Evaluate Vantage

April 08, 2021

Keytruda’s latest kidney cancer win: adjuvant use

Jacob Plieth

If February’s positive readout of the Clear study gave Merck & Co’s Keytruda an important lead over its rivals in front-line kidney cancer, today’s apparent win in Keynote-564 could stretch the advantage further still. Keynote-564 was the first of several pivotal immunotherapy studies to read out in this cancer’s even earlier, adjuvant setting, a market currently untapped by anti-PD-(L)1 drugs. Adjuvant and neoadjuvant settings are becoming key battlegrounds for checkpoint-blocking drugs, but kidney cancer is somewhat under the radar. Nevertheless, all the big players are running phase 3 trials. Merck has said nothing about the magnitude of Keytruda’s disease-free survival win in Keynote-564, except that this is statistically and clinically significant; whether this endpoint is sufficient for approval rather than the gold standard of overall survival is up to regulators. However, bulls will note that DFS is a more robust measure than pathological complete response, the endpoint on which Merck tripped up when trying to extend Keytruda’s label to perioperative triple-negative breast cancer; that setting will require the company to wait until the Keynote-522 trial reads out for event-free survival.

Pivotal trials of anti-PD-(L)1 drugs in adjuvant renal cell carcinoma			
Study	**Drug(s)**	**Primary endpoint(s)**	**Result**
Keynote-564	Keytruda vs placebo	DFS	Said to be statistically significant & clinically meaningful for DFS
Immotion-010	Tecentriq vs placebo	DFS	Primary completion Jan 2022
Checkmate-914	Opdivo +/- Yervoy vs placebo	DFS	Primary completion Apr 2023
Rampart	Imfinzi +/- tremelimumab vs placebo	DFS & OS	Primary completion Jul 2024
Source: Mizuho & clinicaltrials.gov.			