KCCure Statement on Kidney Cancer Treatment Denial in Europe

July 30, 2018

On July 26, 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending against approval by the European Medicines Agency (EMA) of ipilimumab (Yervoy) combined with nivolumab (Opdivo) for the first line treatment of high and intermediate risk metastatic renal cell carcinoma (kidney cancer). The objection from CHMP is based on the failure of the trial sponsor to adequately show the contributory effects of ipilimumab over single agent use of nivolumab.

The question of single-agent versus combination therapy is relevant in kidney cancer today and we agree with CHMP that additional data showing the superiority of adding ipilimumab to nivolumab would benefit the field and broaden our understanding of how these agents work in kidney cancer. However, we don't believe this question alone is sufficient enough to justify denying kidney cancer patients access to a treatment that offers a significant survival advantage over the current standard of care.

The CHECKMATE 214 trial combining ipilimumab and nivolumab showed significant superiority for the combination over the current standard of care, sunitinib (Sutent). In the combination arm, 42% of patients with intermediate and poor risk features experienced significant shrinkage of their tumors with a 9% complete disappearance rate versus 27% and 1% on sunitinib. The median duration of response for sunitinib was 18 months but has not been reached yet for the immunotherapy arm. Importantly, the overall survival was significantly better for the immunotherapy arm with a 37% reduced chance of dying from kidney cancer. The median survival for sunitinib was 26 months but has not been reached yet for the immunotherapy arm.

The complete response rate of the combination arm in CHECKMATE 214 was among the highest complete response rates seen in a phase 3 trial for kidney cancer. We cannot stress enough the significance of being able to render a patient who has a high or intermediate risk of death from kidney cancer to being free of disease.

We agree with CHMP that data with single-agent nivolumab in the first-line setting would be important to determine the contribution of each of the components of the combination as first-line therapy for patients with advanced clear-cell RCC. However, the answer to this question won't change the outcome of the trial, which shows that the combination of the two drugs is markedly superior to any other available therapy in this setting at this time. Given the observed benefits and curative potential of this therapy we strongly advocate for approval or at the very least temporary approval while additional supportive clinical trial data are being generated.

This combination therapy is the most significant achievement in the field of kidney cancer in over a decade, providing a profound overall survival advantage for most and for some a curative result, at an acceptable toxicity level with improved quality of life over the previous standard of care therapies.

As an organization representing kidney cancer patients, physicians, and researchers around the globe, we implore EMA to grant access to this life-saving therapy for kidney cancer patients.

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