Ophthalmic Solution)
Xelafaslatide (ONL1204) is an investigational first-in-class small-molecule Fas inhibitor designed to protect key retinal cells, including photoreceptors, from cell death that occurs across a range of retinal diseases and conditions. Death of these retinal cells, through both direct and inflammatory signaling pathways, is the root cause of vision loss and the leading cause of blindness. The company’s later-stage clinical development program for xelafaslatide includes a Phase 2 study for the treatment of GA associated with AMD (NCT06659445) and a completed Phase 2 study in the U.S. for the treatment of macula-off retinal detachment (RD) (NCT05730218), a condition for which the compound has been granted orphan drug designation by the United States Food and Drug Administration (FDA). The company has also completed a Phase 1b clinical trial in patients with GA associated with AMD (NCT04744662), a Phase 1b clinical trial in patients with progressing open-angle glaucoma (NCT05160805) and a Phase 1 clinical trial in macula-off RD patients at sites in Australia and New Zealand (NCT03780972).

About Geographic Atrophy (GA) Associated with Dry Age-related Macular Degeneration (AMD)
AMD has become a major cause of visual disability and legal blindness globally. Although generally affecting only the central retina (macula), this region of photoreceptors provides the visual acuity necessary for reading, driving, and the performance of fine vision-related tasks. Associated with aging, cigarette smoking, obesity, diets low in certain nutrients, a lifestyle related to cardiac risk, and a growing list of genetic factors, AMD is becoming an increasingly prevalent public health concern, especially as the global population ages. GA, also called atrophic AMD, is an advanced form of AMD.

About ONL Therapeutics
ONL Therapeutics (ONL) is a clinical-stage biopharmaceutical company committed to developing first-in-class therapeutics to protect and improve the vision of patients with retinal disease. By advancing a breakthrough technology designed to protect key retinal cells from Fas-mediated cell death, ONL is pioneering a new approach to preserving vision.

For more information about ONL Therapeutics, please visit www.onltherapeutics.com.

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