

# THORAX

Pour retrouver tous ces essais et adresser vos patients rapidement : une seule plateforme [www.klineo.fr](http://www.klineo.fr)

STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
AMGEN 20220028	I	AMG 355 (Anti CCR8 monoclonal Ab)	A1 dose escalation	NSCLC		No limit for prior treatment
BI-1479-0009	II	BI 1810631	5	NSCLC	Her2 overexpressed/amplified	
BT8009	II	zelenectide pevdotin (BT8009) monotherapy	B9	NSCLC	negative for oncogenic driver mutations	at least 1 line of platinum-based chemotherapy and ≤ 1 prior taxane containing regimen in the metastatic setting and ≥ 3 months from most recent taxane
DS8201-A-U106	Ib	Trastuzumab + Deruxtecan IV + Pembrolizumab iV	3	NSCLC	HER2-expression (IHC 1+, 2+, or 3+)	Patients must not have received prior treatment with anti-PDL-1, anti-PD-1, or anti-HER2
EP0031-101	I/II	EP0031-101	1A	NSCLC	RET fusion-positive NSCLC (prior SRI), monotherapy	Prior selective RET inhibitor and chemotherapy
			1C		RET fusion-positive NSCLC (prior SRI), chemotherapy combinaison	Prior Selective RET inhibitor
			2B		RET fusion-positive NSCLC, chemotherapy combinaison	treatment naive
IMC-F106	I	IMC-F106C (IV)	22, 23, 40, 41	NSCLC	HLA-A*02:01- positive, PRAME-positive tumor	Participants must not have received prior treatment with an ImmTAC, including tebentafusp, IMCnyeso, or IMC-C103C.
		IMC-F106C + Docetaxel	36	NSCLC	HLA-A*02:01- positive, PRAME-positive tumor	Participants must not have received prior treatment with an ImmTAC, including tebentafusp, IMCnyeso, or IMC-C103C.
		IMC-F106C + Osimertinib	39	NSCLC	HLA-A*02:01- positive, PRAME-positive tumor	Participants must not have received prior treatment with an ImmTAC, including tebentafusp, IMCnyeso, or IMC-C103C.



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LOXO-RAS-20001	lb 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
RMC LUNG-101a	I	RMC-6291 + Pembrolizumab	Part2 cohort1	NSCLC	KRAS G12C and TPS >= 50%	No prior line
RMC LUNG-101b	I	RMC-6236 + Pembrolizumab	Part2 cohort1	NSCLC	RAS mut and TPS >= 50%	No prior line
RMC-6291	I	RMC6291 + RMC6236	Dose escalation	NSCLC	KRAS G12C	previously treated with a KRASG12C (OFF) inhibitor
					KRAS G12C	naïve to KRASG12C (OFF) inhibitors
			expansion	NSCLC	KRAS G12C	previously treated with a KRASG12C (OFF) inhibitor
					KRAS G12C	naïve to KRASG12C (OFF) inhibitors
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 EFGR Exon19 deletion or L858R mutation, prior osimertinib or other third generation TKI treatment is required



# Senology

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BI-1479-0009	II	BI1810631	8	Breast cancer	Her2 mut
BT8009	II	zelenectide pevedotin (BT8009) monotherapy	B8	BC: RH+ HER2 neg and TNBC	<=3 lignes M+ ( 1)at least 1 line of chemotherapy in the metastatic setting and must have received sacituzumab govitecan OR trastuzumab deruxtecan per local standards 2) ≤ 1 prior taxane containing regimen in the metastatic setting and ≥ 3 months from most recent taxane
INCB123667-101	I	INCB123667	Part 1b Group 4	TNBC	2 prior lines of chemotherapy max
RLY 2608-101	I	RLY-2608 + Fulvestrant	2	group 1b : Advanced/metastatic breast cancer PIK3CAmut	PIK3CAmut, HR+, HER2-RP2D1 (400mg BID) Expansion  with NO prior PI3K alpha inhibitor RP2D1 (dose recommended 1)
STX-487-101	I/II	STX-478	Part 1,1 A1	Breast cancer	PI3KαH1047X mutation or other kinase domain mutations, HR+/HER2-  Must have received for stage III or IV disease : ≥1 CDK4/6 inhibitor regimen ≥1 antiestrogen therapy including, but not limited to, SERDs (eg, fulvestrant), SERMs (eg, tamoxifen), and AIs (eg, letrozole, anastrozole, and exemestane) ≤2 prior systemic chemotherapy regimen No prior treatment with PI3K/AKT/mTOR inhibitor
		STX-478 + Fulvestrant	Part 2,1 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) ≤ 1 prior line of chemotherapy



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			COHORT NUMBER	TUMOR TYPE	
STX-487-101	I/II	STX-478 + Fulvestrant + Ribociclib	C0	Breast cancer HR+/HER2- or HR+/HER2low measurable disease per RECIST 1.1	PI3K $\alpha$ H1047X mutations, or other kinase and/or helical domain mutations  At least 1 but no more than 2 prior lines of therapy: <ul style="list-style-type: none"> <li>• CDK4/6 inhibitor, unless the participant is deemed by the investigator intolerant to or ineligible for these agents</li> <li>• Antiestrogen therapy (see inclusion criterion 13) for additional details               <ul style="list-style-type: none"> <li>• <math>\leq 1</math> prior line of chemotherapy</li> </ul> </li> </ul> Or, participants can be treatment-naïve in the metastatic breast cancer setting
		STX-478 + Fulvestrant + Palbociclib	Part 3,1 cohorte D0	Breast cancer HR+/HER2- or HR+/HER2 low, measurable disease per RECIST 1,1	PI3K $\alpha$ H1047X mutations or other kinase domain mutations  At least 1 but no more than 2 prior lines of therapy, including the following: Must have progressed on a CDK4/6 inhibitor or deemed by the investigator to be intolerant to or not eligible for such therapy. Must have progressed on, is intolerant to, or deemed ineligible for antiestrogen therapy including, but not limited to SERDs, SERMs (e.g., tamoxifen), and AIs (e.g., letrozole, anastrozole, exemestane) $\leq 1$ Prior line of chemotherapy OR No prior systemic treatment for metastatic breast cancer except for neoadjuvant or adjuvant therapy



# DERMATOLOGY

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			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
AMGEN 20220028	I	AMG 355 (anti CCR8 monoclonal Ab)	A1 dose escalation	Melanoma		
KN-8701	Ib	KIN-2787	B1	Melanoma	NRAS mut	
		KIN-2787 + BINIMETINIB	A2	Melanoma	NRAS mut	
R7075-ONC-2009	I/II	REGN7075 + Cemiplimab	B	Cutaneous squamous cell carcinoma	Metastatic CSCC or locally advanced CSCC	Anti-PD-1/PD-L1 naïve

# ORL

STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
R7075-ONC-2009	I/II	REGN7075 + Cemiplimab	D	Head and neck squamous cell carcinoma	locally advanced or metastatic HNSCC PD-L1 expression of CPS $\geq 1\%$ on a specimen collected within the past 3 months	anti-PD-1/PD-L1 naïve Have received no prior systemic treatment for recurrent or metastatic HNSCC (adjuvant or neoadjuvant systemic treatments will not be counted as a prior line)
STX-478-101	I/II	STX-478	Part 1,2A3	HNSCC	PI3K $\alpha$ H1047X mutations, or other kinase and/or helical domain mutations	No prior treatment with PI3K/AKT/mTOR inhibitor



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# UROLOGY

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
AGADIR	II	Atezolizumab + BDB001 + radiothérapie	5	UBC	Refractory anti PD-1/L1	
BI-1479-0009	II	BI1810631	1	urothelial	Her2 overexpressed/amplified	
			7	urothelial	Her2 mutated	
D926UC0001	II	6C : Dato-DXd seul 6D : Dato-DXd + Cisplatine ou Carboplatine	6	6C : urothelial carcinoma (transitional cell and mixed transitional/non-transitional cell histologies) of the urothelium (including renal pelvis, ureters, urinary bladder, and urethra) : Dato-DXd monothérapie 6D : Advanced or metastatic urothelial carcinoma (transitional cell and mixed transitional/non-transitional cell histologies) of the urothelium (including renal pelvis, ureters, urinary bladder, and urethra) that progressed on prior EV/pembrolizumab.	No specific molecular alteration	6C : at least 1 prior line of therapy including an immune checkpoint inhibitor
LOXO-FG3-22001	I	Loxo 435 + Pembrolizumab	A2	Urothelial	FGFR3 alteration	must have received at least one prior regimen, prior FGFR inhibitor treatment is permitted, but not required



# GYNECOLOGY

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
BI-1479-0009	II	BI1810631	3	Uterine carcinoma	Her2 overexpressed/amplified	
			4	cervical	Her2 overexpressed/amplified	
INCB123667-101	I	INCB123667	Part 1b grp 2	endometrial/uterine cancer	CCNE1 amplification	3 prior lines of systemic therapy max
IMC-F106C	I	IMC-F106C (IV)	34	High Grade Serous Ovarian Carcinoma	HLA-A*02:01- positive, PRAME-positive tumor	Participants must not have received prior treatment with an ImmTAC, including tebentafusp, IMCnyeso, or IMC-C103C.
		IMC-F106C + Gemcitabine	35	Ovarian and uterine/endo	HLA-A*02:01- positive, PRAME-positive tumor	Participants must not have received prior treatment with an ImmTAC, including tebentafusp, IMCnyeso, or IMC-C103C.
		IMC-F106C + Carboplatin / Paclitaxel	37	Ovarian and uterine/endo	HLA-A*02:01- positive, PRAME-positive tumor	Participants must not have received prior treatment with an ImmTAC, including tebentafusp, IMCnyeso, or IMC-C103C.
		IMC-F106C + Bevacizumab	38	High Grade Serous Ovarian Carcinoma	HLA-A*02:01- positive, PRAME-positive tumor	Participants must not have received prior treatment with an ImmTAC, including tebentafusp, IMCnyeso, or IMC-C103C.



# DIGESTIF

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			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
AMGEN 20220028	I	AMG 355 (anti CCR8 monoclonal Ab)	A1 dose escalation	CRC (MSS)		
		AMG 355 (anti CCR8 monoclonal Ab)	A1 dose escalation	Gastric cancer		
BI-1479-0009	II	BI1810631	2	Biliary tract / Hepatocellular	Her2 overexpressed/amplified	
			9	GEAC	Her2 mutated	
INCB123667-101	I	INCB123667	Part1b group 3	Gastric, GEJ and esophageal adenocarcinomas	CCNE1 amplification	3 prior lines of systemic therapy max
LOXO-RAS-20001	Ib expansion	LY3537982 monotherapy	F1	Pancreas	KRAS G12C TUMOR TISSUE OR LIQUID BIOPSY	Patient must have progressed/be intolerant/ineligible for immunotherapy and platinumium 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		
RMC-6291	I	RMC6291 + RMC6236	Expansion	CRC	KRAS G12C	naïve to KRASG12C (OFF) inhibitors



# SARCOMAS

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
Multisarc	II	Olaparib-Durvalumab		STS	Unresectable, 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)

# SNC

STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
F8394-201	II	FORE8394 + Cobicistat	Csubproto B	SNC	BRAF V600E mutation	At least one line, including radiotherapy
M23-385	I	ABBV-706	4a	CNS tumors		



# Solid tumors

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			COHORT NUMBER	TUMOR TYPE	SPECIFICITY	
ANV600-001	I/II		Phase I	Resistantes solid tumors	Pancreas	Progressive disease after or during standard of care
BI1456-0001	I/II	BI 1831169 IT	Arm A	Solid tumors	At least two accessible lesions, one with a minimum lesion diameter for injection of BI 1831169, and one which is amenable to biopsy	At least one line
		BI 1831169 IV	Arm B	Solid tumors	At least two accessible lesions, one with a minimum lesion diameter for injection of BI 1831169, and one which is amenable to biopsy	At least one line
		BI 1831169 IV + IT	Arm C	Solid tumors	At least two accessible lesions, one with a minimum lesion diameter for injection of BI 1831169, and one which is amenable to biopsy	At least one line
BI-1479-0009	II	BI 1810631	10	Solid tumors	Her2 mut	
CO42800	I	Inavolisib + taxol	2	Cohorte 1 HNSCC	PI3KCA TUMOR TISSUE OR LIQUID BIOPSY	Must have received standard therapy
				Cohorte 2 Ovarian	PI3KCA TUMOR TISSUE OR LIQUID BIOPSY	Must have received standard therapy



# Solid tumors

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STUDY NAME	PHASE	MOLECULE	COHORT TYPE			PREVIOUS LINE
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DF6215-001	I/Ib	DF6215	Part 1) b) 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		
ELVN-002-001	Ib	ELVN-002	Dose expansion	NSCLC	HER2 mutation documented	Progressed after receiving at least 1 prior systemic therapy including a platinumbased
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
IDE397-001	I	IDE397 monotherapy	Part 2 dose expansion	<ul style="list-style-type: none"> <li>Lung (squamous and adenocarcinoma)</li> <li>Urothelial cancers (bladder and upper urinary tract)</li> </ul>	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)
		IDE397 + Sacituzumab govitecan	Part 5 dose escalation	Urothelial cancers (bladder and upper urinary tract)	homozygous loss of MTAP or MTAP deletion	Treatment with no more than 3 prior treatment regimens in the setting of advanced or metastatic disease
KN-8701	Ib	KIN-2787	B1	Solid tumors	BRAF class II	received prior locally approved standard of care appropriate for their tumor type and stage of disease
			A2	Solid tumors	BRAF II SNV, Indels	



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# Solid tumors

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LOXO-FG3622001	I	Loxo 435 + Pembrolizumab	A1	Solid tumors	FGFR3 alteration or ligand amplification	Prior FGFR inhibitor treatment is permitted, but not required
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 tissus or liquid biopsy Except melanoma, lung and CRC	At least one line for metastatic disease
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	Imunogenic, MSI high Except lung, urothelial, head, neck and CNS cancers	At least one line and max 2 lines



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PMV586-101	I/II	Olaparib	3	Solid tumors	HRD positif except ovarian and sarcoma	At least one line and max 2 lines, platine-sensitive if applicable
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
RMC 6291	I	RMC6291 + RMC6236	Dose escalation	Solid tumors exclude NSCLC and CRC	KRAS G12C	Standard therapy
			expansion	Solid tumors	KRAS G12C	naïve to KRASG12C (OFF) inhibitors
TAPISTRY	II	Entrectinib	B	Solid tumors	NTRK1/2/3 fusion-positive TUMOR TISSUE OR LIQUID (VALIDATION NEEDED)	

