NeOnc Receives FDA Written Feedback on NEO212 CMC Development and Capsule-to-Tablet Transition

July 15, 2026

FDA feedback provides detailed manufacturing and formulation requirements for continued late-stage development of NEO212

CALABASAS, Calif., July 15, 2026 (GLOBE NEWSWIRE) -- NeOnc Technologies Holdings, Inc. (NASDAQ: NTHI) ("NeOnc" or the "Company"), a clinical-stage life sciences company focused on the development of treatments for central nervous system cancers, today announced that it has received written feedback from the U.S. Food and Drug Administration ("FDA") regarding the chemistry, manufacturing and controls ("CMC") development program for NEO212, the Company's novel temozolomide-perillyl alcohol conjugate.

The written feedback was provided in advance of a Type B End-of-Phase 1 meeting scheduled for July 9, 2026. FDA's preliminary comments expressly provided NeOnc the option to cancel the meeting if the written responses were sufficiently clear, in which case the written responses would constitute the official record of the meeting. After reviewing the detailed responses, the Company determined that an additional meeting discussion was not required at this stage and canceled the July 9 meeting.

Key elements of the FDA's written feedback include:

- FDA stated that NeOnc's proposed approach to CMC development appears reasonable, while identifying additional comparative assessments that may be required if the drug-substance manufacturing process or physical characteristics change during development.
- FDA stated that the general drug-product development plan may proceed in parallel with the Company's planned late-stage clinical program, subject to the development and submission of appropriate supporting data.
- FDA indicated that a staged stability program supporting clinical development, followed by registration stability studies, is a commonly accepted approach.
- FDA advised that the transition from the current capsule formulation to a tablet formulation should be supported by an in vivo relative bioavailability study.
- FDA identified CMC work to be completed before representative tablet material is used in a confirmatory clinical phase, including finalization of the tablet formulation and manufacturing process, manufacture of at least one GMP batch, establishment of appropriate in-process controls, solid-state and particle-size characterization, and development of an appropriate dissolution method.

NeOnc is incorporating the FDA's feedback into its NEO212 development plan and is evaluating the associated study design, manufacturing activities, timelines and costs. The Company expects to provide an updated development plan after completing this assessment.

"The FDA's written feedback is detailed, constructive and actionable," said Amir Heshmatpour, Chief Executive Officer, Executive Chairman and President of NeOnc. "It provides greater clarity regarding the manufacturing, formulation and bioavailability work required to support the transition of NEO212 from the current capsule formulation to a tablet intended for late-stage clinical development. We are now integrating these requirements into a disciplined development plan and will continue working with the FDA as the program advances."

The FDA feedback relates principally to the CMC development of NEO212 and the capsule-to-tablet transition. The written responses do not constitute FDA approval of NEO212 or agreement on the design or adequacy of any future registrational clinical trial. Any future clinical study remains subject to applicable regulatory requirements and continued FDA review.

About NEO212
NEO212 is a novel covalently conjugated compound combining the chemotherapeutic agent temozolomide with perillyl alcohol. NeOnc is developing NEO212 as a potential treatment for malignant brain tumors and other central nervous system cancers.

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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