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Clinical Trials Corner: Another Approach to Treatment of Advanced Papillary Renal Cell Carcinoma

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Dear Readers,

The Clinical Trials Corner of *Kidney Cancer* highlights planned or ongoing high-impact studies in renal cell carcinoma (RCC). In this issue, we highlight the PAXIPEM trial, a Phase II study examining the combination of axitinib alone or in combination with pembrolizumab in patients with advanced Type 2 papillary RCC.

In the future, if you feel that you would like to draw attention to a specific trial, please feel free to email us at mbparikh@ucdavis.edu or kca@iospress.com.

Sincerely,

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Multicenter Phase II Study of Axitinib +/- Pembrolizumab in First Line Treatment of Patients with Locally Advanced or Metastatic Papillary Renal Cell Carcinoma (pRCC)

Status: Recruiting

Clinicaltrials.gov identifier: NCT05096390

Sponsor: Centre Leon Berard

Enrollment: 72

Rationale: The optimal treatment of advanced papillary RCC (PRCC), which constitutes <15% of all RCCs, remains in question. The Axipap Phase II study evaluated axitinib in patients with advanced papillary RCC, and demonstrated a 35.7% investigator assessed response rate in the Type 2 subgroup of PRCC. Pembrolizumab has also been studied in non-clear cell RCC patients, including those with papillary RCC. In PRCC patients, in a single-arm study of pembrolizumab, an objective response rate of 28% was observed. As such, this study seeks to examine whether the combination of pembrolizumab plus axitinib could improve outcomes in Type 2 PRCC patients.

Study Design: This randomized Phase II multicenter study enrolls patients with histologically proven Type 2 or mixed PRCC that is either locally advanced or metastatic. Patients must have adequate organ and hematologic function and good performance status. Participants cannot have received prior systemic therapy for RCC even in the adjuvant setting, and cannot have untreated brain metastases. Patients are randomized to receive either axitinib (5 mg orally twice daily) plus pembrolizumab (200 mg every 3 weeks intravenously) or axitinib (5 mg orally twice daily) until the time of disease progression or unacceptable toxicity. Axitinib dosing may be increased to up to 10 mg twice daily if patents tolerate.

Endpoints: The primary endpoint of this study is 6-month objective response rate (ORR), evaluating the efficacy of axitinib + pembrolizumab versus axitinib alone. The secondary outcomes include duration of response, best overall response, progression-free survival, overall survival and incidence of adverse events.

Comments: As mentioned in the previous issue of Clinical Trials Corner, defining optimal treatments for non-clear cell RCC histologic subtypes is challenging. The Phase II PAPMET study was a landmark trial in that it was the first randomized trial assessing targeted therapies in patients with PRCC, and in this study cabozantinib was found to have a longer progression free survival compared with sunitinib. However, axitinib was not one of the comparator arms in that study. While the Axipap Phase II study was a single-arm study of axitinib, the efficacy demonstrated in this study was encouraging, in particular in patients with Type 2 PRCC. Of note, the PAPMET2 study that is currently accruing in the United States of America enrolls patients with both Type 1 and 2 PRCC to receive either cabozantinib alone or in combination with atezolizumab. Thus, if both of these trials successfully accrue, there will be much more insight into the role of immune checkpoint inhibition, as well as the role of axitinib and cabozantinib, in patients with advanced PRCC.

CONFLICT OF INTEREST

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Consultant: AstraZeneca, Exelixis, Seagen, Oncocyte, Natera