

THORAX

Tous ces essais sont à retrouver sur ACTIS Oncology sur l'application Oncoclic pour un adressage facilité de vos patients, télécharger l'application :



STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
AGADIR	II	Atezolizumab + BDB001 + radiothérapie	3	NSCLC	Refractory anti PD-1/L1	
CFT1946-1101	I/II	CFT1946	Phase 1 (escalade de dose)	NSCLC	BRAFi, platinum-based therapy (if eligible), and an immunotherapy regimen including ICI (in any sequence or in combination)	If the immunotherapy regimen (or the immunoncology combination) was given in the neoadjuvant or adjuvant setting, subjects are eligible if they progressed either on treatment or within the 6 months following completion.
LOXO-RAS-20001	Ib expansion	LY3537982	B8	NSCLC with Brain metastasis	KRAS G12C TUMOR TISSUE OR LIQUID BIOPSY	Patient must have progressed/be intolerant/ineligible for immunotherapy and platinum based therapy No mutation : EGFR, ALK, BRAF (V600), MET (exon 14), ROS1, RET or NTRK 1/2/3
		LY3537982 + pembrolizumab + pemetrexed + platinum therapy	B9	NSCLC 1st line	KRAS G12C TUMOR TISSUE OR LIQUID BIOPSY	
		LY3537982 + pembrolizumab	G	NSCLC 1st line	KRAS G12C TUMOR TISSUE OR LIQUID BIOPSY	
Regomune	II	Regorafenib + Avelumab	P	Malignant pleural mesothelioma		At least one line and max 1 line of PD(L)1/CTLA-4 mAb (received at least 4 month), anti PDL1 not mandatory



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R7075-ONC-2009	I/II	REGN7075 + Cemiplimab+chimiotherapie	C	NSCLC	Advanced or metastatic NSCLC do not have previously documented targetable molecular alterations (eg, ALK, ROS1, EGFR, Met Ex14, etc)	anti-PD-1/PD-L1 naïve no prior systemic treatment for recurrent or metastatic NSCLC (adjuvant or neoadjuvant systemic treatments will not be counted as a prior line)
		REGN7075 + Cemiplimab+chimiotherapie	G	EGFR-mutant NSCLC post third generation TKI	NSCLC that harbors EGFR Exon 19 deletion - NSCLC that harbors EGFR L858R mutation - NSCLC with activating EGFR exon20 insertion - NSCLC with exon 18/21 atypical mutations, Stable CNS disease allowed, Small cell transformation is excluded	anti-PD-1/PD-L1 naïve Chemotherapy naïve Have received treatment with a third generation TKI : For patients whose tumors harbor previously documented EGFR Exon19 deletion or L858R mutation, prior osimertinib or other third generation TKI treatment is required
		REGN7075 + Cemiplimab	H	EGFR-mutant NSCLC post TKI	locally advanced or metastatic non-squamous NSCLC, NSCLC that harbors EGFR Exon 19 deletion - NSCLC that harbors EGFR L858R mutation - NSCLC with activating EGFR exon20 insertion - NSCLC with exon 18/21 atypical mutations	anti-PD-1/PD-L1 naïve Have received treatment with a third generation TKI : For patients whose tumors harbor previously documented EGFR Exon19 deletion or L858R mutation, prior osimertinib or other third generation TKI treatment is required Have received treatment with platinum-doublet chemotherapy



Senology

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
INCB123667-101	I	INCB123667	Part 1b Group 4	TNBC		2 prior lines of chemotherapy max
REGOMUNE	II	Regorafenib + Avelumab	L	TNBC		At least one line and max 1 line of PD(L)1 mAb (received at least 4 month) anti PDL1 mandatory
RLY 2608-101	I	RLY-2608 + Fulvestrant	2	group 1a : Advanced/metastatic breast cancer PIK3CAmut	PIK3CAmut, HR+, HER2-RP2D1 (600mg BID) Expansion	with NO prior PI3K alpha inhibitor RP2D1 (dose recommended 1)
		RLY-2608 + Ribociclib 400mg + Fulvestrant	1	Advanced/metastatic breast cancer	PIK3CAmut HR+ HER2-Dose escalation	with NO prior PIK3CA α inhibitor
		RLY-2608 + Ribociclib 600mg + Fulvestrant	1	Advanced/metastatic breast cancer	PIK3CAmut HR+ HER2-Dose escalation	with NO prior PIK3CA α inhibitor
STX-487-101	I/II	STX-478	Part 1,2A1	Breast cancer	PI3KαH1047X mutation or other kinase domain mutations, HR+/HER2-	Must have received for stage III or IV disease : at least 1 CDK4/6 inhibitor regimen at least 1 anti-estrogen therapy and no more 2 prior systemic chemotherapy No prior treatment with PI3K/AKT/mTOR inhibitor
		STX-478 + Fulvestrant	Part 2 cohorte B	Breast cancer	PI3Kα H1047X mutations or other kinase domain mutations	No prior treatment with PI3K/AKT/mTOR inhibitor Have received CDK4/6 inhibitor, unless the participant is deemed by the investigator intolerant to these agents Antiestrogen therapy (see inclusion criterion 13)



Thyroid

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
CFT1946-1101	I/II	CFT1946 + Tramétinib	Arm B (CFT1946 + trametinib)	ATC	SoC therapy options per their physician's best judgment	All subjects must have received ≥1 prior line of SoC therapy for their unresectable locally advanced or metastatic disease,

DERMATOLOGY

STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
CFT1946-1101	I/II	CFT1946	Phase 1 (dose escalation)	Melanoma	BRAFi and an immunotherapy regimen including ICI (in any sequence or in combination). <i>NOTE : experimental small molecule checkpoint/BRAF inhibitors given in the context of a clinical trial are acceptable.</i>	All subjects must have received ≥1 prior line of SoC therapy for their unresectable locally advanced or metastatic disease, with disease progression on or after last prior treatment.
EVICION-ICT-01-101	I/IIa	ICT01 + Pembrolizumab	G	Melanoma CPI-refractory	Circulating γ962 T cell count ≥ 20000 cells/mL Pembro Combo	At least one line
R7075-ONC-2009	I/II	REGN7075 + Cemiplimab	B	Cutaneous squamous cell carcinoma	Metastatic CSCC or locally advanced CSCC	Anti-PD-1/PD-L1 naive



UROLOGY

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			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
AGADIR	II	Atezolizumab + BDB001 + radiothérapie	5	UBC	Refractory anti PD-1/L1	
REGOMUNE	II	Regorafenib + Avelumab	J	Urothélial		At least one line and max 1 line of PD(L)1 mAb (received at least 4 month), anti PDL1 not mandatory
			O	Non clear-cell renal carcinoma		

GYNECOLOGY

STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
CPI-0209	II	CPI0209	M2	Ovarian clear cell carcinoma	ARIDA1 mutated	Previous treatment with EZH2 inhibitor forbidden
INCB123667-101	I	INCB123667	Part 1b grp 1	Ovarian/fallopian/primary peritoneal cancer	CCNE1 amplification	With advanced platinum-based chemotherapy-refractory or resistant + max 4 lines of systemic therapy for advanced or metastatic disease
			Part 1b grp 2	endometrial/uterine cancer	CCNE1 amplification	3 prior lines of systemic therapy max
STX-487-101	I/II	STX-478	Part 1,2A2	Endometrial cancer, ovarian cancer and cervical cancer	PI3Kα H1047X mutations or other kinase domain mutations	No prior treatment with PI3K/AKT/mTOR inhibitor



DIGESTIF

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			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
CFT1946-1101	I/II	CFT1946	Arm A (CFT1946 monotherapy)	CRC	Systemic chemotherapy based regimen per SoC for unresectable locally advanced or metastatic disease, and a BRAFi in combination with an EGFR mAb. <i>NOTE : Both MSS and MSI-H CRC are eligible for inclusion in this study, although required prior therapy differs (MSI-H requires prior immunotherapy)</i>	Subjects with microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) CRC must have received immunotherapy. Subjects with microsatellite stable (MSS) CRC are eligible, provided they have received at least 2 prior treatments.
INCB123667-101	I	INCB123667	Part1b group 3	Gastric, GEJ and esophageal adenocarcinomas	CCNE1 amplification	3 prior lines of systemic therapy max
KontRaSt-03	I/II	JDG444 + Cétuximab	3	CRC	Histologically confirmed advanced KRAS G12C mutant	Patients must have had fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy



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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
LOXO-RAS-20001	Ib expansion	LY3537982	F1	Pancreas	KRASG12C Tumor tissue or liquid biopsy	Patient must have progressed/be intolerant/ineligible for immunotherapy and platinum based therapy No mutation : EGFR, ALK, BRAF (V600), MET (exon 14), ROS1, RET or NTRK 1/2/3
MK-345-158	II	Pembrolizumab	K	Gastric	MSI-high	At least one line
				Small intestine		
				Biliary		
REGOMUNE	II	Regorafenib + Avelumab	A'	Colorectal	Not MSI-high or MMR deficient (macrophage infiltrate)	At least one line
R7075-ONC-2009	I/II	REGN7075 + Cemiplimab	F	Microsatellite stable colorectal cancer (MSS-CRC)	with metastatic CRC who have previously documented MSS No active metastases have been identified in the liver or peritoneum at the time of screening, Only sites of disease are present in lung(s) and/ lung or lymph nodes	anti-PD-1/PD-L1 naïve Have received at least one line of therapy in the relapsed/metastatic setting. Patients with previously documented RAS wild type disease must have received anti-EGFR therapy Patients must have received anti-VEGF therapy or have a documented reason why anti-VEGF therapy was not appropriate



SARCOMAS

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
Multisarc	II	Olaparib-Durvalumab		STS	Unresecable, targetable alteration	At least one line for metastatic disease or locally advanced disease

NEUROLOGY

STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
MegaMOST	II	Alectinib BID	C	Neuroblastoma	Activating ALK alterations : translocation, mutation	At least one line for metastatic disease, no previous ALK inhibitor (except crizotinib)



Solid tumors

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
CA120-1001	I	BMS-986449	Part 1C	TNBC	regardless of PD-L1 status	Must not be a candidate for other approved therapeutic regimen
CFT1946-1101	I/II	CFT1946 + Tramétinib	Arm B	Other [non-CNS] Solid tumors	including BRAFi if available and of benefit to the subject	With disease progression on or after last prior treatment
CO42800	I	Inavolisib	2	HNSCC	PI3KCA TUMOR TISSUE OR LIQUID BIOPSY	Must have received standard therapy
				Ovarian	PI3KCA TUMOR TISSUE OR LIQUID BIOPSY	Must have received standard therapy
DF6215	Ia/Ib	DF6215	1a dose escalation (3+3)	Locally advanced or metastatic solid tumors		
			Ib dose escalation (safety, PK/PD)	Locally advanced or metastatic solid tumors : - Melanoma - HPV-positive advanced malignancies - Ovarian cancer - Head and neck cancer - Lung cancer (non-small-cell lung cancer (NSCLC) - Renal cell carcinoma (RCC) - Other tumor types may be eligible after discussion with the Sponsor medical monitor		



Solid tumors

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
EZH-1201	I	Tazemetostat	1	Solid Tumors	Moderate hepatic impairment (NCI-ODWG)	At least one line, no prior anti-EZH2
			2	Solid Tumors	Severe hepatic impairment (NCI-ODWG)	At least one line, no prior anti-EZH2
F8394-201	I/II	FORE8394 (900mg) + Cobicistat (150mg)	Subproto A	solid tumors with or without CNS metastases or recurrent/progressive primary CNS tumors	Fusion of BRAF in tumor tissue or liquid biopsy	At least on standard line
GCT1042-02	I/II	RT+ GEN1042 +/- Pembrolizumab	Part1, cohort 1	Metastatic non-CNS solid tumors		At least 1 line and 3 lines maximum
IDE397-001	I	IDE397 monotherapy	Part2/expansion	Lung (squamous and adenocarcinoma) and urothelial cancers (bladder and upper urinary tract)	Homozygous loss of MTAP or MTAP deletion	At least 1 line and no more 3 prior lines (no more 2 prior lines of cytotoxic chemotherapy)
IMMUNE 132-15	I	Sacituzimab Govitecan		Advanced or metastatic solid tumors and moderate liver impairment	Histologically confirmed advanced or metastatic solid tumor . Creatinine clearance ≥ 30 mL/min, $1.5 \times$ ULN < Total Bilirubin < $3 \times$ ULN	Histologically confirmed advanced or metastatic solid tumor for which no standard therapy is available (TNBC must have received 2 or more prior systemic therapies, including at least 1 for advanced disease)



Solid tumors

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LOXO-RAS-2001	Ib expansion	LY3537982 + cetuximab	H	CRC	KRASG12C Tumor tissue or liquid biopsy	
M21-404	I	ABBV400	5	Solid tumour MET amplified		At least 1 line or no alternative
MegaMOST	II	Cabozantinib QD	B	Solid Tumors	AXL, MET, VEGFR, VEGF, RET, ROS1, MER, TRKB, TIE-2 and/or Tyro3 activating mutations/amplification, and/or NTRK translocation TUMOR TISSUE OR LIQUID BIOPSY	At least one line for metastatic disease
		Alectinib BID	C	Solid Tumors	Activating ALK alterations : translocation, mutation	At least one line for metastatic disease, no previous ALK inhibitor (except crizotinib)
		Regorafenib 3 weeks on / 1 week off	D	Solid Tumors	Activating mutation and/or amplification of VEGFR1-3, TIE-2, KIT, RET, RAF1, BRAF (other than V600 mutations), CRAF, HRAS, KRAS, PDGFR, FGFR1-2, FLT3 and/or CSFR1 ; amplification of the ligands ; biallelic inactivation of SMAD4 TUMOR TISSUE OR LIQUID BIOPSY	At least one line for metastatic disease
		Trametinib QD + Dabrafenib BID	F	Solid Tumors	BRAF V600 mutation, tumor tissue or liquid biopsy Except melanoma, lung and CRC	At least one line for metastatic disease



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MK-7339-002	II	Olaparib	3	Solid tumors	HRD positif Except ovarian and sarcoma	At least one line and max 2 lines, platine-sensitive if applicable
MOST PLUS	II	Nilotinib		PVNS	ABL1, KIT, PDGFRA, PDGFRB, DDR1, DDR2, CSF1R mutations	At least one line
		Olaparib		Solid tumors	HDR pathway mutations	At least one line
		Durvalumab + Tremelimumab		Solid tumors	Immunogenic, MSI high Except lung, head, neck and CNS cancer	At least one line and max 2 lines
PRT3789-01	Ia	PRT3789	Dose escalation	Solid tumors	SMARCA4	Participants with NSCLC with driver mutations in oncogenes (e.g., EGFR, MET, RET, ALK, BRAF, KRAS, ROS1, etc.) are eligible after progression on approved targeted therapies
REGOMUNE	II	Regorafenib + Avelumab	M	Solid tumors	TMB-H (>16 mut/mgb on tissue or blood sample)	At least one line and max 1 line of PD(L)1 mAb (received at least 4 month) anti PDL1 not mandatory
			N	Solid tumors	MSI-H	At least one line, anti PDL1 not mandatory



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			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
STX-487-101	I/II	STX-478	Part 1,2A4	Other solid tumors	PI3K α H1047X mutations or other kinase domain mutations other than the tumor types permitted in Cohorts A1, A2, and A3Disease	No prior treatment with PI3K/AKT/mTOR inhibitor
TAPISTRY	II	ENTRECTINIB	A	Solid tumors	ROS1 fusion-positive (except NSCLC) TUMOR TISSUE OR LIQUID (VALIDATION NEEDED)	
		ENTRECTINIB	B	Solid tumors	NTRK1/2/3 fusion-positive TUMOR TISSUE OR LIQUID (VALIDATION NEEDED)	
		ALECTINIB	C	Solid tumors	ALK fusion-positive (except NSCLC) TUMOR TISSUE OR LIQUID (VALIDATION NEEDED)	

