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				
DODEKA-PHILOGEN	A phase I study to evaluate safety and early signs of efficacy of the human monoclonal antibody-cytokine fusion protein IL12-L19L19.	IL12-L19L19 (tumor-targeted IL-12)	• Advanced solid tumors progressing after immunotherapy • ≥ 3 months of stable disease on prior immunotherapy before progression • No limit on prior systemic therapies	PI: M. Imbimbo
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 / ineligibile 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: A. Stathis
MK-0472-001	A Phase 1/1b Open-label, Multicenter Clinical Study of MK-0472 as Monotherapy and Combination Therapy in Participants with Advanced/Metastatic Solid Tumors.	MK-0472	• KRASG12C mutated cancers • Patient has received, or been intolerant to all available treatment known to confer clinical benefit	PI: I. Colombo
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: A. Stathis

Updated on 10 April 2026

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
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 (sac-TMT, MK-2870) with or without Bevacizumab	Diagnosis of one of the following cancers: • Unresectable or metastatic colorectal cancer • 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	PI: U. Vogl

CAAA617A 12101 RADIODOSE	A Phase I, open-label, multi-center study of radiation dosimetry, safety, and tolerability of extended lutetium (177Lu) vipivotide tetraxetan treatment in chemo-naïve adults with metastatic castration-resistant prostate cancer.	Lutetium (177Lu) vipivotide tetraxetan	• Progressive mCRPC • Participants PSMA-positive per 68Ga-PSMA PET/CT at baseline • Castrate level of serum/plasma testosterone • Must have progressed only once on prior 2nd generation ARPIs	PI: G. Paone
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
Breast				
SAKK 66-22	Open-label single arm phase 1B/2 clinical trial of intratumoral INT230-6 followed by neoadjuvant Pembrolizumab and chemotherapy in triple-negative breast cancer (TNBC). INVINCIBLE-4-SAKK 66/22.	Intratumoral INT230-6 (formulation of cisplatin, vinblastine and SHAO [amphiphilic cell penetration enhancer molecule])	• Histologically diagnosed, previously untreated locally advanced non-metastatic TNBC • Measurable disease in the breast with at least one lesion with a diameter ≥2cm • ECOG PS < 2	PI: L. Rossi

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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**
Breast				
AZ CAMBRIA-2	CAMBRIA-2: A Phase III, 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 for Patients with ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease.	Camizestrant (Selective Estrogen Receptor Degrader - SERD)	• Patients with ER+/HER2- early breast cancer and an intermediate-high or high risk of recurrence who have completed definitive locoregional treatment and have no evidence of disease.	PI: R. Condorelli
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
IVY P3-24-021	A Phase 3, open-label, randomized 2-arm study comparing the clinical efficacy and safety of niraparib with temozolomide in adult participants with newly-diagnosed, MGMT unmethylated glioblastoma.	Niraparib (PARP inhibitor) + radiotherapy	• Patients with glioblastoma • No prior treatment for glioblastoma other than surgical resection or biopsy	PI: B. Muoio

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Gastrointestinal				
BMS-CA240-0030	A Randomized, Phase 2/3 Study Comparing BMS-986504 in Combination with Nab-paclitaxel and Gemcitabine versus Placebo in Combination with Nab-paclitaxel and Gemcitabine in Participants with Untreated Metastatic Pancreatic Ductal Adenocarcinoma Harboring Homozygous MTAP Deletion.	BMS-986504	• Histologically or cytologically confirmed diagnosis of metastatic pancreatic ductal adenocarcinoma (PDAC). • Evidence of homozygous methylthioadenosine phosphorylase (MTAP) deletion or MTAP loss detected in tumor tissue. • Metastatic disease with at least 1 measurable lesion as per RECIST v1.1.	PI: S. De Dosso
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
Gynecological				
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
MCLA-158-CL02	A Phase 3 open-label, randomized, controlled study to evaluate the efficacy and safety of petosemtamab compared with Investigator's choice monotherapy treatment in previously treated patients with incurable, metastatic/recurrent head and neck squamous cell carcinoma.	Petosemtamab	• Histologically previously confirmed HNSCC with evidence of metastatic or locally advanced disease not amenable to standard therapy with curative intent. • HNSCC patients progressed on or after anti-PD-1 therapy and platinum-containing therapy.	PI: V. Espeli
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

Leukemia (CLL)				
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
KRT-232-115	A Phase 3, Randomized, Double-blind, Add-on Study Evaluating the Safety and Efficacy of Navtemadlin Plus Ruxolitinib vs Placebo Plus Ruxolitinib in JAK Inhibitor-Naïve Patients with Myelofibrosis Who Have a Suboptimal Response to Ruxolitinib (Poiesis trial).	Ruxolitinib + Navtemadlin (MDM2 inhibitor) or placebo	• Patients with myelofibrosis • ECOG-PS < 3 • JAK-inhibitor treatment naïve • Suboptimal response to run-in ruxolitinib treatment	PI: G. Stüssi

Lung				
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
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
Lymphomas				
MK-2140-010	A Randomized, Open-Label, Multicenter, Phase 3 Study of Zilovertamab Vedotin (MK-2140) in Combination With R-CHP Versus R-CHOP in Participants With Previously Untreated Diffuse Large B-Cell Lymphoma (DLBCL).	MK-2140 (Zilovertamab Vedotin, ROR1-directed antibody drug conjugate)	• Histologically confirmed diagnosis of DLBCL • PET-positive disease at screening • No prior treatment for DLBCL • ECOG PS < 3	PI: A. Stathis
MorningLyte	A Phase III randomized, open-label, international, multicenter, study evaluating the efficacy and safety of mosunetuzumab plus lenalidomide in comparison to anti-CD20 mAb plus chemotherapy in subjects with previously untreated FLIPI 2-5 follicular lymphoma.	Mosunetuzumab (bispecific CD20-targeted CD3 T-cell engager) and lenalidomide (immunomodulatory agent)	• Patient with histologically proven previously untreated CD20+ follicular lymphoma grade 1, 2, or 3a • At least one bi-dimensionally measurable nodal lesion, defined as > 1.5 cm in its longest dimension, or at least one	PI: M. Pirosa
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

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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				
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
BMS CA244-0012	Phase 2/3 Trial of Izalontamab Brengitecan vs Platinum-based Chemotherapy for Metastatic Urothelial Cancer with Disease Progression on or After Immunotherapy	Izalontamab Brengitecan (EGFR- and HER3-directed antibody-drug conjugate)	• Histologically confirmed advanced urothelial carcinoma • Participants must be eligible to receive platinum-based chemotherapy • Participants must be Anti-PD-(L)1-experienced • Participants must have ≥ 1 measurable lesion per RECIST v1.1 • ECOG-PS < 2	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