Kantonsspital Graubünden

Phase 1

Protocol Title	Diagnosis	Eligibility	Study Design
SAKK 65/16 **TLD-1, a novel Liposomal Doxorubicin, in patients with Advanced Solid Tumors; a multicenter open-label single arm phase I (First in Human) trial.** PI: Dr. Sara Bastian CRC: Eun Joo Beers	Only for advanced malignant tumors of breast, ovary, uterine and sarcoma.	**Inclusion:** Histologically or cytologically confirmed advanced malignant tumors of the **breast**, **ovary**, **uterine** or **sarcoma** who failed standard therapy or whom no effective standard therapy is available. Patient may have received up to 3 prior lines of palliative systemic chemotherapy. **Exclusion:** Prior systemic chemotherapy/ treatment for metastatic disease, radiotherapy, immunotherapy or investigational agents within 28 days before registration. Significant cardiac disease or abnormality.	**Arm A:** Q4w Cycle 1: TLD-1, Cycle 2: Caelyx Q3w, Cycle 3- 6 (9): TLD-1 **Arm B:** Q4w Cycle 1: Caelyx Cycle 2: TLD-1 Q3w Cycle 3- 6 (9): TLD-1 Treatment consists of maximal 6 or 9 cycles (depending on previous anthracycline therapies).
SAKK 66/17 **Intratumoral N-Dihydrogalactochitosan (IP-001) injection following intratumoral thermal ablation in patients with advanced solid tumors.** **A multicenter Phase Ib/IIa trial with expansion cohorts in melanoma and soft tissue sarcoma patients**	advanced solid tumors. A multicenter Phase Ib/IIa trial with **expansion cohorts in melanoma and soft tissue sarcoma patients**	**Inclusion:** **Part 2 - Melanoma expansion cohort**, **Part 2 - Sarcoma expansion cohort**: • Presence of at least one tumor lesion that is laser-accessible, with a minimum size of 1.0 cm and located (typically subcutaneously) that it can be treated with Ablation + IP-001 without risk of skin necrosis or serious damage to other adjacent vital and healthy tissue. This tumor lesion may either belong to the skin, lymph nodes, muscles or subcutaneous tissue. • Measurable or evaluable disease, determined with the most suitable imaging method (CT, PET-CT or MRI), according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 • No evidence of CNS progression for at least 4 weeks **Exclusion:** • Patients who have received chemotherapy, RT, immunotherapy, within 21 days (7 days for single	Intratumoral N-Dihydro-galactochitosan (IP-001) injection following intratumoral thermal ablation

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SAKK 66/17 PI: Dr. Michael Mark CRC: Alexandra Jori		fraction of palliative radiotherapy, 42 days for nitrosoureas or mitomycin C) prior to registration. • Patients who have not recovered to ≤ CTCAE grade 1 from all side effects of prior therapies • Oral anti-coagulation with vitamin K antagonists Severe or uncontrolled cardiovascular disease • Known allergic reaction to shellfish, crabs, crustaceans	
SAKK 67/20 **Open-label dose escalation phase 1b trial of a new micellar docetaxel compound in patients with metastatic castration-resistant prostate cancer** PI: PD Dr. Richard Cathomas CRC: Stefania Merlo	Metastatic castration-resistant prostate cancer (mCRPC)	**Inclusion:** -Histologically confirmed adenocarcinoma of the prostate, metastatic castration resistant, progressive disease as defined as per PCWG3 criteria. -Medical or surgical castration -Willingness to have a central venous line inserted (PICC or PAC) if not already present -ECOG 0-1 **Exclusion:** -Prior chemotherapy for the treatment of prostate cancer (previous administration of chemotherapy concomitant with ADT is not allowed) -Prior systemic treatment, immunotherapy, hormonal therapy (with exception of GnRH agonists or antagonists) or investigational agents within 21 days before registration (palliative radiotherapy within 2 weeks) -Prior use of taxane-based chemotherapy for any other pervious cancer -Peripheral neuropathy > CTCAE grade 1	Docetaxel micellar (new formula!) intravenous on day 1 of every cycle. 1 cycle= 21 days Treatment consists of maximal 10 cycles. Docetaxel micellar infusion is given **without steroid pre- or post-medication for all cycles except cycle 2**. The visits will take place weekly during the first 2 cycles, and on day 1 of each cycle thereafter.

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		-Localized or general edeme > CTCAE grade 1	
MK1088 - 002 **A Phase 1/Phase 2 Study to Evaluate the Safety and Tolerability of MK-1088 as Monotherapy and in Combination with Pembrolizumab in Participants with Advanced Solid Tumors** **Initierung am 3.6.22** **Slot Reservierung !**	Histologically- or cytologically-confirmed diagnosis of advanced/metastatic solid tumor or metastatic castrate-resistant prostate cancer (mCRPC)	**In:** The participant must have a histologically- or cytologically-confirmed diagnosis ofadvanced/metastatic **solid tumor** by pathology report and have received, have beenintolerant to, or have been ineligible for treatment known to confer clinical benefit. -ECOG 0-1 **Prostata:** Must have previously received docetaxel, prior treatment with one otherchemotherapy is allowed as well as up to 2 second-generation hormonalmanipulations. - Have prostate cancer progression within 6 months prior to screening, asdetermined by the investigator, by means of one of the following:a. PSA progression using local laboratory values as defined by a minimum of 2 rising PSA levels with an interval of ≥1 week between each assessment where the PSA value at screening should be ≥2 ng/mL. Excl: Has had chemotherapy, definitive radiation, or biological cancer therapy within 4 weeks (2 weeks for palliative radiation) before the first dose of study intervention, or has notrecovered to CTCAE Grade 1 or better from any AEs that were due to cancer therapeutics administered more than 4 weeks earlier (this includes participants with previous immunomodulatory therapy with residual immune-related AEs). .	Part 1 Arm 1: MK 1088 Monotherapy (Dose escalation) Part 1 Arm 2: MK 1088 in Combination with Pembrolizumab