



NeOnc Technologies Secures UAE IND Approval for NEO212 Following Successful Phase 1 Completion, Advancing Toward Global Phase 2 Development

June 16, 2026

Clearance enables Phase 2 evaluation of NEO212, the Company's oral perillyl alcohol-temozolomide conjugate, in the United Arab Emirates

Follows completion of Phase 1 dose escalation and selection of 610 mg as the recommended Phase 2 dose

Adds an international clinical pathway alongside continuing U.S. FDA discussions on a potential registrational pathway for NEO212

CALABASAS, Calif., June 16, 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 NEO212, the Company's orally administered perillyl alcohol-temozolomide carbamate conjugate being developed for patients with aggressive brain tumors. The authorization marks the first international regulatory clearance for NEO212 following completion of Phase 1 clinical evaluation and represents a significant step toward expanding the program into multiple global markets.

NEO212 recently completed the Phase 1 dose-escalation portion of its Phase 1/2 study, which established 610 mg as the recommended Phase 2 dose. In that study, the Company reported encouraging early signs of clinical activity, including potential durable disease stabilization, in heavily pretreated patients with recurrent glioblastoma (GBM) and brain metastases. NeOnc expects this authorization to support the advancement of NEO212 into Phase 2 clinical development while continuing discussions with the U.S. Food and Drug Administration regarding the design of a potential registrational pathway. The Company believes parallel regulatory and clinical activities across multiple jurisdictions may accelerate the overall development strategy for NEO212.

Under the terms of the DOH authorization, NeOnc must satisfy a number of conditions before patient enrollment in the UAE, including separate approval from the DOH Institutional Review Board (IRB) and amendments to the study protocol, investigator's brochure, and product labeling. The DOH clearance applies to the conduct of clinical research and does not constitute marketing authorization.

The Company has also submitted applications to the Department of Health – Abu Dhabi for its NEO100 clinical programs, including NEO100-01, NEO100-02, and NEO100-03, and is currently awaiting regulatory decisions. If approved, these programs would further expand NeOnc's clinical development footprint in the UAE and support the Company's strategy of advancing multiple brain cancer and neurological therapeutic programs in parallel across key international markets.

"This clearance represents an important international milestone for NeOnc and for the NEO212 program," said Amir Heshmatpour, Chief Executive Officer, Executive Chairman and President of NeOnc. "Brain cancers such as glioblastoma remain among the most difficult diseases in oncology, and patients urgently need new treatment options. We are grateful to the Department of Health – Abu Dhabi for its rigorous and collaborative review, and we look forward to working with investigators and healthcare institutions in the UAE as we advance NEO212 toward Phase 2 development."

Glioblastoma remains one of the deadliest forms of cancer, with limited treatment options and poor long-term survival outcomes. NEO212 is designed to combine the chemotherapeutic temozolomide with perillyl alcohol in a single orally administered conjugate intended to improve delivery across the blood-brain barrier. The Company expects to work with healthcare institutions, investigators, and regulatory authorities in the UAE as clinical development activities advance.

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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