



## 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"> <li>• MTAP-null and/or CDKN2A-null or lost MTAP expression advanced solid tumors</li> </ul>	PI: A. Stathis <a href="mailto:anastasios.stathis@eoc.ch">anastasios.stathis@eoc.ch</a>
AMGEN 355	A Phase 1 First-in-Human Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of AMG 355 as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors	AMG 355 (anti-CCR8) + Pembrolizumab (anti-PD-1)	<ul style="list-style-type: none"> <li>• Metastatic/locally advanced NSCLC, colorectal cancer, gastric cancer, and melanoma that relapsed after and/or are refractory to or ineligible for established/available therapies. Additional indications may be explored.</li> <li>• ECOG PS &lt; 2</li> </ul>	PI: M. Imbimbo <a href="mailto:martina.imbimbo@eoc.ch">martina.imbimbo@eoc.ch</a>
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-2Rβ/γ selective anti-IL-2 antibody/IL-2 fusion protein) + Pembrolizumab (anti-PD-1)	<ul style="list-style-type: none"> <li>• Advanced unresectable or metastatic solid tumors for which standard treatments are not available, or not tolerated</li> <li>• Measurable disease per RECIST v1.1</li> <li>• ECOG PS &lt; 2</li> <li>• Life-expectancy ≥ 3 months</li> <li>• Currently not open for pancreatic cancer</li> </ul>	PI: M. Imbimbo <a href="mailto:martina.imbimbo@eoc.ch">martina.imbimbo@eoc.ch</a>
DEBIO 0123	A Phase 1, 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)	<ul style="list-style-type: none"> <li>• Locally advanced or metastatic solid tumors</li> <li>• Disease progression under or following standard therapy and/or disease for which no standard therapy of proven benefit is available</li> <li>• No limit on prior systemic therapies</li> <li>• Currently open of ovarian cancer with Cyclin E overexpression, and for pancreatic, renal or breast cancer with selected biomarkers.</li> </ul>	PI: A. Stathis <a href="mailto:anastasios.stathis@eoc.ch">anastasios.stathis@eoc.ch</a>

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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)	<ul style="list-style-type: none"> <li>• Histologically or cytologically confirmed advanced or metastatic solid tumors</li> <li>• Progressed after / intolerant to / ineligible for available therapies known to confer clinical benefit (including anti-PD-(L)1 or anti-CTLA4, if applicable)</li> <li>• ECOG performance status score of 0 or 1</li> </ul>	PI: A. Stathis <a href="mailto:anastasios.stathis@eoc.ch">anastasios.stathis@eoc.ch</a>
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"> <li>• Advanced/metastatic solid tumor by pathology report intolerant to, or ineligible for treatment known to confer clinical benefit</li> <li>• Currently open for endometrial, gastric and triple negative breast cancer</li> </ul>	PI: I. Colombo <a href="mailto:ilaria.colombo@eoc.ch">ilaria.colombo@eoc.ch</a>
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"> <li>• Histologically or cytologically confirmed unresectable advanced / metastatic solid tumor with oncogenically activated RTK</li> <li>• Patient has received, or been intolerant to all available treatment known to confer clinical benefit</li> </ul>	PI: I. Colombo <a href="mailto:ilaria.colombo@eoc.ch">ilaria.colombo@eoc.ch</a>
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)	<ul style="list-style-type: none"> <li>• Untreated metastatic NSCLC with KRAS G12C mutation and TPS ≥1% per IHC 22C3 assay (local or central testing)</li> </ul>	PI: A. Stathis <a href="mailto:anastasios.stathis@eoc.ch">anastasios.stathis@eoc.ch</a>
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"> <li>• Histological diagnosis of local advanced or metastatic selected solid tumors</li> <li>• Performance status ≤2 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale</li> <li>• Life expectancy of &gt;12 weeks</li> </ul>	PI: I. Colombo <a href="mailto:ilaria.colombo@eoc.ch">ilaria.colombo@eoc.ch</a>
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"> <li>• Any advanced-metastatic solid tumors</li> <li>• Progression to standard treatment</li> <li>• Currently open for KRAS- or EGFR-mutated NSCLC, prostate cancer, NUT carcinoma</li> </ul>	PI: I. Colombo <a href="mailto:ilaria.colombo@eoc.ch">ilaria.colombo@eoc.ch</a>



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])	<ul style="list-style-type: none"> <li>• Histologically diagnosed, previously untreated locally advanced non-metastatic TNBC</li> <li>• Measurable disease in the breast with at least one lesion with a diameter <math>\geq 2</math>cm</li> <li>• ECOG PS &lt; 2</li> </ul>	PI: L. Rossi <a href="mailto:lorenzo.rossi@eoc.ch">lorenzo.rossi@eoc.ch</a>
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.	MK-2870 (TROP2-directed antibody-drug conjugate)	Diagnosis of one of the following cancers: <ul style="list-style-type: none"> <li>• Unresectable or metastatic colorectal cancer</li> <li>• Advanced and/or unresectable biliary tract cancer (BTC)</li> </ul>	PI: S. De Dosso <a href="mailto:sara.dedosso@eoc.ch">sara.dedosso@eoc.ch</a>
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"> <li>• Relapsed or refractory Non-Hodgkin Lymphomas</li> </ul>	PI: A. Stathis <a href="mailto:anastasios.stathis@eoc.ch">anastasios.stathis@eoc.ch</a>
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"> <li>• Subjects with histologically or cytologically confirmed mCRPC</li> </ul>	PI: U. Vogl <a href="mailto:ursula.vogl@eoc.ch">ursula.vogl@eoc.ch</a>



## 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				
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 Degradar) 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 Degradar - SERD)	<ul style="list-style-type: none"> <li>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.</li> </ul>	PI: R. Condorelli <a href="mailto:rosaria.condorelli@eoc.ch">rosaria.condorelli@eoc.ch</a>
IBCSG 67-22 - PREcoopERA	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 Degradar - SERD), Triptorelin (LHRH analogue), anastrozole (aromatase inhibitor)	<ul style="list-style-type: none"> <li>Premenopausal women age <math>\geq 18</math> years</li> <li>Histologically confirmed, operable invasive breast carcinoma</li> <li>Eligible for upfront breast conservative surgery or upfront mastectomy</li> <li>Documented estrogen receptor (ER)-positive and human epidermal growth factor receptor-2 (HER2)-negative tumor</li> <li>Ki-67 <math>\geq 10\%</math> in diagnostic biopsy as determined per local assessment.</li> <li>ECOG PS <math>&lt; 2</math></li> </ul>	PI: L. Rossi <a href="mailto:lorenzo.rossi@eoc.ch">lorenzo.rossi@eoc.ch</a>



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"> <li>• 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</li> <li>• No prior cytotoxic or targeted therapy</li> <li>• No prior partial or complete esophagogastric tumor resection</li> <li>• ECOG <math>\leq</math> 1</li> <li>• Adequate hematological, hepatic and renal function</li> </ul>	PI: S. De Dosso <a href="mailto:sara.dedosso@eoc.ch">sara.dedosso@eoc.ch</a>
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"> <li>• Untreated, primary colorectal adenocarcinoma (&gt; 15 cm from the anal verge)</li> <li>• Colonoscopy with endoscopic biopsy for disease confirmation and correlative studies</li> <li>• Candidates for surgical resection prior to administration of any therapy</li> </ul>	PI: S. De Dosso <a href="mailto:sara.dedosso@eoc.ch">sara.dedosso@eoc.ch</a>
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"> <li>• 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</li> </ul>	PI: I. Colombo <a href="mailto:ilaria.colombo@eoc.ch">ilaria.colombo@eoc.ch</a>
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"> <li>• Histologically-confirmed diagnosis of endometrial carcinoma or carcinosarcoma</li> <li>• 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</li> </ul>	PI: I. Colombo <a href="mailto:ilaria.colombo@eoc.ch">ilaria.colombo@eoc.ch</a>
MS201924_0002	An open-label, multicenter, randomized Phase 2 study of the ATR inhibitor tuvusertib in combination with the PARP inhibitor niraparib or the ATM inhibitor lartesertib in participants with BRCA mutant and/or homologous recombination deficiency (HRD)-positive epithelial ovarian cancer that progressed on prior PARP inhibitor therapy.	Tuvusertib (ATR inhibitor) with niraparib (PARP inhibitor) or with lartesertib (ATM inhibitor)	<ul style="list-style-type: none"> <li>• Histologically or cytologically confirmed ovarian cancer</li> <li>• Tumors with mutations in the genes BRCA1 and/or BRCA2 and/or positive HRD status</li> <li>• Platinum-sensitive progression under treatment with PARPi.</li> </ul>	PI: I. Colombo <a href="mailto:ilaria.colombo@eoc.ch">ilaria.colombo@eoc.ch</a>



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"> <li>• CLL/SLL patients who are relapsed or refractory to prior therapy with a covalent, irreversible BTKi, BCL2i, and PI3Ki (cohort A)</li> <li>• CLL/SLL patients who are relapsed/refractory after ≥1 line of therapy and are BTKi treatment naïve (cohort B)</li> <li>• CLL/SLL patients with 17p deletion who are relapsed/refractory following ≥ 1 line of prior therapy (cohort C)</li> <li>• Patients with Richter's transformation who are relapsed or refractory following ≥ 1 line of prior therapy (Cohort D)</li> <li>• 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)</li> <li>• Patients with MZL (including splenic, nodal, extra nodal MZL) who are relapsed or refractory to a covalent irreversible BTKi and chemoimmunotherapy (Cohort F)</li> <li>• Patients with FL who are relapsed or refractory to chemoimmunotherapy, immunomodulatory agents (i.e. lenalidomide + rituximab) (Cohort G)</li> <li>• Cohort H: confirmed diagnosis of WM; patients who are relapsed or refractory to standard therapies for WM including chemoimmunotherapy and a covalent irreversible BTKi</li> </ul>	PI: D. Rossi <a href="mailto:davide.rossi@eoc.ch">davide.rossi@eoc.ch</a>
Other hematological diseases				
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"> <li>• Subject has documented diagnosis of MDS</li> <li>• Subject must be one of the following:</li> <li>• Refractory or intolerant to prior ESA (erythropoiesis-stimulating agents) treatment or ESA ineligible</li> <li>• Refractory to- /relapsed after prior HMA (hypomethylating agents) treatment</li> <li>• Refractory to- /relapsed after prior lenalidomide treatment</li> </ul>	PI: G. Stüssi <a href="mailto:georg.stuessi@eoc.ch">georg.stuessi@eoc.ch</a>



Lung				
AMG 757 - 20200041	A Phase 3, Open-label, Multicenter, Randomized Study of Tarlatamab in Combination With Durvalumab vs Durvalumab Alone in Subjects with Extensive-Stage Small-Cell Lung Cancer Following Platinum, Etoposide and Durvalumab (DeLLphi-305).	Tarlatamab (bispecific DLL3-targeted CD3 T-cell engager)	<ul style="list-style-type: none"> <li>• Histologically or cytologically documented ES-SCLC, or T3 to T4 due to multiple lung nodules that are too extensive or have too large tumor/nodal volume for a tolerable radiation plan.</li> <li>• Patients with prior LS-SCLC allowed if interval &gt; 6 months since end of previous therapy and progression</li> <li>• Completed 4 cycles of platinum-etoposide CTx with concurrent durvalumab as first-line treatment without disease progression.</li> <li>• Patients with 3 cycles of concurrent durvalumab eligible, provided 4 cycles of platinum-etoposide CTx are completed.</li> <li>• ECOG PS &lt; 2</li> </ul>	<p>PI: P. Frösch  <a href="mailto:patrizia.froesch@eoc.ch">patrizia.froesch@eoc.ch</a></p>
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)	<ul style="list-style-type: none"> <li>• Histologically confirmed NSCLC.</li> <li>• Stage IIB-IIIB (T1-4 N0-2)</li> <li>• Absence of EGFR mutation or ALK translocation</li> <li>• Primary tumour resectable and functionally operable</li> <li>• ECOG-PS &lt; 2</li> </ul>	<p>PI: M. Imbimbo  <a href="mailto:martina.imbimbo@eoc.ch">martina.imbimbo@eoc.ch</a></p>
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"> <li>• Resectable stage III NSCLC</li> <li>• Tumor is considered primarily resectable based on a multidisciplinary tumor board decision</li> </ul>	<p>PI: P. Frösch  <a href="mailto:patrizia.froesch@eoc.ch">patrizia.froesch@eoc.ch</a></p>
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"> <li>• Tissue confirmed, pre-treatment clinical stage IV NSCLC</li> <li>• ECOG PS ≤ 1</li> <li>• The primary tumor and all oligopersistent metastases must be amenable for radical LAT (surgery or radiotherapy)</li> <li>• 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</li> </ul>	<p>PI: P. Frösch  <a href="mailto:patrizia.froesch@eoc.ch">patrizia.froesch@eoc.ch</a></p>



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"> <li>• R/R after at least one prior line of therapy</li> </ul>	PI: A. Stathis <a href="mailto:anastasios.stathis@eoc.ch">anastasios.stathis@eoc.ch</a>
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"> <li>• Confirmed diagnosis of SMZL</li> <li>• Previously untreated disease</li> <li>• ECOG PS 0-2</li> </ul>	PI: M. Piroso <a href="mailto:maria.piroso@eoc.ch">maria.piroso@eoc.ch</a>
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)	<ul style="list-style-type: none"> <li>• 1st line</li> <li>• Resectable disease</li> </ul>	PI: C. Mangas <a href="mailto:cristina.mangas@eoc.ch">cristina.mangas@eoc.ch</a>
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)	<ul style="list-style-type: none"> <li>• Histologically or cytologically confirmed locally advanced or metastatic NSCLC with a documented ALK rearrangement</li> <li>OR</li> <li>• Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation</li> </ul>	PI: P. Frösch <a href="mailto:patrizia.froesch@eoc.ch">patrizia.froesch@eoc.ch</a>



**Urogenital**

<p>ACTIDIET-PRO</p>	<p>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.</p>	<p>Physical activity and diet</p>	<ul style="list-style-type: none"> <li>• Histology of adenocarcinoma of the prostate</li> <li>• Patients with PCa receiving ADT alone or ADT+NHT (Abiraterone, Enzalutamide, Apalutamide or Darolutamide)</li> <li>• Rising PSA (two consecutively rising PSA levels &gt; 25% above nadir at least three weeks apart), with no evidence of clinical or radiographic progression on instrumental evaluation</li> <li>• PSA doubling time &gt; 8 weeks</li> </ul>	<p style="text-align: center;">PI: U. Vogl <a href="mailto:ursula.vogl@eoc.ch">ursula.vogl@eoc.ch</a></p>
<p>HYPO-FOCAL SRT</p>	<p>A single arm phase II trial of ultrahypofractionated focal salvage radiotherapy for isolated prostate bed recurrence after radical prostatectomy.</p>	<p>Commercial LHRH agonists and radiotherapy</p>	<ul style="list-style-type: none"> <li>• Lymph node negative adeno-carcinoma of the prostate treated with radical prostatectomy (RP) at least 6 months before trial registration.</li> <li>• Evidence of measurable local recurrence at the prostate bed detected by PSMA PET/CT and mpMRI within the last 3 months</li> <li>• Non-metastatic (N0, M0) disease, as defined by a lack of nodal or distant metastases seen on PSMA PET/CT scan</li> <li>• Non-castrate levels of serum testosterone (<math>\geq 50</math> ng/dL)</li> <li>• Patients must not have previously received hormonal therapy (LHRH agonists, antiandrogen, or both, or bilateral orchiectomy)</li> </ul>	<p style="text-align: center;">PI: T. Zilli <a href="mailto:thomas.zilli@eoc.ch">thomas.zilli@eoc.ch</a></p>
<p>PEACE 6</p>	<p>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.</p>	<p>ADT +/- darolutamide (androgen receptor antagonist)</p>	<ul style="list-style-type: none"> <li>• Men with histologically or cytologically confirmed adenocarcinoma of the prostate</li> <li>• De novo metastatic disease defined by clinical or radiographic evidence of metastases</li> <li>• Ineligible for treatment with all of the following drugs: docetaxel, abiraterone, enzalutamide, apalutamide</li> <li>• 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) <math>\leq 21</math> kg/m<sup>2</sup> and/or &gt;5% weight loss in the last 6 months; Timed up and go test (TUG) &gt; 14 sec</li> </ul>	<p style="text-align: center;">PI: S. Gillessen <a href="mailto:silke.gillessensommer@eoc.ch">silke.gillessensommer@eoc.ch</a></p>



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"><li>• Histologically proven urothelial cell carcinoma of the bladder</li><li>• Location of tumor must allow placement of catheter without risk of bleeding</li></ul>	PI: U. Vogl <a href="mailto:ursula.vogl@eoc.ch">ursula.vogl@eoc.ch</a>
SAKK 08/23	Addition of Darolutamide to first line treatment of mCRPC: a randomized open label phase II trial	Darolutamide	<ul style="list-style-type: none"><li>• Progressive mCRPC</li><li>• One line of previous ARPI therapy for at least 18 months within mHSPC setting</li></ul>	PI: U. Vogl <a href="mailto:ursula.vogl@eoc.ch">ursula.vogl@eoc.ch</a>