EVALUATION OF SAFETY, TOLERABILITY AND ACTIVITY OF TEMSIROLIMUS IN PATIENTS (PTS) WITH ADVANCED OR METASTATIC RENAL CELL CARCINOMA (A/MRCC) IN ROUTINE CLINICAL PRACTICE

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Aim: Temsirolimus (TEM), an i.v. mTOR inhibitor, is approved in the EU for the first-line treatment of pts with a/mRCC who have at least 3 of 6 prognostic risk factors. A pivotal study demonstrated significantly increased overall survival with TEM in poor risk pts compared to the former standard Interferon (10.9 vs. 7.3 mo; p = 0.0078). To evaluate the safety profile and efficacy of TEM in a clinical routine setting, collection of data in a post-approval non-interventional trial is useful.

Methods: A German multicenter registry for a/mRCC pts treated with TEM was started in Jan 2008 (NCT00700258). Objectives are evaluation of safety, tolerability and anti-tumor activity of TEM, pts profile, and sequence of systemic therapies. Inclusion criteria are histologically confirmed a/mRCC treated with TEM and written informed consent.

Results: From Feb 2008 to Feb 2014, 169 study centers recruited 496 pts: 68.9% male, median age 68.7 years, median Karnofsky index 80%. Histological subtype: 74.8% clear cell, 12.1% papillary, and 2.2% chromophobe RCC. 158 pts were evaluable with regard to modified MSKCC criteria. 80.4% of these pts were classified as poor risk. All adverse and serious adverse events were observed in 72.2 % and 42.3 % of the pts (drug related in 41.3 % and 9.5% of the pts), respectively (n = 496). Most common drug-related toxicities (incidence ≥ 3%) of any grade were fatigue (7.3 %), rash (5.4 %), pruritus (5.4 %), nausea (4.0 %), diarrhoea (4.0 %), stomatitis (4.0 %), mucosal inflammation (3.8 %), anemia (7.5 %), thrombocytopenia (4.0 %) and peripheral oedema (3.6 %). Median progression-free survival for total patient population was 4.4 mo, for the subgroup of 1st line pts (n = 202) 4.2 mo, and for pts ≥ 65 yrs (n = 308) 4.5 mo. Median overall survival for all pts was 10.3 mo.

Conclusions: The population in our registry is consistent with the expected pattern of pts with a/mRCC regarding distribution of age, sex, and histology. Safety profile and clinical efficacy of TEM in routine clinical practice confirm current phase III data. Besides, safety and clinical efficacy of TEM for pts ≥ 65 years are comparable to the results for the overall study population.

Disclosure: M. Woike: Employee of Pfizer Pharma GmbH, Germany; L. Bergmann: Advisory Board, Honoraria: Pfizer Pharma GmbH; T. Steiner, P.J. Goebell and E. Herrmann: Advisory Board, Honoraria: Pfizer Pharma GmbH; U. Rebmann: Employee of Pfizer Pharma GmbH, Germany. All other authors have declared no conflicts of interest.