NeOnc Technologies Reports Updated Clinical Results

December 15, 2025

Expanded Clinical Experience Demonstrates Additional Long-Term Survival and Radiographic Remission in Recurrent Grade III/IV IDH1-Mutant Astrocytoma Treated with Intranasal NEO100

CALABASAS, Calif., Dec. 15, 2025 (GLOBE NEWSWIRE) -- NeOnc Technologies Holdings, Inc. (Nasdaq: NTHI) ("NeOnc" or the "Company"), a multi-Phase 2 clinical-stage biopharmaceutical company developing novel therapies for central nervous system (CNS) cancers, today announced updated clinical results from its ongoing Phase 1/2a and compassionate-use experience evaluating intranasal NEO100 in patients with recurrent WHO Grade III/IV IDH1-mutant astrocytoma.

Since the Company's prior announcement and 8K event on November 12, 2025, an additional patient has achieved both durable long-term survival and radiographic remission, further strengthening the clinical signal observed with intranasal NEO100. With this update, the expanded clinical cohort now includes 25 patients, reinforcing the reproducibility and durability of treatment benefit.

Updated results demonstrate that treatment with intranasally delivered NEO100 has resulted in significant radiographic remission in 6 of 25 patients (24%), representing 3X increase over the 8% response rates typically reported with salvage therapies in recurrent high-grade gliomas.

Additionally, 44% of patients achieved six-month progression-free survival (PFS-6), exceeding historical benchmarks of 21–31% for IDH1-mutant recurrent high-grade gliomas. Importantly, 9 of 25 patients (36%) remain alive ≥18 months following initiation of NEO100, providing further evidence of meaningful long-term survival in this heavily pretreated population.

No significant toxicity has been observed with intranasal administration of NEO100, even with prolonged and chronic dosing.

Amir F. Heshmatpour, Executive Chairman, President & CEO of NeOnc Technologies Holdings, Inc., stated: "The addition of another patient achieving both long-term survival and radiographic remission further validates what we believe is a highly compelling and differentiated therapeutic signal. With radiographic responses now 300% higher than the rate historically reported with salvage therapies, these updated data reinforce our conviction that NEO100 may represent a meaningful advance for patients with recurrent IDH1-mutant high-grade gliomas—patients who have historically had few options. As we move toward a complete data readout, the consistency and durability of these responses continue to exceed expectations."

Mr. Heshmatpour added: "We view this expanding dataset as a critical value-inflection point for NeOnc and for the neuro-oncology field, suggesting a potential shift away from purely palliative approaches toward durable disease control."

Founder, Vice-Chairman, and Chief Medical Officer Dr. Thomas Chen commented: "With each additional durable responder, the data increasingly support the hypothesis that intranasal NEO100 may be a first-in-class, CNS-penetrant metabolic therapy capable of inducing sustained radiographic remission and multi-year survival in recurrent IDH1-mutant gliomas."

Dr. Henry Friedman of Duke University emphasized the implications of these findings, stating, "The results from NEO100 signify a potential paradigm shift in the treatment of recurrent IDH1-mutant gliomas."

Key Data Highlights:

Radiographic Response: 24% (6 of 25 patients) achieved significant radiographic remission confirmed by contrast-enhanced, T2-FLAIR, and perfusion MRI. This response rate exceeds the <8% typically observed with salvage therapies for recurrent gliomas.

Progression-Free Survival (PFS-6): 44% of patients achieved 6-month progression-free survival (PFS-6), outperforming historical benchmarks of 21–31% for IDH1-mutant recurrent high-grade gliomas.

Long Term Survival: 36% (9 of 25) demonstrated durable survival ≥18 months post-initiation of NEO100.

Tolerability: No significant toxicity observed even with prolonged, chronic intranasal administration.

Study Context: All patients in the combined analysis (1 compassionate-use case, 5 from Phase 1, and 18 from Phase 2a) had confirmed WHO recurrent Grade III/IV IDH1-Mutant Astrocytoma and were included in the analysis if they had been enrolled in the study for at least six months prior to data cutoff. Patients received intranasal NEO100, and results were assessed using Response Assessment in Neuro-Oncology (RANO) criteria.

Collectively, these findings indicate that NEO100 could represent a first-in-class, CNS-penetrant metabolic therapy potentially inducing significant radiographic response and extending survival in patients with recurrent Grade III/IV IDH1-Mutant Astrocytoma, thereby potentially offering a major advancement over past approaches predominantly limited to palliative care.

ABOUT NEONC TECHNOLOGIES HOLDINGS, INC. NeOnc Technologies Holdings, Inc. is a clinical-stage life sciences company focused on the development and commercialization of central nervous system therapeutics that are designed to address the persistent challenges in overcoming the blood-brain barrier. The company's NEO™ drug development platform has produced a portfolio of novel drug candidates and delivery methods with patent protections extending to 2038. These proprietary chemotherapy agents have demonstrated positive effects in laboratory tests on various types of cancers and in clinical trials treating malignant gliomas. NeOnc's NEO100™ and NEO212™ therapeutics are in Phase II human clinical trials and are advancing under FDA Fast-Track and Investigational New Drug (IND) status. The company has exclusively licensed an extensive worldwide patent portfolio from the University of Southern California consisting of issued patents and pending applications related to NEO100, NEO212, and other products from the NeOnc patent family for multiple uses, including oncological and neurological conditions.

For more about NeOnc and its pioneering technology, visit neonc.com.

Important Cautions Regarding Forward Looking Statements This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements can be identified by terminology such as "may," "will," "should," "intend," "expect," "plan," "budget," "forecast," "anticipate," "believe," "estimate," "predict," "potential," "continue," "evaluating," or similar words. Statements that contain these words should be read carefully, as they discuss our future expectations, projections of future results of operations or financial condition, or other forward-looking information.

Examples of forward-looking statements include, among others, statements regarding whether a definitive agreement will be reached with Quazar. These statements reflect our current expectations based on information available at this time, but future events may differ materially from those anticipated.

The "Risk Factors" section of our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, along with other cautionary language in that report or in our subsequent filings, outlines important risks and uncertainties. These may cause our actual results to differ materially from the forward-looking statements herein, including but not limited to the failure to finalize the agreement with Quazar, modifications to its terms, or alternative uses of proceeds.

We assume no obligation to revise or update any forward-looking statements, whether as a result of new information, future developments, or otherwise, except as required by applicable securities laws and regulations.

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