A phase III study of atezolizumab (atezo) vs placebo as adjuvant therapy in renal cell carcinoma (RCC) patients (pts) at high risk of recurrence following resection (IMmotion010).

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- Abstract

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Background: Nephrectomy is the SOC in early RCC; however, the 5-y relapse rate is 30-40% in stage II or III pts, with tumor stage and grade correlating with survival and recurrence after surgery. Currently, there is a limited role for adjuvant therapy after nephrectomy in pts who have had complete tumor resection; observation is standard. In a Ph II first-line metastatic RCC study, treatment with single-agent atezo (anti–PD-L1) resulted in an ORR of 25%. Thus, IMmotion010, a Ph III, multicenter, randomized, placebo-controlled, double-blinded trial, will evaluate the efficacy and safety of atezo as adjuvant therapy in RCC pts who are at high risk of recurrence after resection (NCT03024996). **Methods:** Eligible RCC pts (clear cell or sarcomatoid histologies) will have undergone nephrectomy (radical or partial) and be at high risk of recurrence (T2 Grade 4, T3a Grade 3-4, T3b/c any Grade, T4 any Grade or TxN+ any Grade) or have had complete resection of limited metachronous/synchronous metastasis. Pts must show no residual disease or evidence of metastases by CT scan at enrollment. ECOG PS ≤ 1 and tumor specimens evaluable for PD-L1 will also be required. Pts will be randomized 1:1 to receive atezo 1200 mg IV q3w or placebo IV q3w for 16 cycles or 1 y; stratification will be by disease stage (T2/T3a vs T3b/c/T4/N+ vs metastasectomy), region (North America [excluding Mexico] vs rest of world) and PD-L1 status on tumor-infiltrating immune cells (IC; PD-L1 IC expression < 1% vs ≥ 1%). The primary endpoint is independent review facility (IRF)-assessed disease-free survival (DFS), defined as the time from randomization to the first documented recurrence event (local recurrence, new primary RCC, distant metastasis) or death. Secondary endpoints include OS, investigator-assessed DFS, IRF-assessed and investigator-assessed DFS in pts with ≥ 1% PD-L1 IC, disease-specific survival, distant metastasis-free survival and the 3-y rates of IRF-assessed DFS and investigator-assessed DFS. Safety and biomarkers will be evaluated. The planned analysis will occur when at least ≈ 65% of pts in the 2 populations have died. 664 pts will be enrolled at 150-200 sites worldwide. Clinical trial information: NCT03024996.