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TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: Protocol Development and Regulatory Compliance

DATE: February 8, 2021

RE: PROTOCOL NRG-GI007 – PROTOCOL AMENDMENTS 1 and 2

Phase I Trial With Expansion Cohort of OBP-301 (Telomelysin™) and Definitive Chemoradiation for Patients With Locally Advanced Esophageal and Gastroesophageal Adenocarcinoma Who Are Not Candidates for Surgery

NCI Version:
Amendment 1: December 7, 2020
Amendment 2: January 6, 2021

Study Chair: Geoffrey Ku, MD, 646-888-4588, kug@mskcc.org

The NCI Central Institutional Review Board (CIRB) has approved this protocol amendment. Protocol documents can be obtained from the CTSU website.

IRB Review Recommendation:

(X) Expedited review per 45 CFR 46.110 and 21 CFR 56.110

() Full board review

Sites must have Amendments 1 and 2 locally implemented within 30 days of notification (posting on the CTSU website). Sites that do not meet this timeline are not able to enroll patients.