NRG ONCOLOGY

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TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: Protocol Development and Regulatory Compliance

DATE: December 10, 2020

RE: PROTOCOL NRG-HN008 – ACTIVATION

Phase I Trial with Expansion Cohort of DNA-PK Inhibition and IMRT in Cisplatin-Ineligible Patients with Stage 3-4 Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)

NCI Version: November 09, 2020

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Effective December 10, 2020, NRG-HN008 is open to patient entry.

The NCI Central Institutional Review Board (CIRB) has approved this protocol. The protocol, consent form, patient brochure, and patient history forms are located on the CTSU website. All other protocol related documents are available on the NRG Oncology website. Please note: This is a limited institution study, with current participation open to NRG Oncology sites.

Before registering patients on this trial, all sites must have CIRB approval. All IRB approvals must be submitted to the CTSU Regulatory Office via the Regulatory Submission Portal at www.ctsu.org (members' area) → Regulatory Tab → Regulatory Submission.

The peposertib (M3814) Investigator Brochure from PMB/NCI is available via the CTEP Online Agent Order Processing (OAOP) website (https://ctepcore.nci.nih.gov/OAOP/). Log-in using your CTEP IAM credentials, select the Investigator Brochures tab, and provide the requested information to access the IB.

Additional protocol-specific requirements are needed prior to patient enrollment:

- Letter of Intent

See Protocol Section 8 for all Registration and Study Entry Procedures.

- Patient enrollment for this study will be facilitated using the Slot Reservation System in conjunction with the registration system in OPEN. Prior to discussing protocol entry with the patient, all site staff must use the CTSU OPEN Slot Reservation System to ensure that a slot on the protocol is available to the patient. Once a slot reservation confirmation is obtained, site staff may then proceed to enroll the patient to this study.