NeOnc Reports Additional Partial Response in Phase 2a Study of Intranasal NEO100

November 17, 2026

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Median overall survival was 26.1 months from the start of NEO100 treatment at recurrence, as previously reported

CALABASAS, Calif., Nov. 17, 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 reported updated interim results from the Phase 2a portion of NEO100-01, an open-label study of intranasal NEO100 in patients with recurrent or progressive Grade III or Grade IV IDH1-mutant glioma. One additional partial response brought the objective response rate to 12.5% (3 of 24 patients), compared with 8.3% (2 of 24 patients) in the August 12, 2026 topline results. Both rates were assessed using RANO 2.0 criteria.

By RANO 2.0 criteria, three patients had a partial response (12.5%), 13 had stable disease (54.2%) and eight had progressive disease (33.3%). The disease control rate was 66.7%. Five patients remained on treatment at the interim database lock.

As previously reported, six-month progression-free survival, the study's primary endpoint, was 48.9% (95% CI, 26.3%–68.1%) by RANO 2.0 using Kaplan–Meier estimation, compared with the prespecified 20% historical benchmark (one-sided p = 0.0047). Median overall survival was 26.1 months (95% CI, 8.5–27.1 months) from the start of NEO100 treatment at recurrence. The single-arm, open-label study used a historical benchmark and had no randomized control group. Results differ under the response criteria and estimation method specified in the study protocol. Interim results may change at final analysis.

"We are encouraged by the additional partial response in this update," said Amir F. Heshmatpour, Executive Chairman, President and Chief Executive Officer of NeOnc. "We remain focused on advancing the development of NEO100 for patients with recurrent high-grade glioma."

At the interim analysis, all reported treatment-related adverse events were Grade 1 or 2 and consisted predominantly of local nasal or upper-airway effects. NeOnc reported no treatment-related serious adverse events or discontinuations due to treatment-related adverse events.

About the NEO100-01 Study

NEO100-01 is an open-label, multicenter Phase 1/2a study of intranasal NEO100 in patients with radiographically confirmed progression or recurrence of primary or secondary Grade IV glioma or Grade III astrocytoma harboring an IDH1 mutation. In Phase 2a, 28 patients received the recommended Phase 2 dose of 1,152 mg/day. The efficacy population consisted of 24 patients with IDH1-mutant tumors, including 21 with Grade IV disease. Enrollment is complete.

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 Orphan Drug designation from the FDA 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 regarding the interpretation and significance of the updated Phase 2a results, the Company's clinical development programs and the clinical potential of NEO100 and NEO212. These statements reflect current expectations and involve risks and uncertainties. NEO100 and NEO212 are investigational, and neither has 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 NEO100 Phase 2a study was a single-arm, open-label study that was not powered as a confirmatory trial. The interim results may change at final analysis. Comparisons with historical benchmarks were made without a randomized control group. The efficacy results presented reflect RANO 2.0 criteria and Kaplan–Meier estimation, and results differ under the response criteria and estimation method specified in the study protocol. 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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