NeOnc Announces FDA Agreement on Single Study Design and Accelerated Approval Pathway for NEO212

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Interim analysis could support earlier marketing approval in recurrent glioblastoma, with continued follow-up in the same study intended to confirm clinical benefit

CALABASAS, Calif., Nov. 24, 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 met with the U.S. Food and Drug Administration (FDA) on November 23, 2026, and reached agreement on the design of a single randomized, controlled study of oral NEO212 intended to support marketing approval for recurrent glioblastoma. Based on the Company's understanding of the End-of-Phase 1 Type B meeting, FDA also agreed to an accelerated approval pathway using a planned interim analysis, with continued follow-up in the same study intended to verify clinical benefit. The Company's summary of the meeting remains subject to the FDA's official meeting minutes.

The planned interim analysis would evaluate tumor response and duration of response to support a potential application for accelerated approval. This approach could allow NEO212 to reach patients sooner than waiting for the study's final clinical benefit results, provided the interim data are sufficient and FDA grants approval. Longer-term follow-up in the same study is intended to confirm clinical benefit. Study design agreement does not constitute approval of NEO212, and approval remains dependent on adequate safety and efficacy data and satisfaction of applicable FDA requirements.

"This meeting represents an important step toward our goal of bringing NEO212 to patients with recurrent glioblastoma," said Amir F. Heshmatpour, Executive Chairman, President and Chief Executive Officer of NeOnc. "Agreement on a single study design and an accelerated approval pathway gives us a clearer development plan. If the interim results meet FDA requirements, we could seek earlier marketing approval while continuing the same study to confirm clinical benefit. Our focus now is on advancing the program and executing the study with the rigor patients deserve."

Management anticipates hosting an investor webinar after the FDA's official meeting minutes are issued to discuss the Agency's feedback, the study design and the Company's next steps for NEO212. 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 planned NEO212 study and its ability to support accelerated approval and verify clinical benefit; the timing and results of interim and final analyses; the potential for earlier patient access and marketing approval; protocol finalization and study initiation; issuance and receipt of the FDA's official meeting minutes; the anticipated investor webinar and its timing; and 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. Agreement on a study design or potential regulatory pathway does not constitute marketing approval or guarantee that a future application will be accepted or approved. The Company's account of the meeting reflects its understanding pending receipt of the FDA's official meeting minutes; those minutes may clarify or differ from that understanding. Additional clinical, nonclinical, dose-optimization or manufacturing work may be required; study designs and regulatory requirements may change; future studies may not demonstrate adequate safety or efficacy;

and clinical development remains subject to applicable clinical, regulatory and institutional requirements. Accelerated approval, if granted, would be subject to requirements to verify clinical benefit, and failure to verify benefit could result in withdrawal of approval. Issuance of meeting minutes and the anticipated investor webinar may be delayed, and the webinar may not occur. 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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