Object: EUDRACT 2017-001963-19 (CABOPEN) _ prematurely ended trial

Principal Investigator: A. Necchi

The primary objective of the CABOPEN study was to evaluate the antitumor activity of Cabozantinib monotherapy until surgical removal of nodal disease (locally-advanced setting) or until disease progression or onset of unacceptable toxicity (metastatic setting).

The study is planned according to Simon's Optimal two-stage design, with H1¼20% and H0¼5%, and type I and type II error rates set at the 10% level. In stage 1, 12 evaluable pts will be accrued. If 1 pt at least will be responding, enrolment will be extended to the 2nd stage for further 25 pts. If, out of the total of 37 pts, 4 at least will be responding, treatment will be declared worthy for further investigations. Stopping rules based on the Bayesian posterior probability (PP) to demonstrate that the ORR exceeded 20% are set

From May 2018 to December 2020, 2 patients were treated. we have decided to stop enrollment of participants early since the accrual established was not reached due to difficulty in finding patients who met the requirements of the study.

.Hence, according to study design, accrual was stopped. None data was published.

Prof. Filippo de Braud

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