ONL Therapeutics Announces First European Patient Randomized in its Global Phase 2 GALAXY Trial of Xelafaslatide (ONL1204) in Patients with Geographic Atrophy (GA) Associated with Dry AMD

Enrollment begins in Switzerland as the company continues to activate clinical sites beyond the U.S. market

ANN ARBOR, Mich., **March 16, 2026** – ONL Therapeutics, Inc., a clinical-stage biopharmaceutical company developing novel therapies for protecting the vision of patients with retinal disease, today announced that the first European participant has been randomized in the company's Phase 2 GALAXY trial. GALAXY is a global Phase 2 clinical trial designed to evaluate the efficacy and safety of xelafaslatide (formerly ONL1204) in patients with geographic atrophy (GA) associated with dry age-related macular degeneration (AMD). This milestone, which took place at a clinical trial site in Switzerland, marks the beginning of European participation in the GALAXY trial and represents another key step toward the company's goal of enrolling approximately 324 patients across Europe, Canada and the U.S.

"Geographic atrophy remains one of the most devastating challenges in ophthalmology, and treatment options in Europe remain limited," said David N. Zacks, M.D., Ph.D., chief scientific officer of ONL Therapeutics. "With its unique and differentiated mechanism of action targeting the Fas pathway, xelafaslatide has the potential to bring a much-needed neuroprotection therapy to patients facing this progressive, vision-threatening disease. Enrolling our first European patient in the GALAXY trial represents an important milestone in our effort to provide clinicians with potentially more effective and durable treatment options for their GA patients."

"Activating GALAXY clinical sites across Europe while simultaneously advancing enrollment in the U.S. and Canada demonstrates our team's capability to execute a complex, global trial," said Penny Fleck, MT, MBA, chief development officer of ONL Therapeutics. "This achievement is a testament to the strength of our clinical development team and our unwavering commitment to delivering a safe and effective treatment option for patients with GA."

GALAXY (NCT06659445) will enroll approximately 324 patients across sites in the U.S., Canada and Europe. The trial seeks to build 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, will be 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 will be applicable to patients at U.S. sites only.

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 Phase1 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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