SAKK 35/15: a phase 1 trial of obinutuzumab in combination with venetoclax in patients with previously untreated follicular lymphoma

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Pretreatment Evaluation and Safety Assessments

Pretreatment evaluation consisted of a complete medical history, physical examination, vital signs, ECG, blood sample for complete bloud count (CBC) (i.e., hemoglobin, white bloud cells count (WBC) count with differential, platelet count), serum biochemistry analysis (alkaline phosphatase, total bilirubin, AST, ALT, calcium, phosphate, potassium, sodium, uric acid, lactate dehydrogenase, creatinine, ß2 microglobulin), IgA, IgG, IgM, PT/INR and PTT, serology (HBsAg, HBcAb, anti-HCV, HIV) serum pregnancy test and baseline tumor measurements (CT or PET/CT or total body MRI). The diagnosis of FL had to be confirmed by histology within 6 months from study entry. A bone marrow biopsy was requested at baseline unless it was performed within 6 months before study entry.

Safety assessments during cycle 1 were as follows: On cycle 1 before each obinutuzumab infusion (days 1, 8 and 15), evaluation consisted of a brief history and physical examination, vital signs, blood samples for CBC and serum biochemistry (alkaline phosphatase, AST, ALT, bilirubin, creatinine, lactate dehydrogenase, sodium, potassium, calcium, magnesium, phosphate, uric acid). Due to the risk of TLS associated with venetoclax, additional safety laboratory tests (including serum creatinine, lactate dehydrogenase, sodium, potassium, calcium, magnesium, phosphate, uric acid) were performed on day 2 before, 8, 12 and 24 hours after the first administration of venetoclax.
During cycles 2-6 assessments were performed on day 1 (brief history and physical examination, vital signs, blood samples for CBC, alkaline phosphatase, AST, ALT, bilirubin, creatinine, lactate dehydrogenase, sodium, potassium, calcium, magnesium, phosphorus, uric acid) and on day 15 (brief history and physical examination, vital signs, blood samples for CBC, alkaline phosphatase, AST, ALT, bilirubin, creatinine, lactate dehydrogenase). On day 15 of cycle 6 patients had an ECG and IgA, IgG and IgM levels were determined. For patients on maintenance therapy with obinutuzumab assessments were performed every two months, before each obinutuzumab infusion and included brief history and physical examination, vital signs, blood samples for CBC, alkaline phosphatase, AST,

ALT, bilirubin, creatinine, lactate dehydrogenase. Levels of IgG, IgA and IgM were tested every 6 months during maintenance.