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PRESS RELEASE

AIDS Malignancy Consortium Study # 045: Phase II Trial of Combined Modality Therapy plus Cetuximab in HIV-Associated Anal Carcinoma

Rockville, MD February 7, 2017: The results of the first prospective trial in patients with anal cancer associated with HIV infection was published on December 12, 2016 in the Journal of Clinical Oncology, one of the leading cancer journals. This study investigated the effectiveness and side effects of standard chemotherapy and radiation, plus another drug called cetuximab. Cetuximab is a biologic agent targeting “EGFR” (“epidermal growth factor receptor”) that is approved for the treatment of other cancers that are dependent on the “EGFR” pathway. Activation of “EGFR” stimulates growth of cancer cells, which may be blocked by cetuximab. We thought that cetuximab could also be effective in anal cancer because this cancer also depends partly on the “EGFR” pathway. Everyone enrolled on the study received cetuximab in addition to standard chemoradiotherapy. The study was designed and conducted in conjunction with another study testing the same regimen in patients without HIV infection that was coordinated by the ECOG-ACRIN Research Group, also published in the Journal of Clinical Oncology.

A total of 45 persons living with anal cancer and HIV were enrolled in the AMC045 study. The study showed that the combination of standard chemo and radiation plus cetuximab produced similar cancer remission rates as standard chemo and radiation, and that adding cetuximab resulted in added side effects (mainly diarrhea and skin rash). We cannot determine with certainty whether adding cetuximab improved clinical outcomes compared with chemotherapy alone, because study participants were not randomized to receive cetuximab or not to receive it. Nevertheless, a main conclusion of the study was that cancer remission rates from this regimen are similar for those who have anal cancer and HIV, compared with the same cancer in people without HIV.

Reference: Cetuximab Plus Chemoradiotherapy For HIV-Associated Anal Carcinoma: A Phase II AIDS Malignancy Consortium Trial”, published in the Journal of Clinical Oncology (Sparano, J. et al.) ([Pubmed Abstract](#))

For more information about HIV cancer malignancies, visit the AMC Web site at
<http://www.amcoperations.com>