



## Phase 1 Trials Open to Enrollment

To submit a referral: please send an email to [NTPReferrals@mssm.edu](mailto:NTPReferrals@mssm.edu) with the following information\*

\*see survey at the bottom of this email

### NEO-PV-01 + Adjuvant with Nivolumab

**PI:** Bhardwaj, Friedlander, Galsky, Gomez  
**Contact:** [simona.podgrabinska@mountsinai.org](mailto:simona.podgrabinska@mountsinai.org)

#### Open Slots:

- Melanoma stage III or IV
- Smoking associated NSCLC IIIB or IV
- Unresectable or Metastatic TCC

#### Key Eligibility:

- one site of disease measurable by RECIST 1.1 and one site of disease accessible for repeat biopsy
- no more than one prior systemic therapy for metastatic disease

### PGv001 a multi peptide therapeutic vaccine

**PI:** Bhardwaj, Friedlander, Marron, Dottino, Galsky, Gomez, Landry, Lee, Mehrazin, Port, Posner, Shapiro, Tiersten  
**Contact:** [simona.podgrabinska@mountsinai.org](mailto:simona.podgrabinska@mountsinai.org)

#### Open Slots:

- Solid Tumors
- Multiple Myeloma

#### Key Eligibility:

- NED at time of vaccination and MUST collect fresh tissue
- risk of disease recurrence in a 5 year time period must be  $\geq 30\%$

### Pembrolizumab in patients with HIV, relapsed or disseminated cancer

**PI:** Bhardwaj, Friedlander, Marron, Sung, Ang, Pintova, Brody, Gomez, Dierterich, Kaplan-Lewis  
**Contact:** [simona.podgrabinska@mountsinai.org](mailto:simona.podgrabinska@mountsinai.org)

#### Open Slots:

- HIV+ NSCLC
- NHL
- CHD
- HCC
- KS
- Melanoma

#### Key Eligibility:

- No Prior treatment with anti-PD-1 or anti-PD-L1

### Treatment of Solid Tumors with Intratumoral Poly-ICLC

**PI:** Bhardwaj, Friedlander, Marron, Lee, Hormigo  
**Contact:** [simona.podgrabinska@mountsinai.org](mailto:simona.podgrabinska@mountsinai.org)

#### Open Slots:

- HNSCC
- Sarcoma
- Melanoma
- Non-melanoma skin cancer

#### Key Eligibility:

- One accessible primary or metastatic tumor site for intratumoral injection

### IT or IV Tremelimumab(CTLA4) and IV Durvalumab (PD1) plus IT PolyICLC

**PI:** Bhardwaj, Friedlander, Marron  
**Contact:** [simona.podgrabinska@mountsinai.org](mailto:simona.podgrabinska@mountsinai.org)

#### Open Slots:

- Solid Tumors with Superficial Mets
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#### Key Eligibility:

- No Prior TX with COMBO CTLA-4 and PD-1/PD-L1 blockade
- One measurable lesion and one additional

### ERY974- Anti-GPC3/CD3 Bispecific antibody

**PI:** Pintova, Ang, Sung  
**Contact:** [Elizabeth.roy@mssm.edu](mailto:Elizabeth.roy@mssm.edu)

#### Open Slots:

- 1 slot in cohort 8

#### Key Eligibility:

- Glypican 3 positive advanced solid tumors
- Exclude if regular drainage for ascites and pleural effusion

### BGB-290 with Temozolomide

**PI:** Galsky, Tsao, Pintova, Tiersten, Gomez, Oh  
**Contact:** [emily.aledort@mssm.edu](mailto:emily.aledort@mssm.edu)

#### Open Slots:

- Advanced/Metastatic solid tumors

#### Key Eligibility:

- No Prior TX with COMBO CTLA-4 and PD-1/PD-L1 blockade but single checkpoint is included

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| <p align="center"><b>MK-1454 +/- Pembrolizumab</b></p> <p align="center"><b>PI: Brody, Ang, Galsky, Marron, Misiukiewicz, Tiersten, Shapiro, Shulman, Simpson, Levitt, Landry, Lee</b></p> <p align="center"><b>Contact: emily.aledort@mssm.edu</b></p> |   |
| <p><b>Open Slots:</b></p> <ul style="list-style-type: none"> <li>- Metastatic Solid Tumors</li> <li>- Lymphoma</li> </ul>   | <p><b>Key Eligibility:</b></p> <ul style="list-style-type: none"> <li>- At least 1 superficial injectable lesion which is amenable to injection and biopsy</li> <li>- 1 superficial distal lesion amenable to biopsy</li> </ul> |

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| <p align="center"><b>CPI-444 +/- Atezolizumab in Advanced Cancer</b></p> <p align="center"><b>PI: Brody, Bhardwaj, Posner, Misiukiewicz, Gomez, Friendlander, Marron, Galsky, Shapiro, Smith, Tiersten, Shulman, Ang, Fasano</b></p> <p align="center"><b>Contact: emily.aledort@mssm.edu</b></p> |                                |
| <p><b>Open Slots:</b></p> <ul style="list-style-type: none"> <li>- RCC</li> <li>- TNBC</li> <li>- NSCLC</li> <li>- Melanoma</li> <li>- HNSCC</li> <li>- Prostate cancer</li> <li>- Colorectal cancer</li> <li>- Lymphoma</li> </ul>   | <p><b>Key Eligibility:</b></p> |

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| <p align="center"><b>MEDI9197 +/- Durvalumab</b></p> <p align="center"><b>PI: Brody, Bhardwaj, Posner, Misiukiewicz, Marron, Lee, Galsky, Shulman, Landry, Chung, Shapiro, Ang, Simpson, Cham, Tiersten</b></p> <p align="center"><b>Contact: emily.aledort@mssm.edu</b></p> |   |
| <p><b>Open Slots:</b></p> <ul style="list-style-type: none"> <li>- Solid Tumor</li> <li>- Lymphoma</li> </ul>  | <p><b>Key Eligibility:</b></p> <ul style="list-style-type: none"> <li>- There are different cohorts for deep (CT guided) and superficial (US guided) treatment</li> </ul> |

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| <p align="center"><b>CA-120 Oral Checkpoint blocking therapy</b></p> <p align="center"><b>PI: Brody, Shapiro, Posner, Galsky, Shulman, Gomez, Zakashansky, Tiersten, Misiukiewicz, Marron, Smith</b></p> <p align="center"><b>Contact: emily.aledort@mssm.edu</b></p> |   |
| <p><b>Open Slots:</b></p> <ul style="list-style-type: none"> <li>- Melanoma</li> <li>- NSCLC</li> <li>- RCC</li> <li>- Urothelial</li> <li>- Head &amp; neck squamous carcinoma</li> </ul>  | <p><b>Key Eligibility:</b></p> <ul style="list-style-type: none"> <li>- There are different cohorts for deep (CT guided) and superficial (US guided) treatment</li> </ul> |

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| <p align="center"><b>Molecular Analysis for Therapy Choice</b></p> <p align="center"><b>PI: Shapiro, Irie, Tiersten, Bhardwaj, Hormigo, Ang, Pintova, Sung, Galsky, Oh, Tsao, Posner, Misiukiewicz, Friedlander, Gomez, Smith, Brody, Gabrilove, Parekh, Prasad, Zakashansky, Chari, Cho Jagannath, Lee, Simpson, Argiriadi</b></p> <p align="center"><b>Contact: johnny.chan@mssm.edu</b></p> |   |
| <p><b>Open Slots:</b></p> <ul style="list-style-type: none"> <li>- Solid Tumor - rare mutation confirmed from Foundation, CARIS, MDACC or MSKCC institutional assay</li> </ul>   | <p><b>Key Eligibility:</b></p> <ul style="list-style-type: none"> <li>- Patients must have progressed following at least one line of standard systemic therapy and there must not be other approved/standard therapy available that has been shown to prolong overall survival</li> </ul> |

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| <p align="center"><b>MAGE-A3/A6 T Cell Receptor Engineered T Cells in HLA-DPB1*04:01 Positive</b></p> <p align="center"><b>PI: Tewari, Galsky, Sfakianos, Lubin, Levine, Madduri, Malone, Osman, Renteria, Steingerg, Isola, Jagannath, Ferrara, Scigliano, Keyzner</b></p> <p align="center"><b>Contact: cynthia.knaur@mountsinai.org</b></p> |   |
| <p><b>Open Slots:</b></p> <ul style="list-style-type: none"> <li>- Advanced Urothelial Carcinoma</li> <li>- Advanced Lung carcinoma</li> <li>- Other MAGE A3/A6 positive solid tumors</li> </ul>   | <p><b>Key Eligibility:</b></p> <ul style="list-style-type: none"> <li>- Patient is HLA-DPB1*04:01 Positive</li> <li>- Tumor is MAGE A3/A6 positive</li> <li>- More specific requirements for multiple myeloma subjects<sup>1</sup></li> </ul> <p><small><sup>1</sup>MM subjects must have had both a protease inhibitor and immunomodulatory drugs as part of their latest 3 prior lines of therapy and must have disease progression as defined by IMWG consensus criteria by the onset of treatment</small></p> |

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| <p><b>Unless otherwise noted, all trials require the following:</b></p> <ul style="list-style-type: none"> <li>- ECOG ≤ 1</li> <li>- Previous Immunotherapies are ALLOWED</li> <li>- Measurable disease</li> <li>- No hx of Autoimmune disease</li> </ul> |
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Please provide the following when submitting a referral:

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| Contact Phone Number                              |  |
| Patient Name                                      |  |
| MRN   |  |
| DX  |  |
| Previous Anti-PD1 (y/n)?                          |  |
| Mets accessible for intratumoral injection (y/n)? |  |