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Prospective real-world data confirm the tolerability of cabozantinib in patients with advanced renal cell carcinoma: Interim results of the Belgian REPLICA study

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Introduction & Objectives: Cabozantinib (Cabo) is a well-established agent in the treatment landscape of patients with advanced renal cell carcinoma (aRCC). Cabo monotherapy is approved in 1st line [only for patients with an intermediate or poor International Metastatic RCC Database Consortium (IMDC) risk classification] and following a prior treatment regimen including a vascular endothelial growth factor (VEGF)-directed targeted therapy. In addition, the combination of cabo and nivolumab (nivo) is indicated as 1st line treatment for aRCC patients, across all IMDC risk categories. The descriptive, prospective, and non-interventional REPLICA study assessed the safety & efficacy of Cabo across different treatment lines in a real-life Belgian setting.

Materials & Methods: REPLICA aims to include 150 aRCC patients treated with Cabo, alone or in combination. Here we report the interim safety data in the Cabo monotherapy (N=61) population (across the different treatment lines) and assessed its impact on patients' quality of life (QoL). The latter was measured using the National Comprehensive Cancer Network/Functional Assessment of Cancer Therapy Kidney Cancer Symptom Index – 19 (NFKSI-19).

Results: Patients receiving Cabo monotherapy across different treatment lines (n=61) had a median age of 69 years; 72% were male; 68.9% had metastatic disease (stage IV) at RCC diagnosis and 80.3% had a tumor with a clear-cell histology. Overall, 98.4% of patients experienced at least one treatment emergent adverse event (TEAE). Thirty-nine (63.9%), 15 (24.6%) and 9 (14.8%) patients experienced Grade 3, 4 and 5 TEAEs, respectively. In the phase III pivotal METEOR trial, the incidence of Grade ≥3 TEAEs was reported at 71.3%. In REPLICA, any TEAEs led to a Cabo mono dose reduction or interruption in 21.3% and 68.9% of patients, respectively. Any grade TEAEs warranted permanent Cabo discontinuation in 34.4% of patients, with a median time to discontinuation due to an AE of 19.8 months. The most common Cabo-related TEAEs were diarrhea (41%), a decreased appetite (36%), fatigue (33%) and nausea (23%), which is in line with the METEOR results. The mean NFKSI-19 total score slightly deteriorated over time among Cabo Mono patients. In terms of NFKSI-19 Disease-Related Symptoms – Physical, or Emotional Score, NFKSI-19 Function and Well-Being Subscale Score, no deterioration in QoL was observed.

Conclusions: The interim analysis safety data of the prospective REPLICA trial showed a similar AE profile as reported in the METEOR trial. Furthermore, Cabo monotherapy did not have a detrimental impact on the patients' QoL.