Advanced treatment line (ATL) with lenvatinib and everolimus (Len + Eve) for metastatic renal cell carcinoma (mRCC): Analysis of a national early access program (EAP)

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Background: VEGFR inhibition is a mainstay in the treatment of mRCC. In recent years third generation TKIs offer advantages in treatment efficacy while combinations further improve clinical activity. Treatment with Len + Eve is approved based on a randomized phase 2 study in the second line setting. Data on activity and efficacy of this combination as ATL beyond second line is limited. We aimed to report the activity of Len + Eve in mRCC patients (pts) treated per a national EAP.

Methods: Records from consecutive mRCC (pts) treated with Len + Eve in ATL per a national EAP in 7 centers, were retrospectively reviewed. We report the clinical benefit, progression free survival (PFS), overall survival (OS), and toxicity.

Results: Between 11/2016 – 12/2017, 39 mRCC pts were treated with Len + Eve. Median age 60 (39-82), male 72%. Majority of the pts (82%) underwent nephrectomy. Heng criteria in the context of IO-based regimens.

Conclusions: Len + Eve as ATL in mRCC may benefit patients beyond second line treatment, and is associated with responses similar to those seen in a clinical trial setting in the ATL setting, with manageable toxicity.

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