Département d'oncologie

Service d'immuno-oncologie

ÉTUDES CLINIQUES v. JUILLET 2020

CONTACTS

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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
Any solid tumor	CHUV-DO-0012-SolTIL-2018	• TILs Cyclophosphamide Fludarabine Low dose radiotherapy IL-2	Advanced or metastatic solid tumor except primary brain tumors, lymphoma, melanoma	Progression after ≥1 line of standard therapy	• Intratumoral CD8+ lymphocytes ≥5 per high-power field on recent biopsy • Low tumor burden • No rapid tumor progression, ability to await therapy for at least 2 months • ECOG PS 0-1 • No uncontrolled CNS metastases • At least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5cm in diameter post-resection to generate TIL • Measurable disease according to RECIST after resection • At least one lesion accessible to core biopsy after resection
Any solid tumor	RACIN	•Ipilimumab, nivolumab, celecoxib, low-dose radiotherapy •Nivolumab, cyclophosphamide, celecoxib, low-dose radiotherapy	Advanced solid tumor except soft tissue sarcoma, lymphoma, glioblastoma		• Intratumoral CD8+ lymphocytes <5 per high-power field on recent biopsy • Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No active autoimmune disease (except hypothyroidism, diabetes) • One lesion accessible to core biopsy
GI Colorectal	MORPHEUS	•Atezolizumab + idasanutlin (TP53 wt) •Atezolizumab + regorafenib •Atezolizumab + regorafenib + AB982 •Regorafenib	Metastatic colorectal cancer	3L (progression during or following 2 separate lines of treatment that consisted of fluoropyrimidine-, oxaliplatin-, or irinotecan-containing chemo in combination with a biologic) Or 2L (progression during or following FOLFOXIRI +/- biologic)	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No active autoimmune disease (except hypothyroidism, diabetes, vitiligo, psoriasis) • One lesion accessible to core biopsy • No *BRAF* mutation • No prior immunotherapy
GI Liver	MASTERKEY-318	TVEC or TVEC+ pembrolizumab	HCC	Any line of therapy	• Measurable liver tumors that are suitable for injection (≥1cm) • Liver tumors must not be estimated to invade more than one-third of the liver • Life expectancy ≥ 5 months • No prior therapy with tumor vaccine, TVEC or oncolytic virus • No CNS metastasis
GI Colorectal	MASTERKEY-318	TVEC+ pembrolizumab	Metastatic colorectal cancer	At least 1 prior line of standard therapy for advanced disease	• Measurable liver tumors that are suitable for injection (≥1cm) or injectable cutaneous, subcutaneous metastasis, or involved lymph node • Measurable disease according to RECIST • Liver tumors must not be estimated to invade more than one-third of the liver • Life expectancy ≥ 5 months • No active CNS metastasis

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GYN Cervix	BP40234	FAP-IL2v + Atezolizumab	metastatic, persistent, or recurrent squamous cervical cancer	Experienced progression or intolerance while receiving ≥1 line of standard therapy. IO naïve.	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No active autoimmune disease (except hypothyroidism, diabetes) • One lesion accessible to core biopsy • No prior immunotherapy
GYN Cervix	C-145-04	TILs Cyclophosphamide Fludarabine IL-2	recurrent, metastatic, or persistent squamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix that is not amenable to curative treatment with surgery and/or radiation therapy and for which no other therapies are expected to have significant benefit	Progression during or following at least one, but no more than three prior systemic chemotherapeutic treatments for recurrent, metastatic, or persistent cervical carcinoma	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No steroids • At least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5cm in diameter post-resection to generate TIL; surgical removal with minimal morbidity (defined as any procedure for which expected hospitalization is ≤ 3 days)
ORL	CA224-048	Nivolumab Relatlimab (αLAG3) IDO1 inhibitor	Advanced, recurrent or metastatic squamous cell carcinoma of the head and neck	2L for advanced disease, after a platinum containing regimen (or within 6 months of radio-chemotherapy with platinum). IO-naïve.	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No active autoimmune disease (except hypothyroidism, diabetes, vitiligo, psoriasis) • One lesion accessible to core biopsy
ORL	IOV-COM-202	TILs Cyclophosphamide Fludarabine IL-2 Pembrolizumab	Advanced, recurrent or metastatic squamous cell carcinoma of the head and neck	Up to 3 lines of prior therapy. If previously treated, must be progressing on or after most recent therapy. IO-naive.	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No steroids • At least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5cm in diameter post-resection to generate TIL
THOR	CA224-048	Ipilimumab Nivolumab Relatlimag (αLAG3)	NSCLC Stage IIIB or IV	1L (exception: ALK/EGFR/ROS1/BRAF positive: must have received targeted therapy)	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No active autoimmune disease (except hypothyroidism, diabetes, vitiligo, psoriasis) • One lesion accessible to core biopsy

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THOR	IOV-COM-202	TILs Cyclophosphamide Fludarabine IL-2 +/- pembrolizumab	NSCLC stage IIIB or IV	Up to 3 lines of prior therapy. If previously treated, must be progressing on or after most recent therapy. If activating mutation, must have received TKI	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No steroids • At least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5cm in diameter post-resection to generate TIL
THOR	20160323	AMG757 (HLE-BiTE anti-DLL3) +/- pembrolizumab	Relapsed/refractory small cell lung cancer (SCLC)	progressed or recurred following at least 1 platinum-based regimen (part A and C)	• at least 2 measurable lesions as defined per modified RECIST 1.1 within 21 days prior to the first dose of AMG 757 • ECOG PS 0-2 • No uncontrolled CNS metastases • No steroids • No hypophysitis
MEL	CA224-048	Nivolumab Relatlimab (αLAG3) IDO1 inhibitor	recurrent or metastatic cutaneous or mucosal melanoma	1L	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No active autoimmune disease (except hypothyroidism, diabetes, vitiligo, psoriasis) • One lesion accessible to core biopsy • Adjuvant anti-CTLA4 or anti-PD1 allowed (if >6 months elapsed)
MEL	CA224-020	Nivolumab Relatlimab (αLAG3)	recurrent or metastatic cutaneous or mucosal melanoma	1L	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No active autoimmune disease (except hypothyroidism, diabetes, vitiligo, psoriasis) • One lesion accessible to core biopsy • Adjuvant anti-CTLA4, anti-PD1, or BRAF/MEKi allowed (if >6 months elapsed)
MEL	CHUV-DO-ATATIL-2016	Fludarabine + Cyclo-phosphamide TILS IL2 Nivolumab	Advanced cutaneous or mucosal melanoma	At least one prior first line therapy, including, but not limited to, chemotherapy, BRAF and MEK inhibitors, anti-CTLA-4, anti-PD-1, anti-PD-L1 or anti-LAG3 antibodies or their combination	• Patients are eligible for TIL-ACT only if there are sufficient TILs grown for further expansion. • Patients must have a good general health status (ECOG PS ≤2)

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MEL	MK3475-U02 Substudy A	• Pembrolizumab + MK-1308 (anti-CTLA4) + MK-7684 (anti-TIGIT) • Pembrolizumab + MK-1308 (anti-CTLA4) + lenvatinib	Advanced cutaneous melanoma	Progressed on or within 12 weeks of last anti-PD1. No prior anti-CTLA4. No more than 3 prior lines.	• Measurable disease according to RECIST • ECOG PS 0-1 • No active CNS metastases (irradiated, or <=3 small asymptomatic) • No autoimmune disease that has required systemic treatment in the past 2 years (replacement therapy for hypothyroidism, diabetes, or hypopituitarism allowed) • One lesion accessible to core biopsy
MEL	MK3475-U02 Substudy C	• Pembrolizumab + MK-7684 (anti-TIGIT) • Pembrolizumab + V937 (Cavatak)	clinically detectable and resectable Stage IIIB or IIIC or IIID melanoma per AJCC 8th Edition	Untreated except primary resection and re-resection, and radiotherapy to the primary	• Measurable disease according to RECIST • ECOG PS 0-1 • No autoimmune disease that has required systemic treatment in the past 2 years (replacement therapy for hypothyroidism, diabetes, or hypopituitarism allowed) • No CNS metastasis • Has provided a baseline biopsy
SKIN Squamous	MASTERKEY-318	TVEC + pembrolizumab	Metastatic squamous cell carcinoma of skin (CSCC)	Any line	• Measurable liver tumors that are suitable for injection (≥1cm) or injectable cutaneous, subcutaneous metastasis, or involved lymph node. • Measurable disease according to RECIST. • Liver tumors must not be estimated to invade more than one-third of the liver • Life expectancy ≥ 5 months • No active CNS metastasis
SKIN Basal cell	MASTERKEY-318	TVEC + pembrolizumab	Metastatic basal cell carcinoma (BCC)	At least 1 prior line of standard therapy for advanced disease	• Measurable liver tumors that are suitable for injection (≥1cm) or injectable cutaneous, subcutaneous metastasis, or involved lymph node. • Measurable disease according to RECIST. • Liver tumors must not be estimated to invade more than one-third of the liver • Life expectancy ≥ 5 months • No active CNS metastasis
MEL	IOV-COM-202	TILs Cyclophosphamide Fludarabine IL-2 pembrolizumab	Unresectable or metastatic melanoma	Up to 3 lines of prior therapy. If previously treated, must be progressing on or after most recent therapy. No prior immunotherapy.	• Measurable disease according to RECIST • ECOG PS 0-1 • No uncontrolled CNS metastases • No steroids At least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5cm in diameter post-resection to generate TIL

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SENO	MASTERKEY	TVEC + pembrolizumab	TNBC Or ER positive	At least 1 prior line of standard therapy for advanced disease	• Measurable liver tumors that are suitable for injection (≥1cm) or injectable cutaneous, subcutaneous metastasis, or involved lymph node • Measurable disease according to RECIST. • Liver tumors must not be estimated to invade more than one-third of the liver • Life expectancy ≥ 5 months • No active CNS metastasis