Baseline serum protein levels associated with survival in axalimogene filolisbac (AXAL)-treated metastatic cervical cancer patients: The GOG/NRG-0265 trial

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INTRODUCTION

- Cervical cancer is the most common human papillomavirus (HPV)-associated cancer and the fourth most common cancer in women worldwide.1
- Axalimogene filolisbac (AXAL)-based immunotherapy that expresses and secretes the full length E7 protein of HPV 16 - was developed as a radiation-based immunotherapy for the treatment of survival concerning as well as of other HPV-associated cancers.
- Advancy based immunotherapies act by stimulating innate immunity through multiple mechanisms including the STING pathway, by reducing the frequencies and functions of immunosuppressive cells in the tumor microenvironment, and by generating the generation of tumor antigen-specific T cells that infiltrate and degrade tumor cells.

OBJECTIVE

- Evaluate the association between baseline inflammation-related serum protein levels and OS in AXAL-treated PmCC patients in order to identify candidate prognostic biomarker of clinical outcome.

MATERIALS AND METHODS

- The GOG/NRG-0265 trial is a phase 2 evaluation of AXAL in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix.5 The study design for the GOG/NRG-0265 is summarized in Figure 2.

RESULTS

- In the GOG/NRG-0265 trial, which evaluated the efficacy and safety of AXAL in the treatment of PmCC, AXAL demonstrated
  - a median overall survival of 6.2 months (Figure 3)
  - a 12-month OS rate of 38% (95% CI) (Figure 3).

SUMMARY AND CONCLUSIONS

- We have identified baseline levels of AAT, CRP, TIMP-1 and VEGF as candidate prognostic biomarkers of clinical outcome in PmCC patients.
- Prospective validation of the utility of the baseline levels of the 4 serum proteins as prognostic biomarkers of clinical outcome in PmCC patients is scheduled in the upcoming phase 3 ADVANCE trial, evaluating the safety and efficacy of the Lm-based immunotherapy ADXS-602 in combination with nivolumab compared with single-agent chemotherapy in PmCC patients who have failed or were ineligible to receive first-line therapy with or without radiation.
- Cluster 1 criteria may also identify PmCC patients most likely to benefit from AXAL treatment.

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DISCLOSURES