NeOnc Technologies Announces FDA Rescheduled NEO212 End-of-Phase 1 Type B Meeting to November 23

November 19, 2026

Meeting will address Phase 2 study design and potential regulatory pathways for oral NEO212

CALABASAS, Calif., Nov. 19, 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 the U.S. Food and Drug Administration (FDA) has rescheduled the Company's End-of-Phase 1 Type B meeting concerning oral NEO212 from the previously announced date of November 17, 2026, to Monday, November 23, 2026.

At the meeting, NeOnc intends to seek FDA feedback on its NEO212 clinical development program, including the proposed patient population, trial design, endpoints and dose selection for the Phase 2 portions of the NEO212-01 trial, as well as potential regulatory pathways for NEO212. The meeting provides an opportunity for discussion; its scheduling does not establish FDA agreement on a trial design or eventual approval of NEO212.

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

NeOnc has 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. 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. While these individual patient outcomes do not establish efficacy and require confirmation in larger studies, they provide the clinical rationale for further evaluation of NEO212 in the Phase 2 portions of the NEO212-01 trial.

"We believe the durable activity NEO212 showed in Phase 1, together with a well-defined recommended Phase 2 dose, gives us a compelling foundation for the next stage of development," said Amir F. Heshmatpour, Executive Chairman, President and Chief Executive Officer of NeOnc. "We look forward to discussing our Phase 2 plans with the FDA as we work to advance NEO212 for patients with CNS cancers who urgently need new options."

Management anticipates hosting an investor webinar following issuance and receipt of the FDA's official meeting minutes to discuss the Agency's feedback and the Company's anticipated next steps for the NEO212 development program. The Company expects to announce the webinar date, time and registration details separately.

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 central nervous system cancers. Its investigational programs include intranasal NEO100 and oral NEO212. NEO212 has completed Phase 1 dose escalation and is advancing toward Phase 2 development. NeOnc exclusively licenses a worldwide portfolio of issued patents and pending applications from the University of Southern California related to NEO100, NEO212 and other drug candidates and delivery approaches. 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, issuance and receipt of the FDA's official meeting minutes, the anticipated investor webinar and its timing, future clinical trial design, potential regulatory pathways, the Company's clinical development programs and the clinical potential of NEO212. These statements reflect current expectations and involve risks and uncertainties. NEO212 is

investigational and has not been approved by any regulatory authority. The scheduling of the FDA meeting does not establish FDA agreement on a development plan or eventual approval of NEO212. FDA feedback may differ from the Company's proposals; the meeting may be rescheduled or its format changed; issuance of the FDA's official meeting minutes may be delayed and the anticipated investor webinar may be delayed or may not occur; additional clinical, nonclinical or manufacturing work may be required; future studies may not demonstrate safety or efficacy; clinical development remains subject to applicable clinical, regulatory and institutional requirements; and no regulatory pathway or marketing approval is assured. The individual patient outcomes described in this release do not establish efficacy and require confirmation in larger studies. The Company will require substantial additional capital to fund its operations, which may not be available on acceptable terms or at all. 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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