Open clinical trials at the Oncology Institute of Southern Switzerland

Phase I studies

Newly opened studies are **highlighted in green**

For more information please contact: studiclinici.IOSI@eoc.ch

Phase I				
Short title	**Complete title**	**Study Drug**	**Key Inclusion**	**Contacts**
Solid Tumors				
INCA 33890-101	A Phase 1, Open-Label, Multicenter Study of INCA33890 in Participants With Advanced or Metastatic Solid Tumors.	INCA33890 (bispecific PD-1/TGFβR2 antibody)	• Histologically or cytologically confirmed advanced or metastatic solid tumors • Progressed after / intolerant to / ineligible for available therapies known to confer clinical benefit (including anti–PD-(L)1 or anti-CTLA4, if applicable) • ECOG performance status score of 0 or 1	PI: M. Imbimbo
MK-1084-001	A Phase I, Open-Label, Multicenter Study to Assess Safety, Tolerability, PK, and Efficacy of MK-1084 as Monotherapy and in Combination With Pembrolizumab in Subjects with KRASG12C Mutant Advanced Solid Tumors.	MK-1084 (KRAS G12C inhibitor), Pembrolizumab (anti-PD-1)	• Untreated metastatic NSCLC with KRAS G12C mutation and TPS ≥1% per IHC 22C3 assay (local or central testing)	PI: M. Imbimbo
MK-4884-001-00	A Phase 1 Open-label Study to Evaluate the Safety, Pharmacokinetics, and Preliminary Efficacy of MK-4884 in Participants with Advanced Solid Tumors.	MK-4884	• Histologically or cytologically confirmed diagnosis of selected types of unresectable (locally advanced) and/or advanced (metastatic) solid tumors • Measurable disease by RECIST 1.1	PI: M. Imbimbo
PM54-A-001-22	Phase I/Ib, Open-label, Dose-escalating, Clinical and Pharmacokinetic Study of PM54 Administered Intravenously to Patients with Selected Advanced Solid Tumors.	PM54 (transcriptional inhibitor)	Pathologically confirmed diagnosis of one of the following: • extrapulmonary small cell carcinoma or poorly differentiated grade 3 gastroenteropancreatic NEC with Ki67 index ≥55% • cutaneous melanoma • malignant pleural mesothelioma • endometrial adenocarcinoma • synovial sarcoma	PI: I. Colombo

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TEADES	Two-part, first-in-human study on ODM-212 in subjects with selected advanced solid tumours.	ODM-212 (TEAD inhibitor)	• Histological diagnosis of local advanced or metastatic selected solid tumors (EHE, MPM, Hippo pathway-altered solid tumors, and tumors potentially responsive to TEAD inhibition) • Performance status ≤2 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale	PI: I. Colombo
Gastrointestinal				
MK-9999-02A	MK-9999-02A Sub-Study: A Phase 1/2 Substudy of the MK-9999-U02 Master Protocol to Evaluate the Safety and Efficacy of MK-2870 Monotherapy or in Combination with Other Anticancer Agents in Gastrointestinal Cancers.	Sacituzumab Tirumotecan (MK-2870, TROP2-directed antibody-drug conjugate)	Diagnosis of one of the following cancers: • Unresectable or metastatic colorectal cancer • Advanced or metastatic pancreatic ductal adenocarcinoma (PDAC) • Advanced and/or unresectable biliary tract cancer (BTC)	PI: S. De Dosso
Lymphoma				
CA-123-1000	A Phase 1, Multi-Center, Open-Label, Dose-Finding Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of BMS-986458, Alone and in Combination with Anti-lymphoma Agents in Participants with Relapsed/Refractory Non-Hodgkin Lymphomas (R/R NHL).	BMS-986458 (BCL6 inhibitor)	• Relapsed or refractory Non-Hodgkin Lymphomas	PI: A. Stathis
Urogenital				
Amgen 509 Phase 1	A Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 509 in Subjects With Metastatic Castration-Resistant Prostate Cancer.	AMG 509 (bispecific STEAP1-targeted CD3 T-cell engager)	• Subjects with histologically or cytologically confirmed mCRPC • Slots available from December 2025 (for Part 6).	PI: U. Vogl
ASPIRE	A proof-of-mechanism and proof-of-concept clinical trial evaluating the safety, tolerability, biological and anti-tumour activity of Apalutamide with dual CXCR1 and CXCR2 blockade by SX-682 for men suffering from metastatic castration-resistant prostate cancer (mCRPC)	Apalutamide / SX682	• Metastatic castration-resistant prostate cancer. • Resistance to 1 prior next generation antiandrogen therapy (NAAT) • PSA ≥ 10ng/ml. • Received prior castration by orchiectomy and/or ongoing LHRH agonist treatment. • Ongoing androgen deprivation with serum testosterone < 50 ng/dL • ECOG-PS ≤2.	PI : U. Vogl
PROMIZE	A Phase I/II Trial to Assess the Safety, Tolerability and Preliminary Antitumour Activity of Oral Combination antibiotic therapy to modulate the microbiome in combination with enzalutamide with metastatic castration resistant prostate cancer (mCRPC).	Enzalutamide (androgen receptor pathway inhibitor) and amoxicilline, metronidazole, vancomycin, ciprofloxacin (antibiotics)	• Progressive mCRPC • Patients have progressed after at least 12 weeks of treatment with a Novel Anti-Androgen Therapy (NAAT) • Previously progressed on at least one line of taxane chemotherapy (or not fit or not willing to receive a taxane).	PI: I. Colombo

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Phase II / III studies / others

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Phase II / III / others				
Short title	**Complete title**	**Study Drug**	**Key Inclusion**	**Contacts**
Central nervous system				
EORTC-LEGATO	Lomustine with or without reirradiation for first progression of glioblastoma: a randomized phase III study (LEGATO).	Lomustine (alkylating compound) + radiotherapy	• Patients with first progression or recurrent glioblastoma after first-line treatment • Prior first line therapy may include: any systemic antineoplastic treatment other than nitroureas, tumour-treating fields, conventionally fractionated or abbreviated radiotherapy	PI: B. Muoio
Gastrointestinal				
FusoMetro-001	Preoperative treatment with metronidazole to evaluate the efficacy in reducing Fusobacterium nucleatum tumor colonization in patients with colorectal cancer (CRC): a proof-of-concept trial.	Flagyl (metronidazole)	• Untreated, primary colorectal adenocarcinoma (> 15 cm from the anal verge) • Colonoscopy with endoscopic biopsy for disease confirmation and correlative studies • Candidates for surgical resection prior to administration of any therapy	PI: S. De Dosso
RMC-6236-303	RASolute 303: A Phase 3 Global, Multicenter, Open-label, Randomized, 3-Arm Study of Daraxonrasib Monotherapy or Daraxonrasib Plus Gemcitabine and Nab-paclitaxel versus Gemcitabine and Nab-paclitaxel as a First-Line Treatment for Patients with Metastatic Pancreatic Adenocarcinoma.	Daraxonrasib (multi-selective RAS inhibitor)	• Histologically or cytologically confirmed pancreatic adenocarcinoma • Diagnosis of metastatic disease ≤ 6 weeks prior to informed consent • Documented RAS mutation status, either mutant or wild-type • ECOG-PS < 2	PI: S. De Dosso

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Gynecological				
INCB123667-203	A Phase 2, Single-Arm Study of INCB123667 in Participants With Platinum-Resistant Ovarian Cancer With Cyclin E1 Overexpression	INCB 123667 (CDK2 inhibitor)	• Histological diagnosis of a high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer • Platinum-resistant disease • Willingness to undergo a pretreatment biopsy • Received at least 1 and no more than 4 prior lines of systemic therapy • Must have received bevacizumab unless there was a contraindication for its use	PI: I. Colombo
MATAO	MAintenance Therapy with Aromatase inhibitor in epithelial Ovarian cancer: a randomized double-blinded placebo-controlled multi-center phase III Trial (ENGOT-ov54/Swiss-GO-2/MATAO) including LOGOS (Low Grade Ovarian cancer Sub-study) Clinical Study.	Letrozole (Femara, aromatase inhibitor)	• Primary, newly diagnosed FIGO Stage II to IV and histologically confirmed low or high grade serous or endometrioid epithelial ovarian/fallopian tube/peritoneal cancer before debulking surgery, also during the neoadiuvant chemotherapy	PI: I. Colombo
MK-2870-021	A Phase 3, Randomized, Open-label, Multicenter Study of Sacituzumab Tirumotecan (sac-TMT, MK-2870) Maintenance Treatment With or Without Bevacizumab Versus Standard of Care in Participants With Newly Diagnosed Advanced HRD-Negative Ovarian Cancer Following First-line Platinum-based Chemotherapy (TroFuse-021/ENGOTov85/GOG-3102)	Sacituzumab Tirumotecan (sac-TMT, MK-2870) with or without Bevacizumab	• Histologically confirmed epithelial ovarian, primary peritoneal, or fallopian tube carcinoma • Patient completed primary debulking surgery or interval debulking surgery • Patient completed first-line platinum-based chemotherapy	PI: I. Colombo
Head and neck				
DeEscO	Personalized volume-deescalated elective nodal irradiation in oropharyngeal head and neck squamous cell carcinoma.	Radiation: De-escalation of irradiated volume	• Patients with a newly diagnosed squamous cell carcinoma of the oropharynx (i.e. tonsils, base of tongue, oropharyngeal walls, oropharyngeal surface of epiglottis), T1-4, N0-3. • Treatment with definitive (chemo) radiotherapy planned, with elective irradiation of the lymph nodes. • ECOG PS < 3. • History/physical examination within 30 days prior to study inclusion by head and neck surgeon and/or radiation oncologist. • FDG-PET scan prior to study inclusion. If inability to perform or contra-indication, at least contrast enhanced MRI scan obligatory.	PI: F. Martucci
Hematology (other)				
TL-895-201	A Phase 2 Multicenter Study of TL-895 in Subjects with Myelofibrosis, Indolent Systemic Mastocytosis, Monoclonal Mast Cell Activation Syndrome, or Non-Monoclonal Mast Cell Activation Syndrome.	TL-895 (BTK inhibitor)	• Confirmed diagnosis of myelofibrosis, indolent systemic mastocytosis, or mast cell activation syndrome • ECOG-PS ≤ 2	PI: G. Stüssi

Leukemia (CLL)				
CLL18	Phase 3 multicenter, randomized, prospective, open-label trial of MRDguided venetoclax/pirtobrutinib vs. fixed-duration (15 months) venetocolax / pirtobrutinb vs. fixed-duration (12 months) venetoclax / obinutuzumab in patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphomas (SLL).	Obinutuzumab (anti-CD20), Venetoclax (Bcl2 inhibitor), Pirtobrutinib (BTK inhibitor)	• Documented CLL/SLL • Adequate bone marrow, renal and liver function • ECOG-PS ≤ 2Documented CLL/SLL • Adequate bone marrow, renal and liver function • ECOG-PS ≤ 2	PI: I. Romano
MK-1026-003	A Phase II Study to Evaluate the Efficacy and Safety of MK-1026 in Participants with hematologic malignancies.	MK-1026 (Nemtabrutinib, BTK inhibitor)	Cohort J: • Participants whose disease relapsed or was refractory to prior therapy with a covalent/irreversible BTKi and BCL2i (both classes of therapies are required). • Additional use of noncovalent/reversible BTKi is permitted provided participant's disease relapsed/was refractory to such therapy. • CLL participants must have received and failed, been intolerant to, or determined by their treating physician to be a poor PI3Ki candidate or ineligible for a PI3Ki per local (institution) guidelines. • The participant is not eligible if response cannot be assessed after stopping BTKi and BCL2i. The participant will be eligible once disease progression or refractory status is determined.	PI: D. Rossi
Leukemia (except CLL)				
HOVON 173-EVOLVE 1	Ivosidenib and Azacitidine With or Without Venetoclax in Adult Patients With Newly Diagnosed IDH1-Mutated AML or MDS/AML Considered Ineligible for Intensive Chemotherapy.	Ivosidenib/Azacitidine + Venetoclax (BCL-2 inhibitor) or placebo	• Patient with newly diagnosed IDH1-mutated AML, or IDH1-mutated MDS/AML Patients with AML with both IDH1 and IDH2 mutation are eligible as well • Patient is ineligible for intensive induction chemotherapy • Patient must have a projected life expectancy of at least 12 weeks	PI: G. Stüssi
HOVON 177-EVOLVE 2	Randomized study to assess revumenib in combination with azacitidine + venetoclax in adult patients with azacitidine + venetoclax in adult patients with newly diagnosed NPM1-mutated or KMT2A-rearranged AM L ineligible for intensive chemotherapy EVOLVE 2 : A Joint Study of HOVON, AMLSG and UKAMLRN.	Azacitidine/Venetoclax + Revumenib (Menin inhibitor) or placebo	• Newly diagnosed NPM1-mutated AML or newly diagnosed KMT2A-rearranged AML • Patient ineligible for intensive induction chemotherapy • Life expectancy of at least 12 weeks	PI: G. Stüssi
Lung				
BMS CA266-0001	ROSETTA Lung-201: A Randomized, Multicenter, Open-label Phase 3 study of Pumitamig Monotherapy Compared to Durvalumab in Participants with Unresectable Stage III NSCLC Without Progression After Platinum-based Concurrent Chemoradiation Therapy.	Pumitamig (bispecific PD-L1/VEGF-A antibody)	• Histologically- or cytologically-confirmed NSCLC with unresectable stage III disease • Participants must have received at least 2 cycles of platinum-based concurrent chemoradiotherapy (a total dose of radiation of at least 54 Gy). • No progressive disease following treatment with concurrent chemoradiotherapy • ECOG PS < 2	PI: M. Imbimbo

CTL-002-006 Cachexia	Phase 2/3, Randomized, Double-Blind Trial Investigating the Efficacy and Safety of Visugromab versus Placebo in Patients with Cancer-associated Cachexia	Visugromab (anti-GDF-15 antibody)	• Weight loss • Advanced cancer	PI: P. Frösch
ETOP 25-23 ADOPT-lung	An international multicentre, open-label randomised phase III trial evaluating the benefit of adding adjuvant durvalumab after neoadjuvant chemo-immunotherapy in stage IIB-IIIB (N2) resectable NSCLC.	Durvalumab (anti-PD-L1)	• Histologically confirmed NSCLC. • Stage IIB-IIIB (T1-4 N0-2) • Absence of EGFR mutation or ALK translocation • Primary tumour resectable and functionally operable • ECOG-PS < 2	PI: M. Imbimbo
IOSI-MUSICAL-001	Effect of a music intervention in reducing anxiety and pain in patients with lung cancer undergoing mini-invasive surgery.	Music therapy intervention	• Suspected or confirmed diagnosis of lung cancer • Indication for lung resection through a minimally invasive surgery	PI: P. Frösch
SAKK 18-24	Reduced-dose carboplatin-doublet-chemotherapy + Cemiplimab vs Cemiplimab monotherapy in treatment naive older and frail patients with metastatic NSCLC with PD-L1 <50%. A multicentre randomized open-label phase II trial.	Reduced-dose carboplatin-doublet-chemotherapy + Cemiplimab (anti-PD-1)	• Age ≥ 70 years. • Participant cannot undergo chemotherapy with the usual dosage, for example, due to age	PI: P. Frösch
SALVAGE	Phase III randomized controlled trial comparing maintenance systemic therapy alone with systemic therapy plus local ablative treatment for patients with advanced stage IV non-small cell lung cancer.	Systemic therapy alone or in combination with local ablative treatment (surgery and/or radiotherapy)	• Tissue confirmed, pre-treatment clinical stage IV NSCLC • ECOG PS ≤ 1 • The primary tumor and all oligopersistent metastases must be amenable for radical LAT (surgery or radiotherapy) • Patients responding after 3 cycles (4th bridging cycle up until randomization is allowed) or 3 months of first line SoC systemic therapy with PR or SD in restaging imaging, and presenting with (induced) oligometastatic or oligopersistent NSCLC defined as a maximum of 5 residual extracranial, distant metastases	PI: P. Frösch
AbbVie M23-384	A Phase 3 Randomized, Open Label, Multicenter Study to Evaluate the Safety and Efficacy of ABBV-706 versus Standard of Care in Subjects with Relapsed/Refractory Small Cell Lung Cancer (SCLC)	ABBV-706 (SEZ6-directed antibody-drug conjugate)	• Diagnosis of Relapsed/Refractory (R/R) Small Cell Lung Cancer (SCLC). • Progression on prior systemic therapy, with checkpoint inhibitor (if eligible) and tarlatamab • Participants must be considered suitable to receive SOC comparator (topotecan, lurbinectedin, or amrubicin). • ECOG-PS < 2 • Measurable disease per RECIST v1.1	PI: M. Imbimbo
Lymphoma				
BALANCE	Bendamustine versus Fludarabine/Cyclophosphamide for lymphodepletion in CAR-T therapy: a randomized trial.	Bendamustine or Fludarabine/Cyclophosphamide	• Diagnosis of large B-cell lymphoma (LBCL) with at least one line of previous treatment and indication for commercial CAR-T cell therapy • Planned treatment with commercially available CAR-T cell product	PI: G. Stüssi

Melanoma				
NEO-DREAM	An Open-Label, Rand, Controlled Multi-Center Study of The Efficacy of Daromun (L19IL2 + L19TNF) Neoadjuvant Intratumoral Treatment Followed by Surgery and Adjuvant Th Versus Surgery and Adjuvant Therapy in Stage IIIB/C Melanoma Pats.	Daromun (tumor-targeted IL-2 and TNF)	• 1st line • Resectable disease	PI: C. Mangas
MELCHRONO	MELCHRONO: A prospective randomized study investigating chrono-immunotherapy for advanced melanoma.	Standard immune checkpoint inhibitor (ICI) therapy	• Histologically confirmed unresectable cutaneous stage III or stage IV melanoma. • Measurable or evaluable disease. • Patients deemed suitable for ICI therapy based on the local investigator's clinical assessment. • ECOG-PS < 3.	PI: C. Mangas
Sarcoma				
SAKK 57-24	Feasibility of Total Neoadjuvant Treatment with HYPErthermia in patients with high-risk extremity and trunk soft tissue sarcoma (TNT-HYPE). A multicenter, single arm, open label, phase II trial.	Hyperthermia	• Histologically confirmed primary high-risk soft tissue sarcoma of extremity or trunk • Resectable tumor	PI: T. Zilli
Solid tumors				
MK-2010-003	A Phase 2, Open-Label Study to Evaluate the Safety and Efficacy of MK-2010 in Combination with Sacituzumab Tirumotecan (Sac-TMT) in Participants with Advanced Solid Tumors.	MK-2010 (bispecific PD-1/VEGF-targeting antibody)	• Diagnosis of solid tumor: • ECOG PS < 2	PI: M. Pedrani
NVL-655-1	A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)	NVL-655 (ALK inhibitor)	• Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation (excluding lung cancer)	PI: P. Frösch
Urogenital				
ACTIDIET-PRO	A pilot study to investigate the effects of lifestyle intervention on physical activity and diet in patients with metastatic prostate cancer receiving novel hormonal agents: the ACTIDIET-PRO study.	Physical activity and diet	• Histology of adenocarcinoma of the prostate • Patients with PCa receiving ADT alone or ADT+NHT (Abiraterone, Enzalutamide, Apalutamide or Darolutamide) • Rising PSA (two consecutively rising PSA levels > 25% above nadir at least three weeks apart), with no evidence of clinical or radiographic progression on instrumental evaluation • PSA doubling time > 8 weeks	PI: U. Vogl

CAAA817A12201	A Phase II/III, Open-label, International, Multi-Center, Randomized study of AAA817 versus Best Standard of Care in the Treatment of Adult Participants with PSMA-positive metastatic castration-resistant prostate cancer who progressed on or after [177Lu]Lu-PSMA targeted therapy.	AAA817 ([225-Ac]Ac-PSMA-617)	• PSMA-positive mCRPC • ECOG-PS < 3	PI: U. Vogl
DE-ESCALATE	Intermittent Androgen deprivation Therapy in the era of AR pathway inhibitors; a phase 3 pragmatic randomized trial (DE-ESCALATE).	Continuous or intermittent maximal androgen blockade with ADT and ARPI	• Patient with mHSPC • Patient treated with ADT and an ARPI for 6-12 months • Patient presenting with a PSA ≤ 0.2 ng/mL	PI: F. Turco
PEACE 6	A double-blind randomised phase III 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.	ADT +/- darolutamide (androgen receptor antagonist)	• Histologically or cytologically confirmed prostate adenocarcinoma • 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 • Meets at least one of the following frailty criteria: Activities of daily living (ADL) assessment (excluding urinary incontinence question) score 3 or 4/5; 4-Instrumental activities of daily living (4-IADL) assessment score 2 or 3/4; A Grade 3 event on the Cumulative Illness Score Rating-Geriatrics (CISR-G) questionnaire; Body mass index (BMI) ≤21 kg/m2 and/or >5% weight loss in the last 6 months; Timed up and go test (TUG) > 14 sec	PI: U. Vogl
SAKK 08/23	Addition of Darolutamide to first line treatment of mCRPC: a randomized open label phase II trial.	Darolutamide (androgen receptor antagonist)	• Progressive mCRPC • One line of previous ARPI therapy for at least 18 months within mHSPC setting	PI: U. Vogl
STAMPEDE2	STAMPEDE2: A randomised controlled platform trial testing treatments in metastatic hormone sensitive prostate cancer. Comparison S	Radiotherapy	• Patients with prostate cancer • Confirmation of metastatic sites on CT/MRI and either bone or PET scan • Long-term ADT has started or there is an intention to start for at least 2 years	PI: T. Zilli
TERBINAPRO	SCI 001: Terbinafine for biochemically recurrent prostate cancer (TerbinaPro) - A phase II drug-repurposing Study.	Terbinafine (squalene epoxidase inhibitor)	• Biochemically recurrent prostate cancer after prior local treatment with curative intent • No evidence of distant metastatic disease on conventional imaging or PSMA-PET	PI: T. Zilli