



Advancing Research. Improving Lives.™

TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS
FROM: Protocol Development and Regulatory Compliance
DATE: June 29, 2020
RE: PROTOCOL NRG-GI007 – ACTIVATION

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: May 05, 2020

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

Effective June 29, 2020, NRG-GI007 is open to patient entry.

This is a limited-institution study, with participation open to the following pre-selected sites:

<u>Site</u>	<u>NCI Institution Code</u>
Memorial Sloan Kettering Cancer Center	NY016
Memorial Sloan Kettering Basking Ridge	NJ200
Memorial Sloan Kettering Monmouth	NJ299
Memorial Sloan Kettering Bergen	NJ301
Memorial Sloan Kettering Commack	NY351
Memorial Sloan Kettering Nassau	NY353
Memorial Sloan Kettering Westchester	NY478
Ohio State University Comprehensive Cancer Center	OH007
MD Anderson Cancer Center	TX035
Massachusetts General Hospital Cancer Center	MA034
Dana-Farber/Harvard Cancer Center	MA036
Moffitt Cancer Center	FL065

The NCI Central Institutional Review Board (CIRB) has approved this protocol. All protocol and related documents are available on the CTSU website.

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.ctsuo.org (members' area) → Regulatory Tab → Regulatory Submission.

The OBP-301 Investigator Brochure is available by submitting a *Request for Brochure* form to the CTSU. The form is located on the protocol-specific page on the NRG website.

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

- **Training for gastroenterologists who will perform the intra-tumoral injection of OBP-301 is required prior to registration.**
- **Institutional Biosafety Committee (IBC) review**

See the NRG Oncology website/Documents & Materials tab of the NRG-GI007 homepage for the gastroenterology training.

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

Please distribute this information to the appropriate personnel at participating affiliate institutions.