NeOnc Technologies Granted FDA Type B End-of-Phase Meeting to Discuss Potential Accelerated Approval Pathway and Phase 3 Confirmatory Trial for Intranasal NEO100

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CALABASAS, Calif., Nov. 11, 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 granted the Company a Type B End-of-Phase meeting to discuss a potential accelerated approval pathway for intranasal NEO100 in recurrent or progressive IDH-mutant grade 4 astrocytoma. The meeting is scheduled for early January 2027.

At the meeting, NeOnc intends to review the NEO100 nonclinical and clinical data package, including results from the completed Phase 2a portion of the NEO100-01 trial, and to seek the FDA's feedback on whether these data could support a 505(b)(2) New Drug Application (NDA) seeking accelerated approval under section 506(c) of the Federal Food, Drug, and Cosmetic Act. The Company also intends to seek the FDA's agreement on the design of NEO100-012, a multicenter, randomized, controlled Phase 3 trial comparing intranasal NEO100 with investigator's-choice standard-of-care chemotherapy in patients with recurrent or progressive IDH-mutant grade 4 astrocytoma, with overall survival as the primary endpoint. The Phase 3 is intended to serve as the registrational and confirmatory trial for NEO100: under the accelerated approval framework, the Company would expect the trial to be underway, with enrollment ongoing, at the time of any NDA submission, and its final overall survival analysis to verify clinical benefit and support conversion to traditional approval. Discussion topics will also include the adequacy of the existing nonclinical safety package, the scientific bridge from published perillyl alcohol data to intranasal NEO100, and the eligibility of NEO100 for Breakthrough Therapy designation.

"We believe the safety and efficacy results from the Phase 2a portion of NEO100-01 in recurrent IDH-mutant grade 4 astrocytoma, together with our nonclinical data, provide a sound basis for discussing a potential accelerated approval pathway with the FDA and for aligning with the agency on the design of our Phase 3 confirmatory trial," said Amir F. Heshmatpour, Executive Chairman, President and Chief Executive Officer of NeOnc. "We look forward to exploring this approach with the agency as we work to bring NEO100 to patients who urgently need new options."

On August 12, 2026, NeOnc reported topline results from the Phase 2a portion of NEO100-01. In the analysis of the interim database lock (data cutoff June 24, 2026), the six-month progression-free survival (PFS-6) rate was 48.9% (95% CI: 26.3–68.1) by RANO 2.0 criteria, exceeding the protocol-defined benchmark of 20% for standard of care (one-sided p = 0.0047). Median overall survival was 26.1 months (95% CI: 8.5–27.1), and estimated overall survival was 86.7% at six months, 61.5% at 12 months and 54.7% at 18 and 24 months, with five patients remaining on treatment at the interim database lock. MRI assessments were performed by independent central review. No treatment-related Grade 3 or higher adverse events, treatment-related serious adverse events or discontinuations for treatment-related adverse events were reported; treatment-related adverse events were Grade 1–2 and predominantly local nasal or upper-airway effects.

NeOnc expects to provide an update following receipt and review of the FDA's official meeting minutes.

About Accelerated Approval

The FDA's Accelerated Approval program allows drugs for serious conditions that fill an unmet medical need to be approved based on an effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit, rather than waiting for a direct measure of benefit such as longer survival. Companies whose drugs receive accelerated approval are required to conduct confirmatory trials to verify the anticipated clinical benefit, which may support conversion to traditional approval. Under amendments to the Federal Food, Drug, and Cosmetic Act enacted in 2022, the FDA may require that a confirmatory trial be underway before accelerated approval is granted.

About the NEO100-01 Study

NEO100-01 is an open-label, multi-center Phase 1/2a study of intranasal NEO100 in patients with radiographically confirmed progression of, or recurrence of, primary or secondary Grade IV glioma or Grade III astrocytoma harboring an IDH1 mutation. The Phase 2a portion treated 28 patients at the recommended Phase 2 dose of 1,152 mg/day, of whom 24 patients with IDH1-mutant tumors (21 with grade 4 disease) constitute the efficacy population; enrollment is complete and five patients remained on treatment at the interim database lock. The primary endpoint is the progression-free survival rate at six months.

About NEO100

NEO100 is a highly purified form of perillyl alcohol administered intranasally. Its delivery approach is designed to provide a non-invasive route to the brain. NEO100 remains investigational, and its safety and efficacy have not been established. NEO100 has received Fast Track designation from the FDA for the treatment of high-grade glioma and Orphan Drug designation for the treatment of gliomas.

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 timing of the FDA meeting, the topics to be discussed, a potential accelerated approval pathway, a potential 505(b)(2) New Drug Application, the design, initiation, enrollment and timing of the planned NEO100 Phase 3 trial and whether it will be underway at the time of any NDA submission or will verify clinical benefit, the Company's clinical development programs and the clinical potential of NEO100. Forward-looking statements in this release also include statements regarding the clinical potential of NEO212. These statements reflect current expectations and involve risks and uncertainties. NEO100 is investigational and has not been approved by any regulatory authority; 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 scheduling of the FDA meeting does not establish FDA agreement on a development plan, an accelerated approval pathway or eventual approval of NEO100. NEO212 is also investigational and has not been approved by any regulatory authority. The NEO100 Phase 2a study was a single-arm, open-label study that was not powered as a confirmatory trial. The Phase 2a results described in this release are from an interim database lock and may change at the final analysis; comparisons to historical benchmarks are not based on a randomized comparison. The FDA may not agree that NEO100 Phase 3 as designed is an adequate confirmatory trial, may require changes to its design or enrollment status before any accelerated approval, and the trial may not confirm clinical benefit. 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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