



NeOnc Technologies Announces FDA End of Phase 1 Meeting for NEO212

September 28, 2026

November 17 meeting will address Phase 2 study design and potential regulatory pathways

CALABASAS, Calif., Sept. 28, 2026 (GLOBE NEWSWIRE) -- NeOnc Technologies Holdings, Inc. (Nasdaq: NTHI) ("NeOnc" or the "Company"), a clinical-stage biopharmaceutical company developing therapies for central nervous system (CNS) cancers, today announced that it is scheduled to meet with the U.S. Food and Drug Administration (FDA) on November 17, 2026, for an in-person End-of-Phase 1 Type B meeting concerning NEO212. The meeting is scheduled to take place at FDA's White Oak campus in Silver Spring, Maryland.

The Company plans to seek FDA feedback on its NEO212 clinical development program, including an update to its proposed patient population, trial design, endpoints, dose selection and evidence needed to support a future marketing application. The meeting provides an opportunity for discussion; its scheduling does not establish FDA agreement on a trial design, an accelerated approval pathway or eventual approval of NEO212.

In September 2025, FDA authorized the Company to proceed with the Phase 2a and Phase 2b portions of NEO212-01.

This meeting follows completion of the Phase 1 dose-escalation portion of the NEO212-01 Phase 1/2 clinical trial. NeOnc previously reported that dose escalation was discontinued following a dose-limiting toxicity at 810 mg, administered once daily on Days 1 through 5 of a 28-day cycle, and that 610 mg was selected as the recommended Phase 2 dose.

NeOnc also reported encouraging clinical activity observed during the Phase 1 portion of the trial. In one patient with recurrent IDH1 wild-type, MGMT-methylated glioblastoma (GBM), treatment with NEO212 resulted in a partial response, including an approximately 60% reduction in tumor size, followed by prolonged disease control lasting 21 treatment months. This duration of disease control is notable in the setting of recurrent GBM, where outcomes following recurrence have historically been limited.

In a second patient with lung cancer metastatic to the brain who had previously received and progressed following multiple lines of therapy, including immune checkpoint inhibitors, treatment with NEO212 was associated with stable disease lasting approximately 16 months. Patients with brain metastases from lung cancer who have progressed following multiple prior systemic therapies represent a population with substantial unmet medical need and historically limited treatment options.

While these individual patient outcomes do not establish efficacy and require confirmation in larger studies, the durability of responses observed during Phase 1, together with the established recommended Phase 2 dose, provides the clinical rationale for further evaluation of NEO212 in the Phase 2 portions of the NEO212-01 trial. Building on these findings, NeOnc intends to discuss its potential registrational development strategy and to seek FDA feedback on whether a proposed trial design could support a potential accelerated approval pathway.

"We have completed dose escalation and selected a recommended Phase 2 dose for NEO212," said Amir Heshmatpour, Executive Chairman, President and Chief Executive Officer of NeOnc. "This meeting will help us understand FDA's feedback on the population, study design and endpoints for the next stage of development. We may update our plans after evaluating the agency's feedback."

About High-Grade Glioma

High-grade gliomas, including glioblastoma, are serious brain cancers with substantial unmet medical need. Treatment may include surgery, radiation and drug therapy, but recurrence is common.

About NEO212

NEO212 is an investigational oral conjugate of temozolomide and NEO100. It is being studied for CNS cancers, including recurrent glioblastoma. Preclinical studies support further evaluation of its potential activity and delivery characteristics; clinical efficacy and safety have not been established. NEO212 is being developed under an FDA investigational new drug application.

About NeOnc Technologies Holdings, Inc.

NeOnc Technologies Holdings, Inc. is a clinical-stage biopharmaceutical company developing therapies for CNS cancers. Its investigational programs include intranasal NEO100 and oral NEO212. Neither product is approved by FDA for commercial use. The Company has licensed intellectual property from the University of Southern California relating to its development programs.

For more information, visit <https://neonc.com>.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the anticipated date and format of the FDA meeting, the topics to be discussed, future clinical trial design, a potential registrational development strategy, possible accelerated approval, and the clinical potential of NEO212. These statements reflect current expectations and involve risks and uncertainties. FDA feedback may differ from the Company's proposals; the meeting may be rescheduled or its format changed; additional clinical, nonclinical or manufacturing work may be required; future studies may not demonstrate safety or efficacy; and no regulatory pathway or marketing approval is assured. Actual results may differ materially. Readers should consider the risk factors described in the Company's most recent filings with the Securities and Exchange Commission. These statements speak only as of the date of this release.

The Company undertakes no obligation to update forward-looking statements except as required by law.

"NEO100" and "NEO212" are registered trademarks of NeOnc Technologies Holdings, Inc.

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