**Trial Results: ECOG-ACRIN to Conduct Randomized Phase 3 Trial Based on Recent Results of Phase 2 Study E3311**

The overall intent of E3311, which validated a less intense treatment for certain patients with human papillomavirus-positive (HPV+) throat cancer, was to gather essential data for the design of a future, randomized phase three trial. E3311 met its primary objectives, which were 1) to determine the feasibility of a prospective multi-institutional study of transoral robotic surgery (TORS) for HPV+ oropharynx cancer followed by risk-adjusted adjuvant therapy and 2) to assess the oncologic efficacy following transoral resection and adjuvant therapy in patients determined to be at “intermediate risk” after surgical excision. To evaluate the latter, the study team reviewed the two-year progression-free survival rate.

“For intermediate risk patients—those with uninvolved surgical margins, less than five involved nodes, and less than 1 mm extranodal extension—reduced-dose postoperative radiation therapy without chemotherapy appears sufficient ... this group had better outcomes than the group on usual high-dose radiation plus chemotherapy,” said lead investigator Dr. Robert Ferris (UPMC Hillman Cancer Center), who presented the results at the American Society of Clinical Oncology virtual annual meeting in May.

These findings confirmed the study's patient stratification identified low- and intermediate-risk patients well, preserving their throat function and sparing them unnecessary short- and long-term toxicities.

“ECOG-ACRIN now plans to pursue the current data with a randomized phase three trial of TORS-based treatment deintensification compared with conventional chemoradiation,” said ECOG-ACRIN Head and Neck Committee Chair, Dr. Barbara Burtness (Yale University).