880P Subgroups analysis and circulating biomarkers evaluation of RESORT trial: A randomized phase II study in metastatic renal cell carcinoma (mRCC) patients (pts) to evaluate the efficacy of sorafenib after metastasectomy

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Background: RESORT trial (NCT01444807) was the largest prospective study whose aim was to assess the role of VEGF inhibition in mRCC pts after radical metastasectomy. It showed that sorafenib (SO) was safe and feasible but did not affect Relapse-Free Survival (RFS) compared to observation (OBS) in this population. Early identification of dynamic predictors of outcome, such as Circulating Tumor cells (CTCs) may be helpful to move up clinical tumor relapse.

Methods: Pts were randomized (1:1) within 12 weeks from surgery to receive SO or OBS for a maximum of 52 weeks or until disease recurrence, with stratification according to time from nephrectomy to metastases (more or less than 12 months), site of disease (lung vs others) and number of lesions (single vs multiple). Blood samples for CTCs were performed at baseline, month 6, end of treatment and at disease relapse. Peripheral blood samples (5 mL) were processed with the AdnaTest Prostate Cancer Select kit for CTC enrichment. CTCs identification was based on expression levels of EPCAM, MUC1 and ERBB2 measured by RT-multiplex PCR (Breast Cancer Detect Adna Test kit) using cutoffs defined on purpose based on expression in healthy donors.

Results: From November 2012 to November 2017, 76 pts were enrolled (32 in SO and 36 in Obs arm); 6 were screening failure and 2 pts never started treatment. A total of 55 pts had single metastasis resected, 26 in SO arm and 29 in OBS arm; the remaining 13 pts had multiple lesions, 6 in SO arm and 7 in OBS arm. Pts with single mets showed a longer median RFS in comparison to pts with multiple resected mets (39 vs 29 months), irrespective of the arm. Pts with single mets had an improved RFS when received SO compared to pts in the OBS arm (39 vs 20 months). A positive CTCs status was observed at baseline in 31% of pts in both arms and was not associated with RFS. Similarly, no associations were observed between CTCs status switches during SO or Obs and RFS.

Conclusions: Patients with single metastasectomy had better prognosis compared to pts with multiple lesions; SO improved RFS in this group of pts. CTC status and its changes during treatment were not associated with RFS.

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