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Abstract CT129: Immunity induction with atezolizumab, EIK1001, and radiotherapy in virus-associated tumors: Results of the AGADIR Trial FREE

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Abstract

Background:

Virus-associated tumors, characterized by immune evasion and angiogenic signaling, remain a therapeutic challenge. Human papillomavirus (HPV)-associated cancers such as cervical, anal, and oropharyngeal cancers represent a significant subset of virus-associated tumors and are characterized by immune evasion mediated by viral oncoproteins such as E6 and E7. Toll-like receptor 7/8 (TLR7/8) agonists such as EIK1001 have been shown to activate innate immune pathways, enhancing antigen presentation and inducing a robust adaptive immune response. This is particularly relevant in HPV-related tumors, where viral oncoproteins E6 and E7 suppress immune surveillance. By targeting TLR7/8, EIK1001 may overcome this immune suppression, priming the tumor microenvironment for synergistic effects with immune checkpoint blockade. Additionally, stereotactic radiation therapy of a metastatic site can enhance immunotherapy efficacy by inducing immunogenic cell death, promoting the release of tumor antigens, and facilitating systemic immune activation (the abscopal effect).

Methods:

This phase II trial included 47 patients with metastatic virus-associated tumors across 10 sites between June 2021 and July 2023. Treatment comprised atezolizumab (1200 mg IV every 3 weeks), EIK1001 (0.75 mg/m^2 IV on a weekly schedule for 9 weeks, then every 3 weeks), and stereotactic radiotherapy (27-60 Gy in 3-5 fractions to a metastatic site). Primary endpoint was disease control rate (DCR) at 24 weeks per RECIST v1.1. at 24 weeks per RECIST v1.1. Secondary endpoints included objective response rate (ORR), progression-free survival (PFS),

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overall survival (OS), safety, and biomarkers of immune activation (proteomics and spatial transcriptomics).

Results:

Forty-one patients with virus-associated tumors were enrolled between June 2021 and July 2023. The majority (85%) had HPV-related tumors, including cervical (40%), anal (30%), and oropharyngeal (15%) cancers. At 24 weeks, the DCR was 56.1% (90% CI: 42.1%-69.4%), with an ORR of 19.5% (90% CI: 10.1%-32.5%). Median PFS was 2.6 months (95% CI: 1.4-2.8), and median OS was 10.4 months (95% CI: 6.9-19.0). The most common Grade 3/4 treatment-related adverse events were fatigue (10%), diarrhea (8%), and pneumonitis (5%). Proteomic analyses of plasma demonstrated significant upregulation of immune effector proteins, indicating systemic immune activation. Spatial transcriptomics on tumor biopsies revealed enhanced T-cell infiltration and reprogramming of the tumor microenvironment, correlating with clinical responses.

Conclusions:

The combination of atezolizumab, EIK1001, and radiotherapy met its primary endpoint of disease control rate at 24 weeks, underscoring the potential of this regimen. in virus-associated tumors, particularly HPV-related cancers. Biomarker analyses support the immunogenic potential of this regimen, suggesting a paradigm shift in treating immunologically ‘cold’ virus-associated tumors. Further investigations will explore predictive biomarkers and refine patient selection.

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