## Études Cliniques Thoraciques

<table>
<thead>
<tr>
<th>Indication</th>
<th>Study name</th>
<th>Treatment</th>
<th>Stage &amp; histological type</th>
<th>Line</th>
<th>Other key eligibility criteria</th>
</tr>
</thead>
</table>
| **THOR**   | Amgen 20160323 Phase I | Part A: AMG757 Part C: AMG757 + pembrolizumab | RR SCLC | - Histologically confirmed SCLC  
- If combined diagnosis of small cell carcinoma with predominant small cell, may be considered for inclusion after discussion with medical monitor  
- ECOG 0-2  
- At least 2 measurable lesions per mRECIST1.1 within 21d prior to first dose of AMG757. If 1 lesion only, can be discussed with medical monitor  
- Subject with brain mets are eligible if definitive therapy was completed 2weeks prior 1st dose of AMG757; and no evidence of CNS progression.  
- Patients on chronic anticoagulation therapy who do not meet PT/INR and PTT or aPTT \( \leq 1.5 \text{ ULN} \) may be eligible after discussion with medical monitor  
- Cardiac ejection fraction \( \geq 50\% \), no evidence or pericardial effusion (by Echo or Muga) and no clinically significant ECG findings |
| **THOR**   | Phosphatine Therapeutics PAVE PT112-103 Phase I/I | Avelumab + PT112 (Dose confirmation cohort) | Metastatic or locally advanced NSCLC progressing on PD-1/PD-L1 therapy | - Received no more than three prior regimens, with PD-1 / PD-L1-containing therapy administered as their most recent therapy  
- failed to achieve a PR or CR, – or if not progressing, period of SD must be at least 4 months  
- measurable disease by irRECIST criteria  
- Availability of tumor material (<3months) or tumor biopsy  
- ECOG: 0 or 1  
- Ex: Known symptomatic central nervous system (CNS) metastases  
- Ex: Persisting toxicity related to prior therapy is Grade \( \geq 1 \)  
- Ex: Diagnosis of any other malignancy within 2 years  
- Ex: Clinically significant or active cardiovascular disease  
- Ex: Known alcohol or drug abuse  
- Ex: Known allergic reaction to methotrexate |
| **THOR**   | BMS CA022-001 Phase I | Part 1B (Nivolumab 480mg + BMS 986218) Part 2B monotherapy BMS 986218 (7, 20 ou 70mg) | Advanced or metastatic | Part 1B: Progressed or relapse after at least 2 standard systemic with proven survival benefit according to their tumor type in advanced or metastatic disease  
Part 2B: NSCLC prior anti PD-1 /anti PD-L1 | - ECOG PS: 0-1  
- If anti-PD-1 therapy is approved in a given indication, participants are eligible to receive this treatment as part of the combination regimen in this study prior to having completed 2 prior systemic therapy regimens after discussion and agreement with the Medical Monitor (or designee)  
- Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 1, or deemed irreversible.  
- No Prior participation in an anti-CTLA-4-NF clinical study or therapy  
- Participants with primary CNS malignancies, or tumors with CNS metastases as the only site of disease, will be excluded |
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<tr>
<td>THOR</td>
<td>CHUV-DD-0018-NeoTIL-2019</td>
<td>Lymphodepletion: Cyclophosphamide + Fludarabine + RadiotherapyNeoTILs and IL-2</td>
<td>Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors NSCLC: SQ and non SQ</td>
<td>Patient who progressed or been intolerant to at least one standard therapy regim in the advanced or metastatic setting</td>
<td>• NSCLC: SQ and non SQ • Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI • Measurable disease as per RECIST 1.1 in addition to resectable lesions • ECOG 0-2 with life expectancy ≥ 3 months</td>
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<td>• Prior adjuvant or neoadjuvant chemo therapy permitted at least 6 months prior enrolment) + IO naive • No prior systemic anticancer therapy • IO naive, except for participants with targetable mutations (ALK, EGFR, ROS1, BRAF) who must have had prior treatment with approved targeted therapy • Prior definitive chemoradiation for locally advanced disease is also permitted as long as the last administration of chemotherapy or radiotherapy (which ever was given last) occurred at least 6 months prior to enrollment. • Patient without archived tissue less than 3 months old must undergo a MANDATORY pretreatment biopsy • At least 1 measurable lesion as per RECIST 1.1 • ECOG 1; Life expectancy ≥ 12 weeks at time of informed consent; LVEF ≥ 50% • No history of interstitial lung disease/pneumonitis; No known or suspected CNS metastases; No active, known or suspected autoimmune disease; no uncontrolled or significant cardiovascular disease; No history of life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI &gt; 2 x ULN; no blood transfusion within 4 weeks of C1D1</td>
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<tr>
<td>THOR</td>
<td>BMS CA224-048 Phase I/II</td>
<td>Nivolumab + Relatlimab + Ipilimumab</td>
<td>Stage IIIB, IV or recurrent NSCLC (squamous or non squamous)</td>
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### Service d'immuno-oncologie

#### ÉTUDES CLINIQUES

v. DECEMBRE 2021

gynécologie/sénologie

#### CONTACTS

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#### Indication | Study name | Treatment | Stage & histological type | Line | Other key eligibility criteria
---|---|---|---|---|---
SENO | CHUV-DO-0009- CyberimmunoBreast-2017 | pre-operative SBRT in early stage TNBC +/- CIMP-001 | Histologically confirmed triple negative breast cancer of early stage (cT1-2 cN0-1 cM0) according to immunohistochemistry/FISH and current ASCO guidelines. TNBC subtype is defined as: ER <10% and PR <10% and HER2 negative | Patients who have a diagnosis of early TNBC, for whom a surgical treatment is indicated (Breast Conservative Surgery or Mastectomy), and who do not require neoadjuvant therapy, | • ECOG 0 to 1
• A planned breast cancer surgery
• No planned neoadjuvant chemotherapy/endocrine therapy or other anticancer biologic therapy.
• Presence of measurable disease in the breast, defined as a lesion that can be accurately measured in at least one dimension with conventional techniques (MRI, or ultrasound).
• Primary tumor accessible to injection and biopsy
• Prohibited therapies: Any prior ipsilateral breast irradiation

#### Indication | Study name | Treatment | Stage & histological type | Line | Other key eligibility criteria
---|---|---|---|---|---
Any solid tumor | CHUV-DO-0018- NeoTIL-2019 | Lymphodepletion: Cyclophosphamide + Fludarabine Radiotherapy NeoTILs and IL-2 | Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors For Gyn: HPV induced cancers For Sen: Any BC | Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting | • For Gyn: HPV induced cancer
• Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI
• Measurable disease as per RECIST 1.1 in addition to resectable lesions
• ECOG 0-2 with life expectancy ≥ 3months

#### Indication | Study name | Treatment | Stage & histological type | Line | Other key eligibility criteria
---|---|---|---|---|---
SENO | Amgen TVEC intra-tumoral 20140318 Phase I | TVEC+ pembrolizumab - TNBC - Hormone receptor positive BC At least 1 prior systemic treatment line | | | • Measurable tumor lesions that are suitable for injection (≥ 1 cm)
• Hormone Receptor positive BC: Histologically and/or cytologically confirmed diagnosis of ER positive and/or PR positive
• TNBC: Histologically and/or cytologically confirmed diagnosis of ER negative, PR negative, human epidermal growth factor receptor 2 (HER2)-Neu negative
• Hormone receptor positive BC: No prior treatment with a checkpoint inhibitor.
• Progression on or following at least 1 prior standard of care systemic anti-cancer therapy
• Subjects with previously treated cerebral metastases may be enrolled, provided that all lesions have been adequately treated
• Liver tumors must not be estimated to invade approximately more than one-third of the liver;
• Liver tumor-directed therapy, hepatic surgery, antibody-based therapy, or immunotherapy must not have been performed < 28 days, chemotherapy < 21 days, and targeted small molecule therapy or hormonal therapy < 14 days prior to enrollment;
• ≤ grade 1 toxic effects of prior therapy and/or complications from prior intervention before starting therapy
• No prior therapy with tumor vaccine, TVEC or oncolytic virus
• Life expectancy ≥ 5 months
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| GI Pancreas | CHUV-Do PEP-DC | Adjuvant SOC chemotherapy [capecitabine, gemcitabine]+ Vaccin PEP_DC vaccin Nivolumab maintenance | T1-T4 N0-2 | No distant metastase | • Appropriate amount of tumoral tissue was collected from the cytoreductive surgery and allowed the identification of top 30 personalized peptides (PEP) for preparation of PEP-DC vaccine  
• No measurable tumor lesion according to radiologic criteria  
• Recovery from any toxic effects of prior neo-adjuvant therapy to ≤ Grade 1 per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE v4.03) except for toxicities described below, as long as they do not put at risk the patient’s condition and do not require systemic immunosuppressive steroids at any dose, including but not limited to: Fatigue, Alopecia, Skin disorders, Stable neuropathy, Endocrinopathies requiring replacement treatment |

| GI Colorectal | BMS CA022-001 Part IB (Nivolumab 480mg + BMS 986218 NFPI) | Advanced solid tumor | Part 1B: Progressed or relapse after at least 2 standard systemic with proven survival benefit according to their tumor type in advanced or metastatic disease |  | • ECOG PS: 0-1  
• Progressed after prior immunotherapy with anti-PD-1 / anti-PD-L1 either by itself or in combination with other systemic therapy agents  
• Patients with  
• Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 3, or deemed irreversible.  
• No Prior participation in an anti-CTLA-4-NF clinical study or therapy  
• Participants with primary CNS malignancies, or tumors with CNS metastases as the only site of disease, will be excluded |

| GI Liver | Amgen TVEC intra-tumoral 20140318 Phase I | TVEC ou TVEC+ pembrolizumab •Hepatocellular carcinoma (HCC) with known disease progression  
• With active hepatitis B or C (cohort 6a)  
• Without active hepatitis B or C (cohort 6b)  
•CRC  
•HCC: any;  
•CRC: at least 1 prior systemic treatment line |  |  | • Measurable liver tumors that are suitable for injection (≥ 1 cm)  
• Liver tumors must not be estimated to invade approximately more than one-third of the liver;  
• Liver tumor-directed therapy, hepatic surgery, antibody-based therapy, or immunotherapy must not have been performed < 28 days, chemotherapy < 21 days, and targeted small molecule therapy or hormonal therapy < 14 days prior to enrollment;  
• ≤ grade 1 toxic effects of prior therapy and/or complications from prior intervention before starting therapy  
• No prior therapy with tumor vaccine, TVEC or oncolytic virus  
• Life expectancy ≥ 5 months  
• HCC: no central nervous system (CNS) metastasis  
• CRC: Subjects with previously treated cerebral metastases may be enrolled, provided that all lesions have been adequately treated  
• CRC: Progression on or following at least 1 prior standard of care systemic anti-cancer therapy  
• Cohort 6b: Subjects must have a diagnosis of hepatitis B and/or C (HBV and HCV). Subjects with HCV infection must have completed treatment for their hepatitis C at least 4 weeks prior to study enrollment, and HCV viral load must be undetectable. Subjects with controlled HBV will be eligible as long as they meet the following criteria:  
• Antiviral therapy for HBV must be given for at least 4 weeks and HBV viral load must be < 100 IU/mL prior to enrollment. Participants on active HBV therapy with viral loads < 100 IU/mL should stay on the same therapy throughout study treatment.  
• Subjects who are positive for anti-hepatitis B core antibody HBc, negative for hepatitis B surface antigen (HBsAg), and negative or positive for anti-hepatitis B surface antibody (HBs), and who have an HBV viral load < 100 IU/mL, do not require HBV anti-viral prophylaxis. |
### Indication

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<tr>
<th><strong>Any solid tumor</strong></th>
<th><strong>GI</strong></th>
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<tbody>
<tr>
<td><strong>CHUV-DO-0018-NeoTIL-2019</strong></td>
<td><strong>BMS CA027-002</strong> (Phase I/IIa)</td>
<td><strong>SEAGEN SGN86A-001</strong> (Phase I)</td>
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</table>

#### Treatment

- **Any solid tumor**
  - Lymphodepletion: Cyclophosphamide + Fludarabine + Radiotherapy NeoTILs and IL-2

- **GI**
  - BMS-986253 (any IL6 level) + Nivolumab + Ipilimumab

- **GI**
  - SEAGEN SGN86A-001

#### Stage & histological type

- **Any solid tumor**
  - Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors

- **GI**
  - Histologically or radiologically confirmed HCC (radiological diagnosis must be confirmed histologically at screening)

- **GI**
  - Locally advanced or metastatic esophageal carcinoma

#### Line

- **Any solid tumor**
  - Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting

- **GI**
  - All participants must have received, and then progressed, relapsed, or been intolerant to at least 1 standard treatment regimen in the advanced or metastatic setting according to tumor type

- **GI**
  - Subjects must have received prior platinum-based chemotherapy.

#### Other key eligibility criteria

- **Any solid tumor**
  - Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI
  - Measurable disease as per RECIST 1.1 in addition to resectable lesions
  - ECOG 0-1 and life expectancy > 3 months

- **GI**
  - Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion
  - ECOG 0-1
  - For MSS CRC:
    - Microsatellite instability must be documented
    - Participants must have received and progressed on, or intolerant to fluoropyrimidine, oxaliplatin and irinotecan
    - For HCC:
      - Not eligible for transplant
      - Child-Plug class A

  - Must have documented progressive or recurrent disease on or within 3 months of discontinuation of anti-PD-(L)1 therapy (administered as monotherapy or as part of a combination) as per RECIST 1.1 criteria.

- **GI**
  - Prior PD-(L)1-based therapy must be the most recent treatment.

- **Any solid tumor**
  - Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI

- **GI**
  - Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI

- **GI**
  - ECOG 0-1

- **GI**
  - ECOG 0-1 and life expectancy > 3 months

- **GI**
  - Mandatory biopsy at screening

- **GI**
  - No neuropathy ≥ Grade 2 per NCI CTCAE v5.0

- **GI**
  - No uncontrolled diabetes mellitus
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</table>
| MEL        | BMS CA224-048 | Nivolumab Q4W + Relatlimab Q4W + IDO1 inhibitor oral lV/l | Untreated, unresectable stage III or IV melanoma | 1st line | - Both BRAF V600 wild-type and -mutant melanoma participants are allowed and mutation status must be documented.  
  - Prior neoadjuvant and adjuvant treatments (including cytokines, interferon, and anti-CTLA-4 and anti-PD-1/PD-L1) are allowed, if completed at least 6 months prior to enrollment and all related AEs have either returned to baseline or stabilized. Cannot have had prior exposure to any IO therapies other than cytokines, interferon, anti-CTLA-4 and/or anti-PD-1/PD-L1 antibody therapy.  
  - Uveal melanoma participants are not allowed  
  - Patient without archived tissue less than 3 months old must undergo a MANDATORY pretreatment biopsy  
  - At least 1 measurable lesion as per RECIST1.1  
  - ECOG 1; life expectancy ≥ 12 weeks at time of informed consent; LVEF ≥ 50 %  
  - No history of interstitial lung disease/pneumonitis; No known or suspected CNS metastases ; No active, known or suspected autoimmune disease, no uncontrolled or significant cardiovascular disease; No history of of life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI > 2 x ULN; no blood transfusion within 4 weeks of C1D1 |
| MEL        | BMS CA224-020 | Anti Lag-3 + Nivolumab | Melanoma | ONLY IO NAÏVE MELANOMA COHORT OPEN Cohort 2: participants who have not received prior systemic anticancer therapy for unresectable or metastatic melanoma (confirmed stage III or stage IV) | 1st line | - Histologic or cytologic confirmation of an incurable solid malignancy that is advanced (metastatic and/or unresectable)  
  - BRAF status must be known  
  - Must have measurable disease  
  - ECOG 0-1 and life expectancy > 3months  
  - Mandatory biopsy at screening  
  - Tropinin T or I must be ≤ 2 x ULN  
  - Prior neodjuvant/adjuvant therapies allowed with certain condition  
  - Uveal melanoma NOT eligible |
| MEL        | 20140318     | TVEC+ pembrolizumab | -Basal Cell Carcinoma (BCC) - Cutaneous Squamous Cell Carcinoma (CSCC) | Open Cohort 2: participants who have not received prior systemic anticancer therapy for unresectable or metastatic melanoma (confirmed stage III or stage IV) | | - Measurable tumor lesions that are suitable for injection (≥ 1 cm)  
  - BCC: No prior treatment with a checkpoint inhibitor.  
  - BCC: Progression on or following at least 1 prior standard of care systemic anti-cancer therapy  
  - Subjects with previously treated cerebral metastases may be enrolled, provided that all lesions have been adequately treated  
  - Liver tumors must not be estimated to invade approximately more than one-third of the liver;  
  - Liver tumor-directed therapy, hepatic surgery, antibody-based therapy, or immunotherapy must not have been performed < 28 days, chemotherapy < 21 days, and targeted small molecule therapy or hormonal therapy < 14 days prior to enrollment;  
  - ≤ grade 1 toxic effects of prior therapy and/or complications from prior intervention before starting therapy  
  - No prior therapy with tumor vaccine, TVEC or oncolytic virus  
  - Life expectancy ≥ 5 months |
### Indication: Mélanome

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| CHUV-DD-0018-NeoTIL-2019 | Lymphodepletion: Cyclophosphamide + Fludarabine + Radiotherapy NeoTILs and IL-2 | Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors | Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting | - For Mélanome: Includes cutanéous  
- Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI  
- Measurable disease as per RECIST 1.1 in addition to resectable lesions  
- ECOG 0-2 with life expectancy ≥ 3 months |
| BMS CA027-002 Phase Ia | Melanoma (Part 1B): BMS-986253 (IL8 > 10pg) + Nivolumab  
Melanoma (Part 1C): BMS-986253 (any IL8 level) + Nivolumab + Ipilimumab | Histologically confirmed, unresectable Stage III or Stage IV melanoma. Ocular or uveal melanoma are ineligible. | All participants must have received, and then progressed, relapsed, or been intolerant to at least 1 standard treatment regimen in the advanced or metastatic setting according to tumor type | - Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion  
- ECOG 0-1  
- Participants in Part 1: Must have documented progressive or recurrent disease on or within 3 months of discontinuation of anti-PD-(L)1 therapy (administered as monotherapy or as part of a combination) as per RECIST 1.1 criteria.  
- Prior PD-(L)1-based therapy must be the most recent treatment.  
- BRAF (V600) mutation status must be known |
| BMS CA022-001 Phase I | - Bras 1 Ipilimumab monotherapy  
- Bras 2-3 et 4 monotherapy BMS 986218 (7, 20 ou 70mg | Advanced | Part 2A  
Participants with advanced stage cutaneous melanoma who have received standard therapies with proven survival benefit including prior immunotherapy with an anti-PD-1 or anti-PD-L1 containing regimen and must have progressive or recurrent disease after prior PD-1/PD-L1 directed therapy  
- No more than 1 intervening therapy is allowed but not required between prior anti-PD-1/anti-PD-L1 containing regimen and BMS-986218 | - ECOG PS: 0-1  
- Progressed after prior immunotherapy with anti-PD-1 / anti-PD-L1 either by itself or in combination with other systemic therapy agents  
- Patients with  
- Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 1, or deemed irreversible.  
- No Prior participation in an anti-CTLA-4-NF clinical study or therapy  
- Participants with primary CNS malignancies, or tumors with CNS metastases as the only site of disease, will be excluded  
- Participants with advanced stage cutaneous melanoma who have received standard therapies with proven survival benefit including prior immunotherapy with an anti-PD-1 or anti-PD-L1 containing regimen and must have progressive or recurrent disease after prior PD-1/PD-L1 directed therapy.  
- No more than 70% of the randomized participants should have had progression of disease within a period of 6 months of start of therapy with anti-PD-1/PD-L1 agent |
## ÉTUDES CLINIQUES

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<td><strong>URO</strong></td>
<td>BMS CA022-001</td>
<td>Part IB (Nivolumab 480mg + BMS 986218)</td>
<td>advanced</td>
<td>Part 1B: Progressed or relapse after at least 2 standard systemic with proven survival benefit according to their tumor type in advanced or metastatic disease</td>
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<td>Part 2B: NSCLC prior anti PD-1/anti PD-L1</td>
<td>• ECOG PS: 0-1</td>
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<td>• if anti-PD-1 therapy is approved in a given indication, participants are eligible to receive this treatment as part of the combination regimen in this study prior to having completed 2 prior systemic therapy regimens after discussion and agreement with the Medical Monitor (or designee)</td>
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<td>• Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 1, or deemed irreversible.</td>
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<td><strong>URO</strong></td>
<td>BMS CA027-002</td>
<td>UCC + RCC (Part 1B): BMS-986253 (IL8 &gt; 10pg) + Nivolumab</td>
<td>Histologically confirmed, advanced (ie, unrespectable or metastactic) squamous cell carcinoma of the Urothelium involving the bladder, uretra, ureter or renal pelvis</td>
<td>All participants must have received, and then progressed, relapsed, or been intolerant to at least 1 standard treatment regimen in the advanced or metastatic setting according to tumor type</td>
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<td>Renal cell carcinoma with a clear cell component</td>
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<td>• Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion</td>
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<td>• ECOG 0-1</td>
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<td>• Must have documented progressive or recurrent disease on or within 3 months of discontinuation of anti-PD-(L)1 therapy (administered as monotherapy or as part of a combination) as per RECIST 1.1 criteria.</td>
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<td>• Prior PD-(L)1-based therapy must be the most recent treatment.</td>
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<td>CHUV-DO-0018</td>
<td>Lymphodepletion: Cyclophosphamide +Fludarabine</td>
<td>Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors</td>
<td>Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting</td>
<td>• Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI</td>
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<td></td>
<td>NeoTil-2019</td>
<td>Raditiontherapy NeoTILs and IL-2</td>
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<td>• Measurable disease as per RECIST 1.1 in addition to resectable lesions</td>
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| ORL        | BMS CA224-048 | Nivo 480mg Q4W Relatlimab 160mg Q4W (IDO1 inhibitor oral 1x/s) | Histology restricted to SCCHN from any of the following primary sites only: oral cavity, oropharynx, hypopharynx, and larynx. | Must have metastatic or recurrent SCCHN not amenable to therapy with curative intent (surgery or radiation therapy with or without chemotherapy). Participants who have progressed within 6 months of platinum-based therapy used as part of concurrent chemoradiation (definitive or adjuvant therapy) are also eligible. | • IO naive  
• Patient without archived tissue less than 3 months old must undergo a MANDATORY pretreatment biopsy  
• At least 1 measurable lesion as per RECIST1.1  
• Eligible regardless of HPV status (HPV status must be documented)  
• ECOG 1; Life expectancy ≥ 12 weeks at time of informed consent; LVFE ≥ 50%  
• No G6PD deficiency; No hypersensitivity or idiosyncratic reaction to methylene blue; No history of serotonin syndrome or cyt b5 reductase deficiency or disease that put at risk of methemoglobinemia; No known or suspected CNS metastases ; No active, known or suspected autoimmune disease, no uncontrolled or significant cardiovascular disease; No history of life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI > 2 x ULN; no blood transfusion within 4 weeks of C1D1  
• IO naive  
• Patient without archived tissue less than 3 months old must undergo a MANDATORY pretreatment biopsy  
• At least 1 measurable lesion as per RECIST1.1  
• Eligible regardless of HPV status (HPV status must be documented)  
• ECOG 1; Life expectancy ≥ 12 weeks at time of informed consent; LVFE ≥ 50%  
• No G6PD deficiency; No hypersensitivity or idiosyncratic reaction to methylene blue; No history of serotonin syndrome or cyt b5 reductase deficiency or disease that put at risk of methemoglobinemia; No known or suspected CNS metastases ; No active, known or suspected autoimmune disease, no uncontrolled or significant cardiovascular disease; No history of life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI > 2 x ULN; no blood transfusion within 4 weeks of C1D1  
• IO naive  
• Patient without archived tissue less than 3 months old must undergo a MANDATORY pretreatment biopsy  
• At least 1 measurable lesion as per RECIST1.1  
• Eligible regardless of HPV status (HPV status must be documented)  
• ECOG 1; Life expectancy ≥ 12 weeks at time of informed consent; LVFE ≥ 50%  
• No G6PD deficiency; No hypersensitivity or idiosyncratic reaction to methylene blue; No history of serotonin syndrome or cyt b5 reductase deficiency or disease that put at risk of methemoglobinemia; No known or suspected CNS metastases ; No active, known or suspected autoimmune disease, no uncontrolled or significant cardiovascular disease; No history of life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI > 2 x ULN; no blood transfusion within 4 weeks of C1D1 |

| ORL        | BMS CA027-002 | BMS-986253 (anti-IL-8) + Nivolumab | Histologically confirmed, advanced (ie, unresectable or metastatic) squamous cell carcinoma of the Oral Cavity, Pharynx, Larynx. | All participants must have received, and then progressed, relapsed, or been intolerant to at least 1 standard treatment regimen in the advanced or metastatic setting according to tumor type | Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion  
• ECOG 0-1  
• Participants must have documented progressive or recurrent disease on or within 3 months of discontinuation of anti-PD-L1 therapy (administered as monotherapy or as part of a combination) as per RECIST 1.1 criteria.  
• Prior PD-L1-based therapy must be the most recent treatment.  
• For SCC of the oropharynx, HPV status must be documented. Both HPV-positive or HPV-negative participants are permitted in this cohort.  
• Must have measurable disease  
• ECOG 0-1 and life expectancy > 3months  
• Mandatory biopsy at screening  
• NO neuropathy  
• NO Uncontrolled diabetes mellitus |

| ORL        | SAKK 11/16: MVX-ONCO-1 in advanced HNSCC | MVX-ONCO-1: composed of irradiated autologous tumor cells and an immune-modulator | Patients with advanced HNSCC (stage III/IV) in recurrent or metastatic stage with disease progression | One line of prior anticancer therapy for recurrent or metastatic disease. Patients with locally advanced disease experiencing local relapse within 6 months of last dose of curative intended, platinum-based chemoradiation with or without prior surgery can also be included. | [Incl]Primary tumor and/or metastasis amenable for partial/total surgery or tap and subsequent cell harvest >26x106 cells  
[Incl]WHO performance status 0-2  
[Exc]Known or suspected CNS metastases or active leptomeningeal disease  
[Exc]Any chemotherapy treatment in the 4 preceding weeks of the pre-registration  
[Exc]History of hematologic or primary solid tumor malignancy, unless in remission for at least 3 years from registration with the exception of T1-2 prostate cancer Gleason score <6 , adequately treated cervical carcinoma in situ or localized non-melanoma skin cancer |

| ORL        | SEAGEN SGN86A-001 | SGN86A-001 | Locally advanced or metastatic head and neck cancers | Subjects must have received platinum-based therapy and a PD-1/PD-L1 inhibitor, if eligible by biomarker status and local standard of care. These agents may have been administered either as single agents or in combination | Must have measurable disease  
• ECOG 0-1 and life expectancy > 3months  
• Mandatory biopsy at screening  
• NO neuropathy  
• NO Uncontrolled diabetes mellitus |
<table>
<thead>
<tr>
<th>Indication</th>
<th>Study name</th>
<th>Treatment</th>
<th>Stage &amp; histological type</th>
<th>Line</th>
<th>Other key eligibility criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARC</td>
<td>CHUV-DO-0018-NeoTIL-2019</td>
<td>Lymphodepletion: Cyclophosphamide + Fludarabine + Radiotherapy NeoTILs and IL-2</td>
<td>Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors</td>
<td>Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting</td>
<td>• Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI • Measurable disease as per RECIST 1.1 in addition to resectable lesions • ECOG 0-2 with life expectancy ≥ 3 months</td>
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