NeOnc Technologies Receives UAE IND Approval for NEO100, Expanding Global Development Ahead of Anticipated Phase 2 Data Milestone

June 23, 2026

Authorization covers all three NEO100 programs across adult Phase 1 through Phase 2, plus pediatric studies

Extends NeOnc's UAE footprint beyond NEO212 and complements ongoing U.S. development, where NEO100 holds FDA Orphan Drug, Fast Track, and Rare Pediatric Disease designations

CALABASAS, Calif., June 23, 2026 (GLOBE NEWSWIRE) -- NeOnc Technologies Holdings, Inc. (Nasdaq: NTHI) ("NeOnc" or the "Company"), a clinical-stage biopharmaceutical company developing novel therapies for central nervous system (CNS) cancers, today announced that the Department of Health – Abu Dhabi (DOH) has granted Investigational New Drug (IND) status for NEO100, the Company's lead candidate, an intranasally administered formulation of purified perillyl alcohol designed for non-invasive nose-to-brain delivery. The authorization covers the Company's NEO100-01, NEO100-02, and NEO100-03 protocols across Phase 1, Phase 1b, and Phase 2 studies in adults, together with pediatric studies authorized for Phase 1 and Phase 1b pending further protocol review. The authorized indication is progressive or recurrent Grade III or IV gliomas.

The breadth of the UAE authorization, spanning three protocols and adult studies from Phase 1 through Phase 2 alongside a defined pediatric pathway, is intended to allow NeOnc to advance multiple stages of clinical development in parallel. The authorization follows the DOH's recent IND clearance for the Company's NEO212 program, announced in June 2026, and extends NeOnc's clinical development footprint in the UAE across both of its lead platforms, the intranasal delivery platform represented by NEO100 and the drug-conjugation platform represented by NEO212.

In the United States, NEO100 has received FDA Orphan Drug, Fast Track, and Rare Pediatric Disease designations, and its lead clinical study, the NEO100-01 Phase 2a trial in recurrent IDH1-mutant high-grade glioma, is fully enrolled.

The Company expects to report top-line data from the fully enrolled NEO100-01 Phase 2a trial by the end of July 2026, representing what NeOnc believes may be one of the most important clinical milestones in the Company's history. Based on the strength of the data observed to date and ongoing interactions with regulators, NeOnc believes the upcoming results may support one or more important regulatory pathways, including potential Breakthrough Therapy designation, expansion of existing Fast Track benefits, and enhanced development opportunities under the program's existing Orphan Drug designation. While no assurance can be given regarding regulatory outcomes, the Company believes the upcoming data represent a significant milestone in the continued development of NEO100.

"This authorization is significant because it comes at a pivotal moment for NeOnc and the NEO100 program," said Amir Heshmatpour, Chief Executive Officer, Executive Chairman and President of NeOnc. "NEO100 has already received FDA Orphan Drug, Fast Track, and Rare Pediatric Disease designations, and we are now approaching what we believe could be one of the most important clinical milestones in our Company's history. We anticipate reporting top-line Phase 2a data by the end of July and believe those results may position NEO100 for additional regulatory opportunities, including potential Breakthrough Therapy designation. If the data continue to reflect the encouraging trends observed to date, we believe NEO100 has the potential to meaningfully alter the treatment paradigm for patients suffering from recurrent high-grade gliomas. While regulatory decisions are ultimately made by the FDA, we are encouraged by the progress of the program and remain focused on bringing a non-invasive treatment option to patients facing devastating brain cancers. Our objective is not simply to advance another oncology drug candidate, but to establish a new paradigm for non-invasive delivery of therapeutics to the brain, potentially changing how CNS diseases are treated worldwide."

"NEO100 uses intranasal delivery to reach the brain directly, a practical route that circumvents the blood-brain barrier without surgery or systemic chemotherapy," said Thomas Chen, MD, Ph.D., Founder, Chief Medical Officer and Chief Scientific Officer of NeOnc. "Because it is non-invasive, this approach can enable studies in difficult groups, including children with high-grade gliomas that have few options today. An authorization spanning Phase 1 through Phase 2 with a pediatric pathway lets us pursue that work where it is needed most."

The upcoming Phase 2a readout represents the first controlled evaluation of NEO100 in recurrent IDH1-mutant high-grade glioma following encouraging earlier clinical observations. If the study meets its objectives, NeOnc believes the data could support discussions with regulators regarding accelerated development pathways and potentially serve as the foundation for future registrational planning.

High-grade gliomas, including WHO Grade III and IV disease, are among the most aggressive brain cancers, with limited

treatment options after recurrence. The Company expects to work with healthcare institutions, investigators, and regulatory authorities in the UAE as clinical development activities advance.

The UAE authorization further positions NeOnc to rapidly expand clinical development activities internationally as the Company prepares for multiple anticipated regulatory and clinical milestones throughout the second half of 2026.

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 https://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.

Please refer to the "Risk Factors" section of our quarterly and annual reports on Form 10-Q and Form 10-K as filed with the Securities and Exchange Commission, along with other cautionary language in those reports and risk factors and other cautionary language in our subsequent filings with the Securities and Exchange Commission, which outline 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 fact that results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, announced or published data from our clinical trials may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, and our product candidates are in preclinical and clinical stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.

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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