Open clinical trials at the Oncology Institute of Southern Switzerland

Phase I studies

Newly opened studies are **highlighted in green**.

Phase I				
Short title	**Complete title**	**Study Drug**	**Key Inclusion**	**Contacts**
Solid Tumors				
AMGEN 20210023	A phase I/Ib/II study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of AMG 193 alone and in combination with docetaxel in subjects with advanced MTAP-null solid tumors	AMG 193 (PRMT5 inhibitor), docetaxel	• MTAP-null and/or CDKN2A-null or lost MTAP expression advanced solid tumors	PI: A. Stathis anastasios.stathis@eoc.ch
DEBIO 0123	A Phase I, dose-finding study of Debio 0123 as monotherapy in adult patients with advanced solid tumors, followed by an expansion part to assess safety and preliminary anti-tumor activity	Debio 0123 (Wee1 kinase inhibitor)	• Locally advanced or metastatic solid tumors • Disease progression under or following standard therapy and/or disease for which no standard therapy of proven benefit is available • No limit on prior systemic therapies	PI: A. Stathis anastasios.stathis@eoc.ch
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: A. Stathis anastasios.stathis@eoc.ch
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 anastasios.stathis@eoc.ch
INCB 123667	A Phase 1, Open-Label, Multicenter Study of INCB123667 as Monotherapy in Participants With Selected Advanced Solid Tumors	INCB 123667 (CDK2 inhibitor)	• Advanced/metastatic solid tumor by pathology report intolerant to, or ineligible for treatment known to confer clinical benefit	PI. I. Colombo ilaria.colombo@eoc.ch

Updated on 14 March 2024

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	• Histologically or cytologically confirmed unresectable advanced / metastatic solid tumor with oncogenically activated RTK • Patient has received, or been intolerant to all available treatment known to confer clinical benefit.	PI: I. Colombo ilaria.colombo@eoc.ch
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)	• Metastatic solid tumors with KRAS G12C mutation who have received at least 1 line of therapy for systemic disease • For Arm 2 only: untreated metastatic NSCLC with KRAS G12C mutation and TPS ≥1% per IHC 22C3 assay (local or central testing)	PI: A. Stathis anastasios.stathis@eoc.ch
MK-6598-001	A Phase I, Open-label, Multicenter Study to Assess Safety, Tolerability, PK, and Efficacy of MK-6598 as Monotherapy and in Combination With Pembrolizumab in Participants With Advanced Solid Tumors	MK-6598, Pembrolizumab (anti-PD-1)	• Histologically- or cytologically-confirmed advanced/metastatic solid tumor • Measurable disease by RECIST 1.1	PI: A. Stathis anastasios.stathis@eoc.ch
SAKK 69/22 (IP-IIO-622)	Intratumoral injection of IP-001 following thermal ablation in patients with advanced solid tumors. A multicenter Phase 1b/2a trial in colorectal cancer, non-small cell lung cancer, and soft tissue sarcoma patients	IP-001 (immune stimulant)	• Patients with advanced CRC, NSCLC, or STS who have failed, are ineligible, refused, or become intolerant to at least first line (but no more than 4 lines) of systemic therapy • Only have lesions with the longest diameter of ≤ 5 cm • At least one non-bone tumor lesion that is ablation-accessible	PI: S. De Dosso sara.dedosso@eoc.ch
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 solid tumour • Performance status ≤2 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale. • Life expectancy of >12 weeks.	PI: I. Colombo ilaria.colombo@eoc.ch
TOLREMO	A Phase 1, First-in-Human, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of TT125-802 in Subjects with Advanced Solid Tumors	TT125-802 (CBP/p300 bromodomain inhibitor)	• Any advanced-metastatic solid tumors • Progression to standard treatment	PI: I. Colombo ilaria.colombo@eoc.ch
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 anastasios.stathis@eoc.ch
Urogenital				
Amgen 509	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 ursula.vogl@eoc.ch

Open clinical trials at the Oncology Institute of Southern Switzerland

Phase II / III studies / others

Newly opened studies are **highlighted in green**.

Phase II / III / others				
Short title	**Complete title**	**Study Drug**	**Key Inclusion**	**Contacts**
Breast				
C4891001 (ARV-471)	A Phase III, Randomized, Open-Label, Multicenter Trial Of ARV-471 (PF-07850327) vs Fulvestrant In Participants With Estrogen Receptor-Positive, HER2-Negative Advanced Breast Cancer Whose Disease Progressed After Prior Endocrine Based Treatment	ARV-471 (PROTAC ER degrader) vs Fulvestrant (ER antagonist)	• Histological or cytological confirmation of breast cancer with evidence of locoregional recurrent or metastatic disease which is not amenable to surgical resection or radiation therapy with curative intent. • One prior line of CDK4/6 inhibitor therapy in combination with ET • ≤ 1 prior endocrine therapy in addition to CDK4/6 inhibitor with ET • Most recent endocrine treatment duration must have been given for ≥6 months prior to disease progression • Radiological progression during or after the last line of therapy	PI: L. Rossi lorenzo.rossi@eoc.ch
SAKK 96/12 Breast	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial	Denosumab (Xgeva, anti-RANKL)	• Metastatic breast cancer and ≥ 3 bone metastases	PI: R. Pereira Mestre ricardo.pereiramestre@eoc.ch
MK-7339-002	A Phase II Study of Olaparib Monotherapy in Participants with Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	Olaparib (PARP inhibitor)	• Study open only for patients with breast cancer and somatic BRCA mutation	PI: I. Colombo ilaria.colombo@eoc.ch
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 sara.dedosso@eoc.ch

Updated on 14 March 2024

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 ilaria.colombo@eoc.ch
Head and neck				
MS202359	A randomized, double-blind, placebo-controlled, 2-arm Phase III study to assess efficacy and safety of xevinapant and radiotherapy compared to placebo and radiotherapy for demonstrating improvement of disease-free survival in participants with resected squamous cell carcinoma of the head and neck, who are at high risk for relapse and are ineligible for high-dose cisplatin	Xevinapant (IAP antagonist) and radiotherapy	• Histologically confirmed squamous cell carcinoma of the head and neck with one of the following primary sites: oral cavity, oropharynx, hypopharynx or larynx. • Patients have received surgery with curative intent on these sites in the past 4 to 10 weeks before start of treatment • ECOG PS 0-2	PI: F. Martucci francesco.martucci@eoc.ch
Leukemia (CLL)				
LOXO-BTK-20022	A Phase III Open-Label, Randomized Study of Fixed Duration Pirtobrutinib (LOXO-305) plus Venetoclax and Rituximab versus Venetoclax and Rituximab in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN-CLL-322)	LOXO 305 (Pirtobrutinib, BTK inhibitor), Venetoclax (Bcl-2 inhibitor), Rituximab (anti-CD20)	• Previously untreated CLL • Symptomatic disease	PI: D. Rossi davide.rossi@eoc.ch
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)	• CLL/SLL patients who are relapsed or refractory to prior therapy with a covalent, irreversible BTKi, BCL2i, and PI3Ki (cohort A) • CLL/SLL patients who are relapsed/refractory after ≥1 line of therapy and are BTKi treatment naïve (cohort B) • CLL/SLL patients with 17p deletion who are relapsed/ refractory following ≥ 1 line of prior therapy (cohort C) • Patients with Richter's transformation who are relapsed or refractory following ≥ 1 line of prior therapy (Cohort D) • Patients with pathologically confirmed MCL, documented by either overexpression of cyclin D1 or t(11;14), who are relapsed or are refractory to chemoimmunotherapy and a covalent irreversible BTK inhibitor (BTKi) (Cohort E) • Patients with MZL (including splenic, nodal, extra nodal MZL) who are relapsed or refractory to a covalent irreversible BTKi and chemoimmunotherapy (Cohort F) • Patients with FL who are relapsed or refractory to chemoimmunotherapy, immunomodulatory agents (i.e. lenalidomide + rituximab) (Cohort G) • Cohort H: confirmed diagnosis of WM; patients who are relapsed or refractory to standard therapies for WM including chemoimmunotherapy and a covalent irreversible BTKi	PI: D. Rossi davide.rossi@eoc.ch

Leukemia (except CLL)				
HOVON 150	A phase III, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib or enasidenib in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, respectively, eligible for intensive chemotherapy	Ivosidenib or enasidenib (IDH1 inhibitors)	• Newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with IDH1 or IDH2 mutation, eligible for intensive chemotherapy	PI: G. Stüssi georg.stuessi@eoc.ch
HOVON 156	A phase III, multicenter, open-label, randomized, study of gilteritinib versus midostaurin in combination with induction and consolidation therapy followed by one-year maintenance in patients with newly diagnosed acute myeloid leukemia (AML) or myelodysplastic syndromes with excess blasts-2 (MDS-EB2) with FL T3 mutations eligible for intensive chemotherapy	Gilteritinib (FLT3 inhibitor)	• Newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with FLT3 mutations, eligible for intensive chemotherapy	PI: G. Stüssi georg.stuessi@eoc.ch
LUSPLUS	A phase IIIb, open-label, single arm study to evaluate the efficacy and safety of luspatercept in patients with lower-risk MDS and ring-sideroblastic phenotype (MDS-RS) LUSPLUS	Luspatercept (TGFb superfamily ligand inhibitor)	• Subject has documented diagnosis of MDS Subject must be one of the following: • Refractory or intolerant to prior ESA (erythropoiesis-stimulating agents) treatment or ESA ineligible • Refractory to- /relapsed after prior HMA (hypomethylating agents) treatment • Refractory to- /relapsed after prior lenalidomide treatment	PI: G. Stüssi georg.stuessi@eoc.ch
Lung				
ETOP 18-21 AMAZE	ETOP 18-21 AMAZE-lung A multicentre single-arm phase II trial of amivantamab, lazertinib plus bevacizumab in patients with EGFR-mutant advanced NSCLC with progression on previous third-generation EGFR-TKI	Amivantamab (bispecific EGFR/METR antibody), lazertinib (TKI) plus bevacizumab (anti-VEGF-A)	• Histologically confirmed non-squamous NSCLC, stage IIIB/C (not amenable to radical therapy) or stage IV according to 8th TNM classification • Presence of a sensitising EGFR-mutation (only patients with exon 19 deletion and/or L858R are eligible) and documentation of T790M status, tested locally by an accredited laboratory • Radiologically confirmed disease progression on previous treatment with osimertinib or lazertinib • Treatment with osimertinib must have been stopped at least 8 days before enrolment • Achieved objective clinical benefit from osimertinib or lazertinib treatment (e.g., documented PR/ CR or SD for ≥6 months while on osimertinib or lazertinib treatment). • Measurable disease as defined according to RECIST v1.1	PI: P. Frösch patrizia.froesch@eoc.ch

LAGOON	A randomized, multicenter, open label,phase III Study of Lurbinectidin in combonation with Irinotecan versus Investigator's choice (Topotecan or Irinotecan) in relapsed Small Cell Lung Cancer (SCLC) patients (LAGOON)	Lurbinectidin (RNA polymerase inhibitor) Irinotecan (topoisomerase I inhibitor)	• Confirmed diagnosis of SCLC • One prior line of platinum-containing chemotherapy with/without anti-PD-1 or anti-PD-L1 • Chemotherapy-free interval ≥ 30 days • ECOG PS ≤ 2 • Adequate hematological, renal, metabolic and hepatic function	PI: P. Frösch patrizia.froesch@eoc.ch
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 II trial.	Durvalumab (anti-PD-L1) and radiotherapy	• Resectable stage III NSCLC • Tumor is considered primarily resectable based on a multidisciplinary tumor board decision	PI: P. Frösch patrizia.froesch@eoc.ch
Lymphomas				
ADCT-402-311 (LOTIS 5)	A Phase III Randomized Study of Loncastuximab Tesirine Combined with Rituximab Versus Immunochemotherapy in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL) (LOTIS-5)	Loncastuximab (anti-CD19), Rituximab (anti-CD20), Gemcitabine, Oxaliplatin	• R/R after at least one prior line of therapy	PI: A. Stathis anastasios.stathis@eoc.ch
M20-638	A Phase 3, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma (EPCORE™ FL-1)	Epcoritamab (bispecific CD20-directed CD3 T-cell engager), Rituximab (anti-CD20), Lenalidomide	• Histologically confirmed Grade 1 to 3a FL stage II, III, or IV with no evidence of histologic transformation to an aggressive lymphoma • Subject must have R/R disease to at least one prior systemic regimen that contained an anti-CD20 monoclonal antibody in combination with (an)other anti-lymphoma agent • Subject has one or more measurable disease sites	PI: A. Stathis anastasios.stathis@eoc.ch
MK-4280A-008-02	A Phase 3 Randomized Clinical Study of MK-4280A (coformulated favezelimab [MK-4280] plus Pembrolizumab [MK-3475]) Versus Physician's Choice Chemotherapy in PD-(L)1-refractory, Relapsed or Refractory Classical Hodgkin Lymphoma (KEYFORM-008)	MK-4280A (coformulation of favezelimab, [anti-LAG-3] and pembrolizumab [anti-PD-1])	• Histologically confirmed diagnosis of classical Hodgkin lymphoma • Radiographically measurable disease per the Lugano response criteria • Patient has relapsed or refractory cHL and exhausted all available treatment options with known clinical benefit • Patient has progressed on treatment with an anti-PD-(L)1 mAb	PI: M. Pirosa maria.pirosa@eoc.ch

SAKK 38/19 PEDRO	Assessing a ctDNA and PET-oriented therapy in patients with DLBCL. A multicenter, open-label, phase II trial	Acalabrutinib (Calquence, BTK inhibitor) and R-CHOP	• Treatment naïve NOS that qualifies for 6 cycles of R-CHOP	PI: A. Stathis anastasios.stathis@eoc.ch
ZUMA-25	Phase 2, Open-Label, Multicenter, Basket Study Evaluating the Safety and Efficacy of Brexucabtagene Autoleucel in Adults with Rare B-cell Malignancies (ZUMA-25)	Bruxucabtagene autoleucel (CAR T cells)	• Confirmed diagnosis of Waldenstrom Macroglobulinemia - WM; disease relapsed or is refractory after 2 or more lines of therapy; prior therapy must have included a BTK inhibitor and chemotherapy and/or proteasome inhibitor must have been attempted (Cohort A) • Confirmed diagnosis of CLL; disease relapsed or is refractory to first-line therapy (Cohort B) • Confirmed diagnosis of Burkitt lymphoma – BL ; disease relapsed or is refractory to first-line therapy (Cohort C) • Confirmed diagnosis of Hairy Cell Leukemia – HCL with a need for therapy; at least 2 prior therapies, including at least a PNA and moxetumomab pasudotox if eligible and available (Cohort D)	PI: G. Stüssi georg.stuessi@eoc.ch
Melanoma				
MK-7684A-010	A Phase 3, Randomized, Double-blind, Active-Comparator-Controlled Clinical Study of Adjuvant MK-7684A (Vibostolimab with Pembrolizumab) Versus Adjuvant Pembrolizumab in Participants with High-risk Stage II-IV Melanoma (KEYVIBE-010)	MK-7684A (Coformulation of vibostolimab [anti-TIGIT] and pembrolizumab [anti-PD-1])	• Surgically resected and histologically/pathologically confirmed diagnosis of StageIIB and IIC (pathological or clinical), III, or IV cutaneous melanoma per AJCC eighth edition guidelines • Patient has not been received any prior systemic therapy for their melanoma beyond surgical resection • No evidence of metastatic disease	PI: C. Mangas cristina.mangas@eoc.ch
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 cristina.mangas@eoc.ch
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 ursula.vogl@eoc.ch

HYPO-FOCAL SRT	A single arm phase II trial of ultrahypofractionated focal salvage radiotherapy for isolated prostate bed recurrence after radical prostatectomy	Commercial LHRH agonists and radiotherapy	• Lymph node negative adeno-carcinoma of the prostate treated with radical prostatectomy (RP) at least 6 months before trial registration. • Evidence of measurable local recurrence at the prostate bed detected by PSMA PET/CT and mpMRI within the last 3 months • Patient must have non-metastatic (N0, M0) disease, as defined by a lack of nodal or distant metastases seen on PSMA PET/CT scan • Patients must have non-castrate levels of serum testosterone (≥50 ng/dL) • Patients must not have previously received hormonal therapy (LHRH agonists, antiandrogen, or both, or bilateral orchiectomy)	PI: T. Zilli thomas.zilli@eoc.ch
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)	• 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 • 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: S. Gillessen silke.gillessensommer@eoc.ch
SAKK 06/19	Protocol SAKK 06/19 Intravesical BCG followed by perioperative chemo-immunotherapy for patients with muscle-invasive bladder cancer (MIBC). A multicenter, single-arm phase II trial	Atezolizumab (anti-PD-L1) + intravesical recombinant BCG	• Histologically proven urothelial cell carcinoma of the bladder • Location of tumor must allow placement of catheter without risk of bleeding	PI: U. Vogl ursula.vogl@eoc.ch
SAKK 96/12 Prostate	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial	Denosumab (Xgeva, anti-RANKL)	• Metastatic castration resistant prostate cancer and ≥ 3 bone metastases	PI: R. Pereira Mestre ricardo.pereiramestre@eoc.ch