

# CLINICAL TRIALS NEWSLETTER

Hospital Clínic Barcelona



#### Introduction

Welcome to the June 2025 edition of the Hospital Clinic Clinical Trials Newsletter. We are pleased to inform you about the trials that are currently recruiting.

If there are any patients in your hospital that you feel may benefit from enrolling in any of these trials, please send us an email and we will get back to you as soon as possible.

## **Ongoing Clinical Trials**

You can review the trials for all solid tumors and disease specific trials by clicking the following links.

- 1. All tumors
- 2. Breast Cancer
- 3. Colorectal Cancer
- 4. Esophageal and Gastric Cancer
- 5. **Gynecologic Cancer**
- 6. Head and Neck Cancer
- 7. Lung Cancer
- 8. Melanoma
- 9. Pancreatic and biliary tract cancer
- 10. Prostate Cancer
- 11. Renal Cancer
- 12. Urothelial Cancer
- 13. Central Nervous System Cancer

## **Ongoing Clinical Trials**

1. Advanced Solid Tumors (All tumors)

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
<u>APL-101-01</u> (SPARTA)	Phase I/II APL-101 (c-MET inh)	*Cohort C: Solid tumor type with MET amplif (mec. recist EGFR) *Cohort D: Solid tumor type with cMET fusions *Cohort E: Primary CNS tumors with MET (MET inhibitor naive)	For all cohorts:  - After SOC but no more than prior 3L  - Patients with any prior c-Met inhibitor are excluded
<u>20220073</u>	Phase I AMG305 Dose escalation	Advanced solid tumours: CRC, NSCLC, mesothelioma, PDAC, gastric, HNSCC, epithelial ovarian cancer, cervical carcinoma, uterine endometrial carcinoma, TNBC	-After SOC therapy -Exclusion: presenting an ongoing or active infection requiring IV anti-infective therapy less than 1 week prior to treatment.
20220028	Phase I AMG 355 +- Pembrolizumab	Advanced Solid Tumors Dose Escalation: Non- small cell lung cancer (NSCLC), colorectal cancer (CRC), gastric cancer (GC), melanoma (MEL).  Dose Confirmation: Lead Indication based on data from dose escalation.  Dose Expansion: Tertiary Lymphoid Structure positive (TLS) CRC, GC, and NSCLC. Group A: NSCLC, CRC, GC,	Inclusion: Mandatory fresh biopsy in C2 (before the restaging of CT- scan) Exclusion: Previous ttm with an anti-PD-1, anti- PD-L1, or anti PD- L2 agent or with an agent directed to another stimulatory or co- inhibitory T-cell and discontinued from that ttm due to an immune- related AE.

		and melanoma. <b>Group B</b> : NSCLC, CRC, GC.	
SRP-22C102	Phase I ADU- 1805 *Ask if slot available	Advanced Solid Tumors	Metastatic or unresectable solid tumors
<u>DS7300-203</u> (IDeate Pantumor02)	Phase Ib/II Ifinatamab Deruxtecan (I- DXd ADC anti B7-H3)	Advanced Solid Tumors:  *Endometrial Carcinoma or carcinosarcoma. MSI or MSS. * HNSCC	-Endometrial cancer: PD to Platinum-based CT and IO. Candidates to 2L-4L HNSCC: PD to Platinum-based CT and IO. (Combinado o

- \* PDAC
- \* HCC met or unresectable
- \* Esophageal

ADC/GEJ/Gastric cancer

- \* Urothelial Carcinoma
- \* Biliary tract or gallbladder carcinoma
- \*Breast cancer (Her2low or neg)
- \*Cutaneous Melanoma

secuencial). Candidates to 2L

and 3L.
- PDAC: PD to
Gemcitabine-

based CT. Candidates to 2L.

- HCC PD to 1L containing IO BCLC Stage B o C. Child

Pugh A. ALBI Grade1. Candidates

to 2L.

- Esophageal ADC/GEJ/Gastr ic cancer: PD to 1L. If HER2+ prev ttm. Candidates to

Candidates to 2L.

- Urothelial Carcinoma: PD prev IO line and CT and/or EV

Candidates to 2L-4L.

- Biliary tract or gallbladder carcinoma: Candidates to 2L

and 3L.
- Breast cancer
(Her2low or neg).

Her2low PD to T-Dxd Candidates to 3L and 4L - Cutaneous

Melanoma: PD to at least 1L of PD-L1 inh. BRAF mut prev inh BRAF/MEK

#### 1. Breast Cancer

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria		
	EARLY BREAST CANCER – NEOADJUVANT				
RIBOLARI <u>S</u> (SOLTI- 1911)	Phase II Ribociclib letrozole	*HR+ (ER>10%)  *Her2neg  *Ki67≥20%  *Or high genomic risk (Oncotype DX ≥26, Mammaprint® = Risk of Recurrence High or Prosigna® ROR ≥ 60)  *Grade 2 or 3  *Stage II (T1N1, T2N0, T2N1, T3N0)	-Neoadjuvant and adjuvant for 3 years>40 years-old -Pre/post menopausal -Exclusion: Bilateral breast cancer (multifocal/multicentri c are allowed)		
TROPION BREAST04 (D926QC00001)	Phase III - Dato+Durva -> Durva +-/ QT - Pembro + QT -> Pembro +/- QT	Stage II-III (T1cN1- N2, T2N0-N2, T3N0-N2, T4a- dN0-N2) NO ER o PR ≥10%	Bilateral are allowed		
	EARLY BREAST	CANCER - ADJUVAN	т		
<u>FLAMINGO-</u> <u>01</u> (GLSI-21- 01)	Phase III GLSI-100 vs placebo	* Stage I-III + residual disease * Stage III + PCR	Last dose trastuzumab or TD-M1 <1year Concurrent ET permited Concurrent Neratinib PROHIBITED		
CAMBRIA-1 (D8531C00002)	Phase III Camizestrant vs Standard Endocrine Therapy	High-intermediate risk factors: *T3-4 (>50mm), any nodal status *T1c-T2 (10-50mm) N0-1 (1 positive ipsilateral ALN) with at least 1 of:  ■ GH3 ■ High- risk Prosig na ■ Ki67 ≥ 20% central ■ Any size with	24 to 63 months of previous adjuvant ET		

		N1 (≥2 positive ipsilateral ALN)	
CAMBRIA-2 ( <u>D8535C00001</u> )	Phase III Camizestrant +/- Abemacicli b vs Standard Endocrine Therapy +/- Abemaciclib	Multicentric/multifo ca l OK ER ≥ 10% High-intermediate risk factors: *T4 or ≥ 2 lymph nodes	Max 12m desde la IQ Max 12w de HT (contando NA+ADJ) NO PCR o RCB-0

*T1c-T3 + pN0-1mic with at least 1 of:				
EMBER-4 (J2J-MC-JZLH)	Phase III Imlunestrant vs Standard Endocrine Therapy	High-intermediate risk factors:  *≥ N2: ≥ 4 ipsilateral positive ALN  *N1: 1-3 ipsilateral positive ALN with at least one of:  • ≥ 50mm  • GH3  • 20-50mm  + GH2  *N0  • ≥50mm  • GH3  • 10-50mm  • 20-50mm  • 20-50mm  • GH3	24 to 60 months of previous adjuvant ET	
MIRADOR (MedOPP485)	Phase II  * Standard Endocrine Therapy  * Giredestrant  + Abemaciclib  * Giredestrant  + Inavolisib  Recruitment interrupted	Without NA-QT: - pN2/N3 - pN1, pT3-T4 and/or high genomic risk (Prosigna>40) and or Grade 2/3 + KI67 > 20% With previous NA-QT: - Residual invasive ypT3 or ypT4 - Any macroscopic LN	2-4 years of previous adjuvant ET	
	METASTATIC HR	HER2- BREAST CAN	CER	
ELAINE-3	Phase III Lasofoxifen+Abe m aciclib vs fulvestrant+Abe ma ciclib	ER+/HER2- Breast Cancer with an ESR1 Mutation	- ESR1m in blood or tissue. Central. (Guardant Health) -Previous chemotherapy: YES -Max 2L previous HT -Previous ICDK4/6: Yes, not abema	

DYNASTY BREAST02	Phase III DB1303 vs Capecitabine, Paclitaxel, or Nab- Paclitaxel (Physician's choice)	HR ≥1 HER2 low +1/+2 (CENTRAL)	-HT 2L or <6m on CDKi -Exclusion: *Previous line of CT. *Prior HER2 +3. *History of pneumonitis
ELECTRA	Phase II Elacestrant + abemaciclib in women	HR+, HER2Neg, M1 cerebral	-Previous treatment: At least 1 prior ET Up to 2 lines of CT Up to 2 lines of CDK -Pre/perimenopausal must be co given a LHRH agonist -Exclusion: Prior therapy with elacestrant or abemaciclib in metastatic setting
ACROSS- TROP2 SOLTI-2201	Phase II Sacituzuma b Govitecan	HR+/HER2-	-Disease refractory to CDK4/6 inh, recurrence during/within 12m after the end of adj ttm or PD during or within 6m after end of ttm for adv/met disease -≤1 prior line of CT or ab- drug conjugate -Evaluable disease -Biopsies (screening, on treatment and EOT)
<u>SABINA</u>	Phase II MEN1611 +- Eribulin	Metaplastic BC Known HR status/Her2 negative. PIK3CA mutation and/or PTEN loss (central prescr)	At least one, but no more than four, prior lines of systemic therapy for advanced disease
CAAA603B12101	Phase Ib [177Lu]Lu- NeoB + ribociclib + fulvestrant	ER-positive, HER-2 negative GRPR-positive	-BC experiencing early relapse -Measurable or bone mixte
CAAA603D12101	Phase I/II [177Lu]Lu- NeoB + capecitabine	ER-positive, HER-2 negative GRPR-positive	-After PD on prev endocrine therapy + CDK4/6 inh - Measurable

			or bone mixte
PUMA-ALI- 120 ALISCA- BREAST1	Phase II Alisertib+ET	HR+/Her2-	After 2L of ET Prior ttm must include CDK4/6i CT naive
CAPITANA <u>D3612L00005</u>	Phase IIIB Capvaserti b + Fulvestrant	HR+/Her2- PIK3CA/AKT1/P TEN- altered	≤ 2L previous ET (+/- iCDK4/6) ≤ 1L previous CT
	METASTATIC H	IER2+ BREAST CANCE	ER .
DEMETHER ( <u>MEDOPP562</u> )	Phase II 6 cycles of induction therapy T-DXd + Maintenance therapy Phesgo SC	Centrally confirmed Her2pos	1L CT Stable brain metastases Participants may have received CT or HER2- targeted therapy in the (neo)adjuvant setting with a disease-free

			interval from completion of the systemic ttm (excluding HT) to metastatic diagnosis ≥ 12 months.
<u>ZN-A-1041-101-US</u>	Phase Ic Dose Expansion (Combination Therapy):  Arm 2: ZN-A-1041 in combination with T-DXd	Unresectable locally- advanced or metastatic HER2+ breast cancer with or without brain metastases	Brain metastases: - Previously treated, or untreated as long as no local therapy is needed during the trial period.  Arm 2: candidates to 2L therapy with T- DXd
	Arm 3: ZN-A-1041 in combination with PHESGO		Arm3: patients have received 4-8 cycles (21- day cycles) of prev ttm with trastuzumab, pertuzumab, and taxane as 1L for advanced HER2+ BC with no evidence of PD. Patients can consent during taxane and complete screening prior to dosing of ZN-A-1041.
JZP598-303-01 EmpowHER	Phase III, Zanidatamab + physician's choice CT vs Trastuzumab+phy si cian's choice CT	Metastatic HER2- positive PD progressed on, or intolerant to, previous trastuzumab deruxtecan ttm	At least 2L of HER2- directed therapy for met disease and not more than 4L of HER2- directed therapy. Central Her2 confirmation
	METASTATIC T	NBC BREAST CANCE	R
<u>SABINA</u>	Phase II MEN1611 +- Eribulin	Metaplastic breast cancer Known HR status/Her2 negative PIK3CA mutation and/or PTEN loss (central prescreening)	At least one, but no more than four, prior lines of systemic therapy for advanced disease

TILS001  Recruitment currently on hold	Phase I/II Lymphodeplectiv e Chemotherapy (au xiliary medication); TILs product (IMP) and IL-2 (auxiliary medication).	PD1 positive selected TILs HER2negative, ER and PgR expressions <10%.	-After CT containing taxane for metastatic TNBC prior to study enrollmentEligible participants are expected to have completed 6 to 12 cycles with no PDRun-in safety phase: TNBC after multiple lines of CT are permitted.
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#### 2. Colorectal Cancer

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecul ar Characteristics	Prior lines/Other criteria
<u>BNT122</u>	Phase II RO7198457 versus watchful waiting	Patients with ctDNA positive	Resected Stage II (high risk) and Stage III
LP-IRI-HCPB (GEMCAD- 1802)	Phase II FOLFOX6 m + monoclonal Ab (anti-EGFR or bevacizumab) +- hepatic chemoembolizatio n (Lifepearls-Irinotecan)		Metastatic disease limited to the liver with bad prognosis
GEMCAD 2102 (PEMBROLA )	Phase II Pembrolizuma b + Olaparib	Homologous- recombination Deficient (HRD)	At least 2 and no more than 5 prior lines
SGNTUC-029	Phase III Tucatinib+Trastuzum ab + mFOLFOX6 vs mFOLFOX6 +- Cetuximab or Bevacizum ab	HER2+	Candidates to 1st line
GSK 219606 (Azur2)	Phase III Perioperative Dostarlimab Monotherapy vs SOC	*Untreated resectable Colon Cancer *T4N0 or Stage III *dMMR/MSI-H	
MS202329 000 1	Phase I Antibody- Drug Conjugate M9140	Colorectal cancer	Max 2 previous regimens for metastatic disease but no more than 2 (with the exception of patients with MSI-H disease or BRAF positive disease who are allowed to have 3L previous).

<u>MK-5909</u>	A Phase 2  Nonrandomized, Open- label Evaluate the Safety and Efficacy of Raludotatug Deruxtecan	Gastrointestinal Cancers  • Cohort 1: PDAC • Cohort 2: BTC • Cohort 3: CRC • Cohort 4: GC/GEJ AC	• Cohort 1: 2L • Cohort 2: 2L/3L • Cohort 3: 2L • Cohort 4: 3L
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## 3. Esophageal and Gastric Cancer

Clinical Trial/Cont act	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
<u>MK-5909</u>	A Phase 2  Nonrandomized, Open- label Evaluate the Safety and Efficacy of Raludotatug Deruxtecan	Gastrointestinal Cancers  • Cohort 1: PDAC • Cohort 2: BTC • Cohort 3: CRC • Cohort 4: GC/GEJAC	• Cohort 1: 2L • Cohort 2: 2L/3L • Cohort 3: 2L • Cohort 4: 3L
<u>CLARITY-</u> <u>D9802C0001</u>	A Phase III  Multi-center, Openlabel, Sponsorblinded, Randomized Study of AZD0901  Monotherapy Compared with Investigator's Choice of Therapy	Advanced/Metastati c Gastric or Gastroesophageal Junction Adenocarcinoma Expressing Claudin18.2	Second- or Later-Line

Please see also section 1. Advanced solid tumors (All tumors)

## 4. Gynecologic Cancer

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
SIENDO 2 (XPORT-EC-042)	Phase III Selinexor vs Placebo  Maintenance treatment of patients in response after systemic therapy.	*Advanced or recurrent endometrial carcinoma * p53 WT	
IMGN853-0421 (GLORIOSA)	Phase III Mirvetuxima b Soravtansine + Bevacizuma b v	FRα-high recurrent platinum- sensitive epithelial ovarian, fallopian	No PD after 2L

	Bevacizuma b alone	tube, or primary peritoneal cancers	
ESR-20-21103 (STROBE)	Phase II  characterize the status of HRD leading to a benefit from Olaparib + Bevacizumab	*High Grade Serous or Endometrioid Ovarian, Fallopian Tube, or Peritoneal *Advanced FIGO Stage III-IV	After SOC 1L
<u>MK2870-020</u>	Phase III  MK-2870  Monotherapy vs  Treatment of  Physician's  Choice	Participants with Recurrent or Metastatic Cervical Cancer	

MS201924_000 2	Phase II  Tuvusertib +-  Niraparib  +-Lartesertib	Patients with BRCA mutant and/or homologous recombination deficiency (HRD) positive epithelial ovarian cancer	PD on prior PARP inh therapy
GS-US- 6826769	Phase III Sacituzumab Govitecan Versus Treatment of Physician's Choice	Endometrial Cancer Prior Platinum-based CT and Anti-PD- 1/PD-L1 Immunotherapy	Up to 3l of systemic therapy Documented evidence of recurrent/persiste nt endometrial cancer
MS201924-0020	Phase Ib Part A2 tuvusertib (anti ATR) + lartesertib (anti ATM)	Endometrial cancer with ARID1A mutation	-Previous lines with platinium is requiered -If dMMR, previous treatment with IO requiered
HERTHENA PANTUMOR 01	Phase II PatritumabDeruxtec an (HER3-Dxd) !!mandatory ask for a slot	-Endometrial Cancer -Cervix cancer	-Ovarian: PD between >4w and <6 months of last dose PBCEndometrial: max 3 prior lines, containing PBC and anti-PD(L)1 -Cervix: at least 1 prior line with anti- PD(L)1 +/- factor- directed ADC

#### 5. Head and Neck Cancer

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria	
LOCALLY ADVANCED HNSCC				
NANORAY-312	Phase II ArmA: NBTXR3 +RDT +/- Cetuximab ArmB: RDT +/- cetuximab	*LA-HNSCC	Candidates to 1L	

TTCC-2022-01- RADIAN	Phase Ib/II Neoadjuvant phase: Dostarlimab + Niraparib Concurrent Phase: Cohort A: RDT + cisplatin Cohort B: RDT + Niraparib Maintenance	LA-HNSCC	Cohort A: previously treated with cisplatin- based CT- RT Cohort B: unfit for cisplatin-based CT-RT
	phase: Dostarlimab + Niraparib		

<u>D798EC000</u> <u>01</u>	Phase III Volrustomig (MEDI5752) as Sequential Therapy vs Observation	LA unresected Stages III, IVA or IVB HNSCC	After receiving definitive concurrent chemoradiotherap y (cCRT) and no PD
	RECURRENT/	METASTATIC HNSCC	
BNT113-01	Phase II Pembrolizumab +/- BNT113	*R/M HNSCC *Oropharynx HPV16+ *PDL1 CPS <u>&gt;</u> 1	-Candidates to 1L
INBRX10 6- 01-201	Phase II/III INBRX- 106 + Pembrolizumab vs Pembrolizumab	Patients with first- line R/M HNSCC expressing PD-L1 (CPS ≥20),	-Candidates to 1L

#### 6. Lung Cancer

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
	EAF	RLY STAGE NSCLC	
<u>DUMAS</u>	Phase II CT + nivolumab> if R0: nivolumab	EGFR/ALK/ROS1 WT	-Candidates to neoadj+adjuva nt treatment
<u>EUCALYPTUS</u> 20230127	Phase III ABP 234 vs pembro, after the adjuvant Chemotherapy Standard Treament	Any PDL1	-Candidates to adjuvant treatment
NEOCOAST-2	Phas e II Arm 6: rilvegostom ig + CT Arm7: dato-Dxd + rilvegostomig + single platinum	EGFR / ALK WT PD-L1 >1%	-Candidates to neoadj+adjuva nt treatment

ARIAN GECP23/0 3	Phase II Sacituzumab and Zimberelima b	EGFR WT Any PD-L1	-Candidates to adjuvant treatment
	ADVANCED NSCLC	WITH DRIVER (FIRST LI	NE)
<u>APL-101-01</u> (SPARTA)	Phase I/II APL-101 (c-MET inh) Cohort A-1 Cohort C-1 Cohort C-2	*MET ampl *EGFR WT	-MET ampl & WT EGFR Candidates to 1L to 4L
TAS6417-301	Phase III Zipalertinib + pemetrexed + platin VS Pemetrexed + platin	EGFR ex20ins	Candidates :1L Mandatory: block tissue, slides or cell block
TAS6417-201	Phase II b Zipalertinib (TAS6417/CLN-081	EGFR ex20ins (cohort D, EGFRm non common)	Candidates :1L Block tissue, slides or cell block
KRYSTAL-07	Phase III Cohort 3> Adagrasib 400 mg BID (until pd) + pembrolizumab 200 mg IVQ3W Cohort 4> pembro 200 mg IV Q3W	KRAS G12C PDL1>50 %	Candidates :1L Mandatory: 15 slides
AMG19 3 202301 67	Phase IB AMG 193 + carbo + pacli + pembro vs AMG 193 + carbo + peme + pembro VS AMG193 + pembro	MTAP-deletion	Candidates :1L Mandatory: 11 slides
AMG51 0- 201903 41	Sotorasib + Platinum doublet VS pembrolizumab + Platinum Doublet	KRAS G12C PD-L1 negative (<1%)	Candidates :1L NSCLC (Non squamous) Mandatory: 10 slides

SOHO-02 /BAY ER 22615	Phase III BAY 2927088 20 mg BID VS Cis/carbo) + Permetrexed + Pembrolizumab	HER2 mut	Candidates :1L Mandatory: 15 slides
TROPION- LUNG- 14 D516NC00001	Phase III osimertinib + Dato- DXd VS osimertinib	EGFR mut +	Candidates :1L Mandatory: 6 slides+blood sample
	DVANCED NSCLC WITH		RD LINE)
SAFFRON	Phase I-II Osimertinib and Savolitinib vs Chemotherap y	EGFR (del ex19, L858R y/o T790M) y MET positive (overexpressed and/or mutated)	-Candidates ≥ 2nd line Mandatory Tumor tissue(5 slides for IHC+6 slides FISH)
MK 2870 004	Phase I/II MK-2870 (anti-TROP- 2) vs. Docetaxel or Pemetrexed (PI decision)	EGFR ex19del/ex21 L858R, ALK, ROS1, BRAF V600E, NTRK, MET exon 14 skipping, RET, or less common EGFR mutations	Candidates ≥ 3 <sup>RD</sup> line Mandatory Tumor tissue & need ok central

(exon 20 S768I, exon 21			
		L861Q, and/or exon 18 G719X)	
<u>APL-101-01</u> (SPARTA)	Phase I/II APL-101 (c-MET inh) Cohort A-1 Cohort C-1 Cohort C-2	*MET ampl *EGFR WT	-MET ampl WT EGFR - Candidates to 1L to 4L -Mandatory tumor tissue (10+ slides)
	ADVANCED NSCLC	NO-DRIVER (FIRST LII	NE)
<u>Tropion LUNG</u> <u>08</u> DS1062-A- U304	Phase III Ph Dato-DXd + Pembrolizumab vs Pembrolizumab ase II	*NSCLC (SQ+non- SQ) *PD-L1 > 50%	-Candidates to 1L -Mandatory tumor tissue 10 slides
Tropion LUNG04 D926FC00001	Phase Ib 6.0 mg/kg Dato-DXd + 1120mg Durvalumab + Carboplatin AUC	NSCLC Squamous	Candidates to 1L -Mandatory tumor tissue 20 slides
KEYMAKER- U01 // MK3475-01G	Phase II Arm1:pembro+doble t CT Arm2: HER3-Dxd + pembro	EGFR + ALK + ROS + KRAS WT PD-L1 any	-Candidates to 1L
TROPION – LUNG07 D926FC00001	Phase III Dato-DXd+Pembro vs Dato- DXd+Pembro+CT vsPembro+Pemetrexe d+ CT	NSCLC PD-L1 <50%	-Candidates to 1L -Mandatory tumor tissue 16 slides
TROPION-10 (D7632C0000 1)	Phase III Deruxtecan (Dato- DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy VS Pembrolizumab	NSCLC	-Candidates to 1L -Mandatory tumor
	ADVANCED NSCLC NO-I	DRIVER (SECOND-THII	-
SPECTA (BIORADON)	Molecular characterization of NSCLC patients and exposure to indoor radon in Europe		-Any stage of disease

ARTEMIA- OSE2101C302 M24-536	Phase III OSE2101 (vaccine SC) versus docetaxel Phase Ib- II ABBV- 400 + Budigalimab	HLA-A2 + EGFR, ALK, ROS1 WT Non-sq NSCLC	-Candidates 2nd line Blood sample  -Candidates 2nd line -Mandatory tumor: <12 months archival or if more fresh sample
FS222-19101	Phase I Part B FS222 (CD137/PD-L1 Bispecific Antibody)  Mandatory pre treatment biopsy (or archival tumor tissue <6 months)) + mandatory on treatment biopsy.  *Ask if slot available, they are limited.	NSCLC EGFR, ALK, ROS wt	Max 3L prev ttm. Previously ICI is permitted If prior ICI, SD-PR or CR is required. If prior ICI, local PD- L1 status is required. Measurable disease RECIST 1.1 Prior anti- PD- L1/PD-1 therapy are eligible if therapy was discontinued ≥28days No more than 1 line of a prior ICI. Exclusion: Prior ttm with another co- stimulatory T receptor (C137,OX40,CD40,C D2 7,GITR)
	SMALL CE	ELL LUNG CANCER	
<u>PEERS</u>	Phase II Pembrolizumab + Lenvatinib + Carboplatino + Etopósido	SCLC	-Candidates to 1L -16 Slides tumor tissue
20230016 (DeLLp hi 306)	tarlatamab 10 mg Q2W vs placebo	SCLC	Candidates to has completed chemoradiother apy without progression
<u>DS7300-188</u>	Phase III Ifinatanab deruxtecan Vs topotecan	SCLC	-Candidates to 2L -Tissue biopsy: archival less than 6 m or after the last treatment

<u>Debio 0123-</u> <u>SCLC- 104</u>	Phase I Debio 0123 + carboplatino+etoposido	SCLC	-Candidates to 2L -Archival tissue. 10 slides
MK6070-002	Phase IB/II MK-6070 +/- I-DXd	SCLC	-Candidates to at least 1 prior lines -Archival tissue 18 slides

#### 7. Melanoma and skin cancers

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
ALK 4230-006	Phase II Cohort 2:nemvaleukin monotherapy	Open cohort: Mucosal melanoma	Previous antiPD (L)1 inh
IOV-MEL-301	Phase III LN-144 + pembrolizumab	Untreated, unresectable or metastasic melanoma	Max 1 line, metastasic treatment naïve
IMCgp100-203	Phase II/III Tebentafusp vs	Advanced Melanoma HLA- A*02:01 positive	Previously treated
	tebentafusp +		
	pembrolizumab vs		
	investigator choice		
PRISM-MEL- 301 (IMC- F106C-301)	Phase III IMC- F106C+Nivolumab vs Nivolumab Regimens	Advanced Melanoma HLA- A*02:01-Positive Participants	Previously Untreated
FS222-19101	Phase I Part B FS222 (CD137/PD-L1 Bispecific Antibody) Mandatory pre-ttm biopsy (or archival tissue <6 months)) + mandatory on ttm biopsy.	Melanoma	-2L of prior ICI containing regimens are allowed -ECOG-PS 0-2 -Mandatory pre and on treatment biopsy (or archival tumor tissue <6 months))
	*Ask if slot available, they are limited.		

## 8. Pancreatic and biliary tract cancer

Clinical Trial/Conta	Trial/Drug act	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
HERTHENA PANTUMOR 1	Phase II PatritumabDeruxte can (HER3-Dxd) !!mandatory ask for a	Pancreatic cancer	- at least 1 prior line -no prior irinotecan allowed
<u>MK-5909</u>	Phase II Raludotatug Deruxtecan	Gastrointestinal Cancers  Cohort 1: PDAC Cohort 2: BTC Cohort 3: CRC Cohort 4: GC/GEJAC	<ul><li>Cohort 1: 2L</li><li>Cohort 2: 2L/3L</li><li>Cohort 3: 2L</li><li>Cohort 4: 3L</li></ul>
PRIMS-1	Phase III  Quemliclustat+CT	Treatment-Naive Metastatic	
	vs Placebo+CT	Pancreatic Ductal ADC	

Please see section 1. Advanced solid tumors (All tumors)

#### 9. Prostate Cancer

Clinical Trial/Contact	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
AMG509	Phase I	mCRPC	Mandatory tumor
20180146	Part 1: AMG509 1.5mg		tissue (Archive or
	Part 4a: AMG509 1.5mg +		fresh)
	abiraterone + prednisone <del>Part 4b: AMG509</del> <del>1.5mg +</del>		SLOTS AVAILABLE
	<del>enzalutamide</del>		

<u>C2321001</u>	Phase I Part 1C: Tazemetostat (PF- 06821497, EZH2 inhib)	*mCRPC *Elevated PSA only.	BC Relapse/PSA- only Disease; or Bone only mtx ± nodal disease; or Nodal disease
	Reclutament on- hold, expected in June		(measurable nodal disease, no bone disease); or Visceral measurable (lung, liver, adrenal, CNS) disease (± other sites).
PEACE6-	Phase III	De Novo Metastatic	-Candidates to 1L
<u>Vulnerable</u>	Experimental: ADT +	Prostate Cancer	
	darolutamide	Patients With	
	Placebo Comparator: ADT	Vulnerable Functional	
	+ placebo	Ability	
CELC-G-201 Celcuity	Phase I Gedatolisib + Darolutamide <b>Reclutament on-hold</b>	*mCRPC	-1 NHT -No Doce allowed in mCPRCNo previous lutecium allowed.
<u>C16-174</u> DORA	Phase III Doce +/- radium	mCPRC	-Permited Chaarteed if no PD > 6m post DoceMax 4L of previous treatment
MS201924- 0020	Phase Ib Part A2 tuvusertib (anti ATR) + lartesertib (anti ATM)	mCPRC	-ATM mutation -max 3 prior lines -previous ttm with taxane & nonsteroidal antiandrogen are required

MK5684-004	Phase III	mCRPC	PD on or after prior tt with one Next generation Hormonal Agent (NHA)
C2321014	Phase III PF-06821497 (Mevrometostat) + Enza vs Doce or Enza	mCRPC	Prev. Treated with Abiraterone
TEAM-PC	Phase II Talazopari b + Enzalutamide (1L)	mCRPC	PD to Abiraterone

#### 10. Renal Cancer

Clinical	Trial/Drug	Cancer	Prior
Trial/Conta		Subtype/Molecul	lines/Other
ct		ar Characteristics	criteria

Please see also section 1. Advanced solid tumors (All tumors)

#### 11. Urothelial Cancer

Clinical Trial/Contac t	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
SOGUG- 2020- IEC(VEJ)-11 (NEOWIN)	Phase II Cetrilimab + Erdafitinib vs erdaftinib	Cisplatin-ineligible patients with muscle- invasive bladder cancer (MIBC) FGFR +	Neoadjuvant
HERTHENA PANTUMOR01	Phase II PatritumabDeruxtec an (HER3-Dxd) !!mandatory ask for a slot	Unresectable or metastatic urothelial carcinoma of the bladder, renal pelvis, ureter, or urethra.	Relapsed or PD after ttm with ≥1L(max of 3L) that contains anti- PD-(L)1 Only slots for previous ttm EV+ICI
BT8009-230 (Duravelo-2)	Phase II/III BT8009 (+- pembro)	Locally adv or mtx Urothelial Cancer	Candidates to 1L Recruitment currently on

			hold
SGNDV-001	Phase III Disitamab Vedotin + Pembro vs CT	Locally Adv. or mtx Urothelial Carcinoma HER2 (IHC 1+ and Greater)	1L
<u>M25-204</u>	Phase II Livoniplimab + Budigalimab vs Taxol/Doce/Gem	Mtx urothelial Carcinoma	≥2L (after PD to IO and platinum)
SASAN- SPARING	Phase II (Neoady Gem-CDDP – Restaging) – Manteniment Sasanlimab vs Cistectomia	Localized muscle- invasive urothelial cancer (MIBC)	Neoadjuvant
MK-3120-002	Phase I/II ADC anti nectina - 4 + payload (inh topoisomerasa I)	Urothelial carcinomas of the bladder, kidney, pelvis, or urethra. Histological variants are accepted as long as urothelial histology is predominant (neuroendocrine/s mal l cell variants are not accepted).	At least 1L of ICI ttm and at least 1L of CT or EV.  Prior FGFR inh accepted.  Maximum 4L of prior ttm

# 12. Central Nervous System Cancer

Clinical Trial/Contac t	Trial/Drug	Cancer Subtype/Molecular Characteristics	Prior lines/Other criteria
<u>CAN201</u>	Phase I/II Azeliragon + conventional therapy Ask if slot available	GBM	Newly diagnosed patients
SC9-GBM-03	Phase III SonoCloud-9/ Carboplatin	GMB	first recurrence glioblastoma
IVY-P3-24-021	Phase III GSK3985771/nirapari b	GMB	newly-diagnosed, MGMT unmethylated glioblastoma
ONC201-108	Phase III ONC201/Placebo	*Diffuse glioma *H3 K27M-mutant	Newly diagnosed patients