# GU STUDIES

Clinical Research Department: 407-303-2090

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## PROSTATE

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| **NRG GU002**<br>▪<br>**Adjuvant**<br>▪<br>**Radiation & Androgen Deprivation**<br>▪<br>**Post Radical Prostatectomy**<br><br>**Target Accrual: 5**<br>**Actual Accrual:1** | **Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation following Radical Prostatectomy with or without Adjuvant Docetaxel**<br>▪ Prostatectomy within 365 days<br>▪ Any pT stage; pN0 or pNx; M0; Gleason's score ≥7<br>▪ PSA nadir ≥0.2 |
| **JNJ/56021927**<br>▪<br>**Neo-Adjuvant**<br>▪<br>**High-risk localized or locally advanced prostate cancer**<br>▪<br>**Pre- Radical Prostatectomy**<br><br>**Open to Enrollment**<br><br>**Target Accrual: 20**<br>**Actual Accrual: 0** | **(PROTEUS STUDY) NCT03767244**<br>**ADT and +/- Apalutamide, Prostatectomy, ADT and +/- Apalutamide**<br><br>**A Randomized, Double-blind, Placebo-controlled Phase 3 Study of Apalutamide in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Who Are Candidates for Radical Prostatectomy**<br>▪ 4.1. High risk defined by ≥1 of the following 4 criteria:<br>  ▪ Any combination of Gleason Score 4+3 (=Grade Group [GG] 3) and Gleason Score 8 (4+4 or 5+3) from ≥6 systematic cores<br>  ▪ Any combination of Gleason Score 4+3 (=GG 3) and Gleason Score 8 (4+4 or 5+3) from ≥3 systematic cores and PSA ≥20 ng/mL<br>  ▪ Gleason Score ≥9 (=GG 5) in at least 1 systematic or targeted core; or<br>  ▪ At least 2 systematic or targeted cores with continuous Gleason Score ≥8 (=GG 4), each with ≥80% involvement<br>  ▪ ECOG = 0 or 1 |

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| **C3441021**<br>▪<br>**1st Line**<br>▪<br>**Men with mCRCP**<br>▪<br>**DDR deficient**<br><br>**(COMPLETED COHORT 1)**<br>**COHORT 2**<br>**Enrolling**<br><br>**Target Accrual: 3**<br>**Actual Accrual: 3**<br>**Screen Failure: 3** | **A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study OF Talazoparib with Enzalutamide in Metastatic Castration-Resistant Prostate Cancer (TALAPRO-2)**<br><br>▪ Enrolling Part 2<br>▪ Asymptomatic or mildly symptomatic metastatic castration mCRPC<br>▪ Surgically or medically castrated serum testosterone ≤ 50 ng/dL (≤1.73 nmol/L) at screening<br>▪ Prostate specific antigen (PSA) progression defined by a minimum of 2 rising PSA values from 3 consecutive assessments with an interval of at least 7 days between assessments. The screening laboratory PSA value must be ≥2 µg/L (≥2 ng/mL) if qualifying solely by PSA progression<br>▪ Metastatic disease in bone documented on bone scan or in soft tissue documented on CT/MRI scan. Scans obtained as part of standard of care in the 6 weeks (42 days) prior to Day 1 (Part 1) or randomization (Part 2) can be used if they meet study requirements. Measurable soft tissue disease is not required. (Adenopathy below the aortic bifurcation alone does not qualify). |
| | **BLADDER** |
| **MK-3475-866**<br>▪<br>**Neo-Adjuvant**<br>▪<br>**Resectable Locally Advanced**<br><br>**Open to Enrollment**<br><br>**Target Accrual: 10**<br>**Actual Accrual: 0** | **A Phase 3, Randomized, Double-blind Study to Evaluate Perioperative Pembrolizumab (MK-3475) + Neoadjuvant Chemotherapy versus Perioperative Placebo + Neoadjuvant Chemotherapy in Cisplatin-eligible Participants with Muscle-invasive BladderCancer (KEYNOTE-866)**<br><br>▪ MIBC (T2-T4aN0M0) with predominant (≥50%) urothelial histology |
| | **RENAL** |
| **MK-6482-011**<br>▪<br>**Renal Cell Carcinoma (2nd Line)** | **An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Second-line Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After 1 Prior Anti-PD-1/L1 Combination Regimen**<br><br>• Unresectable, locally advanced/metastatic RCC with clear cell component (with or without sarcomatoid features) ie, Stage IV RCC. Previous nephrectomy or metastasectomy is allowed.<br>• Has experienced disease progression on or after first- or second-line systemic treatment with an anti-PD-1/L1 therapy for locally advanced or metastatic RCC. The anti-PD-1/L1 therapy may have been monotherapy or in combination with other agent(s) such as anti-CTLA4 or VEGF-targeted-TKI. The immediately preceding line of treatment has to have been an anti-PD-1/L1 therapy. |

# ALL SOLID TUMORS OTHER THAN NSCLC

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| **APL-101-01**<br>**1st line or 2nd Line**<br>▪<br>**Advanced/Metastatic**<br><br>**Phase 2 Participation**<br>. | **APL-101-01: Phase 1 / 2 Multicenter Study of the Safety, Pharmacokinetics, and Preliminary Efficacy of APL-101 in Subjects with Non-Small Cell Lung Cancer with c-Met EXON 14 skip mutations and c-Met Dysregulation Advance Solid Tumors**<br><br>**Cohort A:** EXON 14 Non-Small-Cell Lung Cancer – c-Met inhibitor naïve<br>▪ Histologically or cytologically confirmed NSCLC with EXON 14 skip mutations<br>▪ All histologies, including pulmonary sarcomatoid carcinoma and squamous<br>▪ Unresectable or metastatic disease (Stage 3b/4)<br>▪ Pretreated subject's refractory to or intolerable to standard therapies (if available, must include anti-PD-1/PD-L1 based systemic therapy) with no more than three lines of prior therapy<br>▪ Not received any c-Met inhibitor (e.g., crizotinib, capmatinib, savolitinib, etc.)<br><br>**Cohort B:** EXON 14 Non-Small-Cell Lung Cancer – c-Met inhibitor experienced<br>▪ Histologically or cytologically confirmed NSCLC with EXON 14 skip mutations<br>▪ All histologies, including pulmonary sarcomatoid carcinoma and squamous<br>▪ Unresectable or metastatic disease (Stage 3b/4)<br>▪ Refractory to standard therapies with no more than three prior lines of therapy<br>▪ Radiographic progression on any c-Met inhibitor (e.g., crizotinib, capmatinib, savolitinib, etc.) at any point in the past<br><br>**Cohort C:** Basket Tumor Types (c-Met high-level amplifications)<br>▪ Any tumor type regardless of histology, including osimertinib relapsed/refractory NSCLC, excluding NSCLC EXON 14 skip mutation, that meets inclusion criteria c-Met high-level amplification |
| **16-214-05**<br>**(Allowable Diagnosis)**<br>•<br>**Hepatocellular**<br>**Urothelial carcinoma**<br>**Melanoma**<br>**NSCLC** | **A PHASE 1/2, OPEN-LABEL, MULTICENTER STUDY TO INVESTIGATE THE SAFETY AND PRELIMINARY EFFICACY OF NKTR-214 IN COMBINATION WITH PEMBROLIZUMAB IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC SOLID TUMORS**<br><br>**Dose Optimization Cohorts (Cohorts 1a and 1b)** |

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| **Head and Neck**<br><br>**No Slots as of 02/11/21** | |
| **ELVCAP-001-01**<br>**(NRG1 fusion Positive)**<br>**CRESTONE**<br>•<br>**2nd line beyond**<br><br>•<br>**Advanced/ Metastatic**<br><br>**Open to Enrollment** | **A Phase 2 Study of Seribantumab in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors**<br><br>▪ Patients must have received a minimum of one prior standard therapy appropriate for their tumor type and stage of disease<br>▪ NRG1 gene fusion identified through molecular assays.<br>▪ ECOG 0-2<br>▪ Measurable disease per RECIST<br>▪ Excluded if patient has symptomatic or untreated brain metastases.<br>▪ Received anticancer therapy within 28 days prior to planned start of seribantumab or 5 half-lives, whichever is shorter |
| **SGNLVA-005**<br><br>**2nd Line**<br><br>**Men with mCRCP**<br><br>▪ Cohort 7, Part B only<br><br>**Pending Amendment 2 Approval at site**<br><br>**Sponsor approval required prior to screening** | **Open-Label Phase 2 Study of Ladiratuzumab Vedotin (LV) for Unresectable Locally Advanced or Metastatic Solid Tumors (Part A closed; now taking part in Part B)**<br><br>▪ Must have metastatic castration-resistant disease<br><br>▪ ECOG 0-1<br><br>▪ Must have received no more than 1 prior line of androgen receptor-targeted therapy for metastatic castration-sensitive prostate cancer (CSPC) or CRPC<br><br>▪ No prior cytotoxic chemotherapy in the metastatic CRPC setting<br>  ▪ NOTE: Patient who received cytotoxic chemotherapy for CSPC, at least 6 months must have elapsed between last dose and start of study treatment<br><br>▪ Patients with known BRCA mutations are excluded |

| **PENDING GU TRIALS** | |
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| **CA-ALT-803-01-16**<br>▪<br>**High Grade NMIBC** | **QUILT-3.032: A Multicenter Clinical Trial of Intravesical Bacillus Calmette-Guerin (BCG) in Combination with ALT-803 in Patients with BCG Unresponsive High-Grade Non-Muscle Invasive Bladder Cancer** |
| **RTOG-3506**<br>▪<br>**Prostate Cancer** | **STEEL: A Randomized Phase II Trial of Salvage Radiotherapy with Standard vs Enhanced Androgen Deprivation Therapy (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences with Aggressive Disease Features** |

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| **MK-3475-992**<br>▪<br>**Muscle-invasive Bladder Cancer (MIBC)** | **KEYNOTE-992: A Phase 3, Randomized, Double-blind, Placebo-controlled Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Chemoradiotherapy (CRT) versus CRT Alone in Participants with Muscle-invasive Bladder Cancer (MIBC) (KEYNOTE-992)**<br><br>**Pending Activation** |
| **C3851001**<br>▪<br>**Non-small cell lung cancer, head and squamous cell carcinoma, esophageal cancer, endometrial cancer, cervical cancer and bladder cancer** | **A phase 1 study to evaluate the safety, pharmacokinetics and pharmacodynamics of escalating doses of PF 0639999 (PRMT5 INHIBITOR) in participants with advanced or metastatic non-small cell lung cancer, head and squamous cell carcinoma, esophageal cancer, endometrial cancer, cervical cancer and bladder cancer**<br><br>**Pending Activation** |
| **MK-6482-012**<br>▪<br>**Renal Cell Carcinoma (1st Line)** | **An Open-label, Randomized Phase 3 Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with MK-6482 and (MK-7902), Lenvatinib or MK-1308A in Combination with Lenvatinib, versus Pembrolizumab and Lenvatinib, as First line Treatment in Participants with Advanced Clear Cell Renal Cell Carcinoma (ccRCC)**<br><br>**Pending Activation** |