Open clinical trials KSGR Oncology

Breast				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
neoadjuvant	**AXSANA EUBREAST 3**	AXillary Surgery After NeoAdjuvant Treatment. A prospective multicenter cohort study to evaluate different surgical methods of axillary staging (sentinel lymph node biopsy, targeted axillary dissection, axillary dissection) in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy	• Primary invasive breast cancer cN+	PI: Peter Fehr peter.fehr@ksgr.ch CRC: Cornelia Fluri cornelia.fluri@ksgr.ch
neoadjuvant	**VISION 1**	Intelligent vacuum assisted biopsy immediately before surgery as an intra- or pre-operative surrogate for patient response to neoadjuvant chemotherapy for breast cancer (A multicenter prospective feasibility trial)	• Unifocal, histologically confirmd invasive breast Cancer with ICH luminal B • cT1c to cT2, any N, M0 • Neoadjuvant Chemotherapy resulting in a radiological complete response or near complete response by imaging	PI: Martina Maranta martina.maranta@ksgr.ch CRC: Romina Bottoni romina.bottoni@ksgr.ch CRC: Maya Bonderer maya.bonderer@ksgr.ch
neoadjuvant/ adjuvant	**TAXIS**	Tailored axillary surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer. A multicenter randomized Phase 3 trial	• Breast cancer, node positive detected by palpation or imaging (with or without planned neoadjuvant treatment) • M0 • N1, N2a, N3a, N3b	PI: Peter Fehr peter.fehr@ksgr.ch CRC: Romina Bottoni romina.bottoni@ksgr.ch CRC: Maya Bonderer maya.bonderer@ksgr.ch
adjuvant	**CAMBRIA-2**	A phase 3, open-label, randomised study to assess the efficacy and safety of Camizestrant (AZD9833, a next-generation, oral selective estrogen receptor degrader) versus standard endocrine therapy (Aromatase Inhibitor or Tamoxifen) as adjuvant treatment	• ER+/HER2- early breast cancer with intermediate or high risk of recurrence, who have completed definitve locoregional therapy and have no evidence of disease (Definition of intermediate or high risk according to the protocol)	PI: Ursula Hasler-Strub ursula.hasler-strub@ksgr.ch CRC: Alexandra Jori alexandra.jori@ksgr.ch

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Breast				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
adjuvant	**MK2870-012**	A phase 3, randomized, open-label, study to compare the efficacy and safety of adjuvant MK-2870 in combination with pembrolizumab versus treatment of physician's choice (TPC) in participants with triple-negative breast cancer who received neoadjuvant therapy and did not achieve a pathological complete response at surgery	• Had neoadjuvant treatment based on the KEYNOTE-522 regimen (pembrolizumab with carboplatin/ taxanes and pembrolizumab with anthracycline-based chemotherapy) followed by surgery. Completed at least 5 doses of neoadjuvant pembrolizumab and chemotherapy, including at least one dose of anthracycline • Has non-pathologic complete response at surgery. pCR is defined as ypT0/Tis ypN0	PI: Michael Schwitter michael.schwitter@ksgr.ch CRC: Alexandra Jori alexandra.jori@ksgr.ch

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CNS				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
postoperativ	**Gluglio**	A **Phase 1b/2** randomized open-label drug repurposing trial of glutamate signaling inhibitors in combination with chemoradiotherapy in patients with newly diagnosed glioblastoma	• Newly diagnosed supratentorial glioblastoma according to the 2021 (WHO) Classification of CNS TumorTumor • Ability to judge per local investigator estimate (at least oriented to time, place and situation) • Paraffin-embedded tissue for central pathology review	PI: Annalea Patzen annalea.patzen1@ksgr.ch CRC: Daniela Denoth daniela.denoth@ksgr.ch

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Colorectal				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**

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Gastrointestinal				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
neoadjuvant/ adjuvant	**DANTE/FLOT 8**	A randomized, open-label Phase 2/3 efficacy and safety study of atezolizumab in combination with FLOT versus FLOT alone in patients with gastric cancer and adenocarcinoma of the oesophago-gastric junction and high immune responsiveness	• Diagnosed with histologically confirmed adenocarcinoma of the GEJ (Type I-III) or the stomach (cT2, cT3, cT4, any N category, M0), or (any T, N+, M0) that: • a. is not infiltrating any adjacent organs or structures by CT or MRI evaluation b. does not involve peritoneal carcinomatosis c. is considered medically and technically resectable • Assessment of MSI and PD-L1 [and optional TMB/EBV] must be performed locally and results for either of the following MSI-high, PD-L1 CPS≥1, TMB ≥10/MB or EBV+	PI: Sara Bastian sara.bastian@ksgr.ch CRC: Franziska Hellmann franziska.hellmann@ksgr.ch
metastatic 1L	**MK 3475-006 C**	A **Phase 1/2** open-label, umbrella platform design study of MK-2870 with Pembrolizumab (MK-3475) and chemotherapy in participants with first-line locally advanced, unresectable/ metastatic gastroesophageal adeno-carcinoma	• Has histologically and /or cytologically confirmed diagnosis of previously untreated locally advanced unresectable or metastatic 1L gastroesophageal adenocarcinoma (gastric adenocarcinoma, gastroesophageal junction adenocarcinoma, or esophageal adenocarcinoma) • Has gastroesophageal adenocarcinoma that is not HER2/neu positiv	PI: Sara Bastian sara.bastian@ksgr.ch CRC: Franziska Hellmann franziska.hellmann@ksgr.ch
metastatic 2L	**MK 3475-06 B**	A **Phase 1/2** open-label, umbrella platform design study of investigational agents with Pembrolizumab (MK-3475) in participants with advanced esophageal squamous cancer previously exposed to PD-1/PD-L1 treatment	• Histologically or cytologically confirmed diagnosis of locally advanced unresectable metastatic esophageal squamous cell carcinoma • Documented radiographic or clinical disease progression on one prior line of standard therapy that includes a platinum agent and previous exposure to an anti–PD-1/PD-L1 based IO therapy	PI: Sara Bastian sara.bastian@ksgr.ch CRC: Franziska Hellmann franziska.hellmann@ksgr.ch

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Gastrointestinal				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
metastastic 2L	**MK 3475-006 D**	A **Phase 1/2** open-label, umbrella platform design study to evaluate the safety and efficacy of MK-2870 plus Paclitaxel as the second-line treatment of participants with advanced/ metastatic gastroesophageal adenocarcinoma	• Has histologically and/or cytologically confirmed diagnosis of previously treated, 2L (received 1L treatment) gastric adenocarcinoma, GEJ adenocarcinoma, or esophageal adenocarcinoma • Has gastroesophageal adenocarcinoma that is not HER2/neu positive • has received at least one dose of platinum and fluoropyrimidine therapy with or without immunotherapy	PI: Sara Bastian sara.bastian@ksgr.ch CRC: Franziska Hellmann franziska.hellmann@ksgr.ch

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Gynecological				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
adjuvant	**Matao**	Maintenance Therapy with Aromatase inhibitor in epithelial Ovarian cancer: a randomized double-blinded placebo-controlled multi-center Phase 3 Trial	• Primary,newly diagnosed FIGO Stage II to IV, histologically confirmed low or high grade serous or endometrioid epithelial ovarian/fallopian tube / peritoneal cancer • (Interval) debulking performed • Positivity(≥1%) for ER expression	PI: Michael Schwitter michael.schwitter@ksgr.ch CRC: Gillian Roberts gillian.roberts@ksgr.ch
metastatic 2L+	**MK-2870-005**	A Phase 3, randomized, active-controlled, open-label, multicenter study to compare the efficacy and safety of MK-2870 monotherapy versus treatment of physician's choice in participants with endometrial cancer who have received prior platinum-based chemotherapy and immunotherapy.	• Histologically-confirmed diagnosis of endometrial carcinoma or carcinosarcoma • Radiographically evaluable disease, either measurable or non-measurable per RECIST 1.1, as assessed by BICR • Has received prior systemic, platinum-based chemotherapy and anti-PD-1/anti-PD-L1 therapy (up to 3 prior lines)	PI: Ursula Hasler-Strub ursula.hasler-strub@ksgr.ch CRC: Anita Marti anita.marti@ksgr.ch
-	**OvCar**	A retrospektive and prospektive registry of patients with ovarian cancer	• Signed general consent, or signed patient informed consen (prospective) • FIGO stage I-IV ovarian cancer with sufficent data collection from KIS	PI: Ursula Hasler-Strub ursula.hasler-strub@ksgr.ch CRC: Gabriela Manetsch gabriela.manetsch@ksgr.ch

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Haematology				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
diagnostic prospective	**SAKK 38/23**	LIBERTY: Liquid biopsy to diagnose and monitor central nervous system (CNS) involvement in high-risk B cell non-Hodgkin lymphoma	• Newly diagnosed histologically confirmed lymphomas: DLBCL (special characteristics), High-grade B-cell lymphoma, Burkitt lymphoma, Mantle cell lymphoma, Primary CNS lymphoma	PI: Ulrich Mey ulrich.mey@ksgr.ch CRC: Stephanie Bossi stephanie.bossi@ksgr.ch
2L +	**CC-220-MM-002 relapsed or refractory multiple myeloma**	A Phase 3, randomized, multicenter, Open-label Study comparing Iberdomide, Daratumaband Dexamethasone (IberDd) versus Daratumab, Bortezomib, and Dexamethason (DVd) in Subjects with relapsed or Refractory Multiple Myeloma (RRMM)	• 1 to 3 prior anti-myeloma regimens • M-protein quantities 1 g/dL by serum protein electrophoresis (sPEP) or ≥ 200 mg/24-hour urine and /or • Light chain MM without measurable disease in serum or urine: serum-free light chain (FLC) levels > 100 mg/L (10 mg/dL) involved light chain and an abnormal kappa/lambda FLC ratio	PI: Ulrich Mey ulrich.mey@ksgr.ch CRC: Franziska Hellmann franziska.hellmann@ksgr.ch
-	**EMCL registry**	The registery of the European Mantle Cell Lymphoma study group	• Age ≥ 18 years • Known diagnosis of MCL	PI: Ulrich Mey ulrich.mey@ksgr.ch CRC: Stephanie Bossi stephanie.bossi@ksgr.ch

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Lung				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
neoadjuvant/ adjuvant	**MK-2870-019**	A Phase 3 Randomized Open-Label Study of Adjuvant Pembrolizumab With or Without MK-2870 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy Followed by Surgery	• Has histological confirmation of squamous or nonsquamous NSCLC, resectable clinical Stage II, IIIA or IIIB (with nodal involvement [N2]) • Confirmation that *EGFR*-directed therapy is not indicated as primary therapy • Able to undergo surgery and able to receive neoadjuvant pembrolizumab and platinum-based doublet chemotherapy	PI: Michael Mark michael.mark@ksgr.ch CRC: Stephanie Bossi stephanie.bossi@ksgr.ch
perioperativ	**SAKK 16/18**	Immune-modulatory radiotherapy to enhance the effects of neoadjuvant PD-L1 blockade after neoadjuvant chemotherapy in patients with resectable stage III (N2) non-small cell lung cancer (NSCLC). A multicenter Phase 2 trial	• Histologically confirmed NSCLC (adeno, squamous, large cell carcinoma or not otherwise specified (NOS)). • Tumor stage T1-4>7 N2 M0 (i.e. T1-3 N2 or T4 N2 but T4 only allowed if due to size >7cm according to TNM calssification 8th edition • Tumor is considered resectable (complete resection according to Rami-Porta).	PI: Michael Mark michael.mark@ksgr.ch CRC: Anita Marti anita.marti@ksgr.ch
oligo-metastatic	**salVage**	A Phase 3 randomized controlled trial comparing maintenance systemic therapie alone with systemic therapy plus local ablative treatment for patients with advanced stage IV non-small cell lung cancer	• Tissue confirmed, pre-treatment clinical stage IV NSCLC • Neurosurgical diagnostic resection of one single CNS metastasis or laparoscopic resection of one adrenal metastasis before trial inclusion is allowed. • The primary tumor and all oligopersistent metastases must be amenable for radical LAT (surgery and/or radiotherapy)	PI: Michael Mark michael.mark@ksgr.ch CRC: Stephanie Bossi stephanie.bossi@ksgr.ch

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Lung				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
metastatic 2L	**SGNB6A-002**	A randomized, phase 3, open-label study to evaluate SGN-B6A compared with docetaxel in adult subjects with previously treated non-small cell lung cancer	• Histologically or cytologically confirmed diagnosis of locally advanced, unresectable or metastatic NSCLC • Subjects must have NSCLC with nonsquamous histology	PI: Michael Mark michael.mark@ksgr.ch CRC: Stefania Merlo stefania.merlo@ksgr.ch
metastatic 2L+	**IP-IIO-622_SAKK 69/22**	Intratumoral injection of IP-001 following thermal ablation in patients with advanced solid tumors (currently only NSCLS). A multicenter **Phase 1b/2a** trial.	• Patients with either histologically or cytologically confirmed Stage 3 or Stage 4 NSCLC, who have failed, are ineligible, refused, or become intolerant to at least first line (but no more than 4 lines) of systemic therapy and only have lesions with the longest diameter of ≤ 5.5 cm. • Presence of at least two non-bone tumor lesions with a minimum size of 1.0 cm.	PI: Michael Mark michael.mark@ksgr.ch CRC: Stefania Merlo stefania.merlo@ksgr.ch

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Melanoma				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
metastatic 2L+	**SAKK 66/17**	Intratumoral injection of IP-001) following thermal ablation in patients with advanced solid tumors (currently only melanoma). A multicenter **Phase 1b/2a** trial.	• Presence of at least one tumor lesion that is laser ablation-accessible, with a minimum size of 1.0 cm. • No evidence of CNS progression for at least 4 weeks. • Melanoma: advanced or recurrent melanoma who failed standard therapy.	PI: Michael Mark michael.mark@ksgr.ch CRC: Stefania Merlo stefania.merlo@ksgr.ch

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Prostata				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
metastatic 1L	**PEACE 6 Vulnerable**	A double-blind randomised Phase 3 trial evaluating the efficacy of ADT +/- darolutamide in *de novo* metastatic prostate cancer patients with vulnerable functional ability and not elected for docetaxel or androgen receptor targeted agents	• Men with histologically or cytologically confirmed adenocarcinoma of the prostate. • De novo metastatic disease defined by clinical or radiographic evidence of metastases. • Ineligible for treatment with all of the following drugs: docetaxel, abiraterone, enzalutamide, apalutamide	PI: Richard Cathomas richard.cathomas@ksgr.ch CRC: Stephanie Bossi stephanie.bossi@ksgr.ch
metastatic 1L+	**Amgen 20180146**	A **Phase 1** Study evaluating the safety, tolerability, pharmacokinetics and efficacy of AMG 509 in subjects with metastatic castration-resistant prostate cancer	• Part 4a/4b: Subject planning to receive abiraterone or enzalutamide	PI: Richard Cathomas richard.cathomas@ksgr.ch CRC: Alexandra Jori alexandra.jori@ksgr.ch
metastatic 1L	**SAKK 63/12**	Prospective cohort study with collection of clinical data, serum and plasma of patients with prostate disease	• Only Group E: metastatic castration resistant prostata carcinoma	PI: Richard Cathomas richard.cathomas@ksgr.ch CRC: Alexandra Jori alexandra.jori@ksgr.ch CRC: Romina Bottoni romina.bottoni@ksgr.ch
metastatic 1L	**SAKK 08/23**	Addition of Darolutamide to first line treatment of mCRPC: a randomized open label phase II trial	• Metastatic adenocarcinoma of the prostata • Castration resistance: tumor progression after orchiectomy or during treatment with GnRH analogues • One line of previous ARPI therapy for at least 18 months within mHSPC setting	PI: Richard Cathomas richard.cathomas@ksgr.ch CRC: Daniela Denoth daniela.denoth@ksgr.ch

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Renal/ Seminoma/ Urothelial				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
neoadjuvant	**SAKK 06/19**	Intravesical recombinant BCG followed by perioperative chemo-immunotherapy for patients with muscle-invasive bladder cancer (MIBC). A multicenter, single-arm Phase 2 trial	• Histologically urothelial cell carcinoma bladder (cT2, cT3 or cT4a and ≤ cN1 (defined as a solitary lymph node ≤ 2 cm) • Location of tumor must allow placement of catheter without risk of bleeding	PI: Richard Cathomas richard.cathomas@ksgr.ch CRC: Alexandra Jori alexandra.jori@ksgr.ch
adjuvant	**SAKK 01/18**	Reduced intensity radio-chemotherapy for stage IIA/B seminoma. A multicenter, open label phase 2 trial with two cohorts	• Histological confirmed classical seminoma treated with primary inguinal orchidectomy or partialorchidectomy • Seminoma stage IIA or IIB either newly diagnosed or recurrent after primary active surveillance • Any anti-cancer therapy after primary tumor resection	PI: Richard Cathomas richard.cathomas@ksgr.ch CRC: Daniela Denoth daniela.denoth@ksgr.ch
-	**Swiss Austrian German Testicular Cancer Cohort Study (SAG TCCS)**	life-long follow-up of testicular cancer survivors within the setting of a large prospective cohort study to ascertain risks of emerging toxicities and the evolution of known late sequelae	• Histologically proven seminomas or non-seminoma • Seminoma: CR or LN < 3cm or PET negative PR or non-seminoma: CR	PI: Richard Cathomas richard.cathomas@ksgr.ch CRC: Daniela Denoth daniela.denoth@ksgr.ch

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Genetics				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
-	**PRoScreen Trial**	Utility of Polygenic Risk Score for Idividualizing Breast Cancer Screening	• No personal history of breast or other cancer • Positiv family history of breast cancer • Negativ genetic testing for known high and moderate penetrance genes (BRCA1, BRCA2, TP53, CHEK2…)	PI: Ursula Hasler-Strub ursula.halser-strub@ksgr.ch CRC: Romina Bottoni romina.bottoni@ksgr.ch

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Radio-Oncology				
Setting	**Short title**	**Complete title**	**Key Inclusions**	**Contact**
metastatic	**PREOP2**	A multicentre prospective, interventional, randomised trial of preoperative radiosurgery compared with postoperative stereotactic radiotherapy for resectable brain metastases	• MRI-diagnosis of a clearly demarcated contrast-enhancing brain metastasis up to 4.0 cm • Up to 3 other brian metastasis • Karnofsky performance status over 60 and survival estimated by primary clinican over 12 months	PI: Brigitta Baumert brigitta.baumert@ksgr.ch CRC: Romina Bottoni romina.bottoni@ksgr.ch CRC: Alexandra Jori alexandra.jori@ksgr.ch
metastatic	**EORTC 1811/1822 OligoCare**	A pragmatic observational cohort study to evaluate radical radiotherapy for oligo-metastatic cancer patients	• Primary disease type: NSCLC, breast cancer, prostatate cancer or colorectal cancer • Oligometastatic disease is diagnosed synchronously or metachronously • All active cancer lesions were or will be treated with radical intent.	PI: Thomas Mader thomas.mader@ksgr.ch CRC: Romina Bottoni romina.bottoni@ksgr.ch CRC: Alexandra Jori alexandra.jori@ksgr.ch