Object: EUDRACT 2016-001688-35 (APACHE) prematurely ended trial

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The primary objective of the APCAHE study was to evaluate the antitumor activity of Durvalumab plus tremelimumab in patients affected by meta astati germ cell tumors.

APACHE (NCT03081923) is an open-label randomized phase 2 study. Patients were randomized 1:1 to receive 1500 mg of durvalumab intravenously (arm A) or 1500 mg of durvalumab plus 75 mg of tremelimumab intravenously (arm B) for four cycles followed by durvalumab alone. Treatment was administered every 4 wk in both study arms until disease progression (PD), unacceptable toxicity onset, or a maximum of 12 mo was achieved.

The primary endpoint was the objective response rate (according to Response Evaluation Criteria in Solid Tumor [RECIST] version 1.1). The total sample size was divided into a three-stage design. In stage 1, each arm is terminated if no responses are observed in 11 patients

From February 2017 to July 2019, 33 patients were randomized at a single center (11 arm A and 20 in arm B)). The median follow-up. was 7.5 mo. No grade 3–4 adverse events occurred in either arm. All patients but two experienced progression diesease. On the basis of these results, fisrt the monotherapy arm of the APACHE study has been closed to accrual and than even the arm B.

Hence, according to study design, accrual was stopped. Partial data of APACHE study have been published in Eur Urol. 2019 Jan;75(1):201-203. doi: 10.1016/j.eururo.2018.09.010. Epub 2018 Sep 19.

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