NeOnc Technologies Receives FDA Authorization to Proceed with Phase II Clinical Trial of NEO212 – A First-in-Class Oral Chemical Conjugated Chemotherapy Candidate for Brain Cancer

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CALABASAS, Calif., Sept. 10, 2025 (GLOBE NEWSWIRE) -- NeOnc Technologies Holdings, Inc. (NASDAQ: NTHI) ("NeOnc" or the "Company"), a multi-Phase 2 clinical-stage biopharmaceutical company pioneering therapies for central nervous system (CNS) cancers, today announced that the U.S. Food and Drug Administration (FDA) has authorized the Company to proceed with Phase IIa/IIb of its NEO212-01 clinical trial.

The FDA's decision follows the successful completion of the Phase I dose-escalation study, which demonstrated that NEO212 could be safely administered at doses up to 810 mg daily on Days 1–5 of a 28-day cycle. Independent review of the recommended Phase II dose is ongoing, with patient enrollment expected to begin before the end of 2025.

A Next-Generation Standard of Care Candidate

NEO212 is NeOnc's first oral chemical conjugated chemotherapy drug, uniquely combining Temozolomide (TMZ) – the current standard of care for glioblastoma and other brain cancers (marketed as Temodar®) – with NEO100 (a proprietary form of perillyl alcohol (POH), which is owned and patented by NeOnc). This proprietary conjugation is designed to overcome the limitations of TMZ, including resistance and limited efficacy, by enhancing blood-brain barrier penetration and antitumor activity.

NeOnc believes NEO212 has the potential to replace TMZ as the future standard of care for all brain cancers, representing a transformative leap forward in therapeutic options for patients facing glioblastoma, astrocytoma, and other aggressive CNS malignancies.

Phase II Clinical Development Strategy

The NEO212-01 Phase II trial will expand patient enrollment across leading U.S. cancer centers, building on four currently approved and active trial sites:

- NextGen Oncology – Kumar Sankhala, MD
- Northwest Medical Specialties (NWMS) – Jorge Chaves, MD
- Oncology Physician's Network – Vu Phan, MD
- University of Southern California (USC) – Frances Chow, MD

In anticipation of expanded Phase II enrollment, NeOnc is preparing activation at a broad network of premier cancer institutions, including:

Baylor Scott & White • Beverly Hills Cancer Center • Cancer Specialists of North Florida • Cleveland Clinic • Duke University • Inova (Virginia) • New York University Langone • Providence St. John's • RecioMed (Florida) • Sutter Health • Tampa General Hospital • Vanderbilt University Medical Center • University of Texas Southwestern • University of California, San Francisco

Leadership Commentary

"Receiving FDA authorization to advance NEO212 into Phase II is a defining milestone for NeOnc Technologies," said Amir Heshmatpour, Executive Chairman and President of NeOnc Technologies Holdings, Inc. "This program represents years of innovation combining our proprietary molecule NEO100 with the current standard Temozolomide into a powerful conjugated therapy that we believe can redefine treatment outcomes for brain cancer patients. Our Phase II strategy will expand across the country's leading cancer centers and position NEO212 as the first real replacement for Temozolomide in decades."

Dr. Thomas Chen, Chief Executive Officer and Founder of NeOnc Technologies, added:
"From the beginning, our mission has been to give brain cancer patients and their families real hope where few options exist. NEO212 embodies that vision – it is science and compassion fused together. Moving into Phase II is not just a regulatory step forward; it is a step toward changing the future of brain cancer care worldwide."

About NeOnc Technologies Holdings, Inc.

NeOnc Technologies Holdings, Inc. (NASDAQ: NTHI) is a multi-Phase II clinical-stage biopharmaceutical company pioneering

novel therapies for central nervous system cancers and other hard-to-treat malignancies. The Company's portfolio includes NEO100 and NEO212, with proprietary intellectual property and clinical programs designed to deliver transformative outcomes for patients worldwide.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential of NEO212 to become the new standard of care for brain cancer, anticipated patient enrollment timelines, and future clinical trial sites. These statements involve risks and uncertainties that could cause actual results to differ materially, including but not limited to clinical development risks, regulatory review processes, patient enrollment variability, and financial resource availability. NeOnc undertakes no obligation to update any forward-looking statements contained herein.

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