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TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: NRG-DT001 Study Chair
Meng Welliver, MD, PhD

DATE: July 21, 2020

RE: PROTOCOL NRG-DT001 – Cohort A (dose level 3): Temporarily Closed to Accrual

Cohort A (Dose Level 3) Temporarily Closed to Accrual

Cohort A (extremity/body wall) of NRG-DT001, “A Phase Ib Trial of Neoadjuvant AMG 232 (KRT-232) Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma (STS),” is temporarily closed to accrual effectively immediately because 3 DLT-evaluable wild-type p53 patients have been enrolled, which is the maximum allowed per the protocol-specified design. A decision will be made on re-opening Dose Level 3 (Cohort A) to accrual or activating the dose-expansion cohort in mid-September once patients complete their DLT observation period.

Note: Cohort B (abdomen/pelvis/retroperitoneum) is still open to accrual to dose level 2. We encourage all investigators to consider this trial for eligible patients.

Please distribute this information to the appropriate personnel.