



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	<ul style="list-style-type: none">• MTAP-null and/or CDKN2A-null or lost MTAP expression advanced solid tumors	PI: A. Stathis anastasios.stathis@eoc.ch
ANAVEON-600	A first-in-human, open-label, multicenter Phase I/II study to evaluate the safety and anti-tumor activity of ANV600 as single agent and in combination with pembrolizumab in participants with advanced solid tumors (EXPAND-1)	ANV600 (PD-1 targeted IL-2R β / γ selective anti-IL-2 antibody/IL-2 fusion protein) + Pembrolizumab (anti-PD-1)	<ul style="list-style-type: none">• Advanced unresectable or metastatic solid tumors for which standard treatments are not available, or not tolerated• Measurable disease per RECIST v1.1• ECOG PS < 2• Life-expectancy \geq 3 months	PI: M. Imbimbo martina.imbimbo@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/TGF β R2 antibody)	<ul style="list-style-type: none">• 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: 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)	<ul style="list-style-type: none">• 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
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	<ul style="list-style-type: none">• 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 KRAS G12C Mutant Advanced Solid Tumors	MK-1084 (KRAS G12C inhibitor), Pembrolizumab (anti-PD-1)	<ul style="list-style-type: none"> 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 $\geq 1\%$ 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> Relapsed or refractory Non-Hodgkin Lymphomas 	PI: A. Stathis anastasios.stathis@eoc.ch
PRELUDE	A Phase 1 Open-Label, Multi-Center, Safety and efficacy study of PRT2527 as Monotherapy and in combination with Zanubrutinib in Participants with Relapsed/Refractory Hematologic Malignancy	PRT2527 (CDK9 inhibitor) and Zanubrutinib (BTK inhibitor)	<ul style="list-style-type: none"> Histologically or cytologically confirmed relapsed/refractory aggressive B-cell lymphoma, MCL, CLL/SLL (including Richter's syndrome), or T cell lymphoma ECOG PS ≤ 2 	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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none">• 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
IBCSG 67-22 - PREcoopE RA	A Window-of-Opportunity trial of giredestrant +/- triptorelin vs. anastrozole + triptorelin in premenopausal patients with ER-positive/HER2-negative early breast cancer	Giredestrant (Selective Estrogen Receptor Degradator - SERD), Triptorelin (LHRH analogue), anastrozole (aromatase inhibitor)	<ul style="list-style-type: none">• Premenopausal women age ≥18 years• Histologically confirmed, operable invasive breast carcinoma• Eligible for upfront breast conservative surgery or upfront mastectomy• Documented estrogen receptor (ER)-positive and human epidermal growth factor receptor-2 (HER2)-negative tumor• Ki-67 ≥10% in diagnostic biopsy as determined per local assessment.• ECOG PS < 2	PI: L. Rossi lorenzo.rossi@eoc.ch
MK-7339-002	A Phase 2 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)	<ul style="list-style-type: none">• Study open only for patients with breast cancer and somatic BRCA mutation	PI: I. Colombo ilaria.colombo@eoc.ch

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Gastrointestinal				
DANTE	A randomized, open-label Phase II/III 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	Atezolizumab (anti-PD-L1) and FLOT	<ul style="list-style-type: none"> Histologically confirmed adenocarcinoma of the gastroesophageal junction or the stomach that i) is not infiltrating adjacent organs or structures, ii) does not involve peritoneal carcinomatosis and iii) is considered medically and technically resectable No prior cytotoxic or targeted therapy No prior partial or complete esophagogastric tumor resection ECOG \leq 1 Adequate hematological, hepatic and renal function 	PI: S. De Dosso sara.dedosso@eoc.ch
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)	<ul style="list-style-type: none"> 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
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)	<ul style="list-style-type: none"> 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 neoadjuvant chemotherapy 	PI: I. Colombo ilaria.colombo@eoc.ch
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 (ENGOT-en23/GOG3095)	MK-2870 (Sacituzumab Tirumotecan, TROP2-directed antibody-drug conjugate)	<ul style="list-style-type: none"> Histologically-confirmed diagnosis of endometrial carcinoma or carcinosarcoma Prior platinum-based chemotherapy and anti-programmed cell death 1 protein (PD-1)/anti-programmed cell death ligand 1 (PD-L1) therapy, either separately or in combination 	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	<ul style="list-style-type: none"> 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)				
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)	<ul style="list-style-type: none"> • 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 	<p>PI: D. Rossi davide.rossi@eoc.ch</p>
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)	<ul style="list-style-type: none"> • Newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with IDH1 or IDH2 mutation, eligible for intensive chemotherapy 	<p>PI: G. Stüssi georg.stuessi@eoc.ch</p>
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 FLT3 mutations eligible for intensive chemotherapy	Gilteritinib (FLT3 inhibitor)	<ul style="list-style-type: none"> • Newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with FLT3 mutations, eligible for intensive chemotherapy 	<p>PI: G. Stüssi georg.stuessi@eoc.ch</p>



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)	<ul style="list-style-type: none"> • Subject has documented diagnosis of MDS Subject must be one of the following: <ul style="list-style-type: none"> • 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				
LAGOON	A randomized, multicenter, open label, phase III Study of Lurbinectidin in combination 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)	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Resectable stage III NSCLC • Tumor is considered primarily resectable based on a multidisciplinary tumor board decision 	PI: P. Frösch patrizia.froesch@eoc.ch
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)	<ul style="list-style-type: none"> • 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 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	<ul style="list-style-type: none"> • R/R after at least one prior line of therapy 	PI: A. Stathis anastasios.stathis@eoc.ch
IELSG 48	Phase 3, interventional, multicentre, open-label, randomized study comparing rituximab plus zanubrutinib to rituximab monotherapy in previously untreated, symptomatic splenic marginal zone lymphoma (RITZ)	Zanubrutinib (BTK inhibitor, p.os), Rituximab (anti-CD20, iv)	<ul style="list-style-type: none"> • Confirmed diagnosis of SMZL • Previously untreated disease • ECOG PS 0-2 	PI: M. Pirosa maria.pirosa@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])	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Treatment naïve NOS that qualifies for 6 cycles of R-CHOP 	PI: A. Stathis anastasios.stathis@eoc.ch
Melanoma				
NEO-DREAM	An Open-Label, Randomized, Controlled Multi-Center Study of The Efficacy of Daromun (L19IL2 + L19TNF) Neoadjuvant Intratumoral Treatment Followed by Surgery and Adjuvant Therapy Versus Surgery and Adjuvant Therapy in Clinical Stage IIIB/C Melanoma Patients	Daromun (tumor-targeted IL-2 and TNF)	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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