AIO-NZK-0118/ass: Cabozantinib in adult patients with advanced renal cell carcinoma following prior systemic check point inhibition therapy: a retrospective, non-interventional study (CaboCHECK)

AIO-assoziierte Studie

Studiennummer/-Code:	AIO-NZK-0118/ass - CaboCHECK	
Status:	Rekrutierung beendet	
Rekrutierungszeitraum:	Rekrutierungsstart: Q2 2019 Rekrutierungsende: Q1 2021	
Weitere Zentren:	Keine weiteren Zentren in Planung	
Zentren:	geplant: 25	initiiert: 25
Patienten:	geplant: 200	aktuell eingeschlossen: 56
Letzte Aktualisierung	18.10.2021	

APPLICANT/ COORDINATING INVESTIGATOR	Prof. Dr. med. Viktor Grünwald Universitätsklinikum Essen Innere Klinik (Tumorforschung) Hufelandstr. 55 45147 Essen
CONDITION	Advanced renal cell carcinoma (RCC)
OBJECTIVE(S)	Primary objective - To evaluate the safety of cabozantinib tablets in patients with advanced renal cell carcinoma (RCC) after pre-treatment with nivolumab or nivolumab plus ipilimumab Secondary objectives - To describe the efficency of cabozantinib tablets patients with advanced renal cell carcinoma (RCC) after pre-treatment with nivolumab or nivolumab plus ipilimumab.
INTERVENTION(S)	Cabozantinib after pre-treatment with nivolumab or nivolumab plus ipilimumab
KEY EXCLUSION CRITERIA	1. Patients who are unable to consent because they do not understand the nature, significance and implications of the observational trial, except for patients that already deceased at the time of inclusion and will be enrolled anonymously 2. Involvement in the planning and / or conduct of the study (applies to both Ipsen staff and/or staff of sponsor and study site)
KEY INCLUSION CRITERIA	1. Written informed consent and any locally-required authorization (EU Data Privacy Directive in the EU) obtained from the subject, except for patients that already deceased at the time of inclusion and will be enrolled anonymously, except for patients that already deceased at the time of inclusion and will be enrolled anonymously 2. Patients with advanced or metastatic renal cell carcinoma, including all subtypes 3. Age ≥ 18 years 4. Completion of treatment with nivolumab or nivolumab / ipilimumab combination therapy (any line of therapy) directly followed by cabozantinib treatment
OUTCOME(S)	Endpoints • Incidence of serious adverse events at least possibly related to cabozantinib treatment during cabozantinib treatment • Secondary safety endpoints are the number of dose reductions, dose interruptions and terminations of cabozantinib treatment due to adverse events.

	Secondary effectiveness endpoints are objective response rate, clinical benefit rate, duration of response, duration of cabozantinib treatment, and time to next treatment.
STUDY TYPE	Retrospective non-interventional study
STATISTICAL ANALYSIS	The sample size has been set to 200 patients, treated with cabozantinib between June 2015 and today, based on feasibility considerations. This sample size will be sufficient to detect an adverse effect occurring with a true frequency of 2.3% at least once with a probability of 99%. On the other hand, the power to detect an adverse effect with a true incidence rate of 1% would be >80%. This implies that the proposed retrospective analysis will be able to provide important safety information, and a valuable addition to the global cabozantinib safety data base. Appropriate descriptive methods will be applied for all data analyses. If appropriate and unless otherwise specified, 2-sided 95% confidence interval (CIs) will be displayed and if p-values are presented, they will be for exploratory purposes only. Descriptive statistics will include number of available data, number of missing data and the following: - Mean, standard deviation (SD), minimum, interquartile range (0.25, 0.75), median, maximum when appropriate for continuous variables; - Frequency count and percentage for categorical nominal variables; - Both the above for categorical ordinal variables. - Missing data will not be replaced.
SAMPLE SIZE	N=200
TRIAL DURATION	18 months
PARTICIPATING CENTERS	25 sites planned
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