Kantonsspital St.Gallen

An open-label Phase 1/2a study of BAL101553 adminis-tered as 48-hour intravenous infusions in adult patients with advanced solid tumors

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The primary objectives of this study are to determine the maximum tolerated dose (MTD) and to characterize dose-limiting toxicities (DLTs) of BAL101553, administered as an intravenous (IV) infusion over 48 hours on study Days 1, 8 and 15 of a 28-day treatment cycle, to adults with ad-vanced or recurrent solid tumors who have failed standard therapy or for whom no effective standard therapy is avail-able. Secondary objectives: To evaluate the safety and tolerabil-ity of BAL101553 administered as a 48-hour continuous IV infusion. To assess the anti-tumor activity of BAL101553 adminis-tered as a 48-hour continuous IV infusion. To assess the bioavailability of daily oral BAL101553 when administered on study Days 15–21 of Cycle 2. Exploratory objectives: To assess the use of biomarkers to characterize the phar-macodynamic effects of BAL101553,administered as a 48-hour continuous IV infusion. To explore the potential utility of biomarkers in blood and/or tumor tissue as predictive biomarkers.

type of project	clinical studies
status	ongoing - recruiting phase
start of project	2016
end of project	2018
study design	Phase I / II
Swissmedic notification number	2016DR2100
responsible person	PD Dr. med. Markus Jörger