NGOC Clinical Trials List - Printable Version

Head and Neck (C00-C14)

1. Locally Advanced
   - **a. WCR -NGOC AMG 20062080 Phase II, Panitumumab Provided (NGOC Marietta Only)** — **Closed 3/5/09**
     - i. ARM 1: CDDP 100mg/m2 q3w x3 + XRT 70Gy/7w — *Accrual* = 2
     - ii. ARM 2: CDDP 75mg/m2 + Panitumumab q3w x 3 + XRT 70Gy/7w — *Accrual Goal* = 3
2. 1st Line Recurrent / Metastatic
   - **a. MK 3475-048 Phase III Randomized (1:1:1) (Pembolizumab Provided) PI: McCune** — **Closed 11/25/16**
     - i. ARM A: Pembrolizumab q3w — *Accrual* = 4
     - ii. ARM B: Pembrolizumab + Platin/FU q3w — *Accrual Goal* = 3
     - iii. ARM C: Cetuximab + Platin/FU q3w
   - **b. ACORN AMG 20050236 Phase II (Panitumumab Provided)** — **Closed 12/24/07**
     - i. Panitumumab + Docetaxel + Cisplatin — *Accrual* = 0
     - ii. Docetaxel + Cisplatin — *Accrual Goal* = 3
   - **c. MK 3475-669 Phase III Randomized (2:1:2) and Open Label** — **Closed 5/1/18**
     - i. Arm A: Pembrolizumab + Epacadostat
     - ii. Arm B: Pembrolizumab — *Accrual Goal* = 5
     - iii. Arm C: EXTREME Regimen: cetuximab + cisplatin + 5-fluorouracil
   - **d. ACORN H3E-MC-S132 (Opened 8/31/2010) Phase II, Recurrent/Metastatic (Pemetrexed Provided)** — **Closed 8/2/12**
     - i. ARM S: Pemetrexed d1, Carboplatin (or Cisplatin)d1, Cetuximab Weekly, (q21d x6) Cetuximab Maintenance Weekly — *Accrual* = 3; *Accrual Goal* = 3
   - **e. RGN WO40242 Atezo as Adj. Therapy After Definitive Local Therapy, Phase III, Rando** — **Closed 12/10/19**
     - i. Atezolizumab/Placebo 1200mg IV Q3 weeks for 16 doses
   - **f. MK 7902-010 Phase 3 Recurrent/Metastatic PD-L1 Selected Population** — **Closed 7/29/22**
     - i. Arm 1: Lenvatinib 10mg PO QD + Pembrolizumab 200mg IV Q3W
     - ii. Arm 2: Placebo PO QD + Pembrolizumab 200mg IV Q3W
   - **g. RGN BO42533 A PHASE II, RANDOMIZED, DOUBLE-BLIND STUDY OF ATEZOLIZUMAB PLUS TIRAGO** — **Closed 4/15/22**
     - i. Arm A:Atezolizumab 1200mg IV q 3 weeks+ tiragolumab 600mg IV q 3 weeks
     - ii. Arm B: Atezolizumab 1200mg IV q 3 weeks + placebo IV q 3 weeks
   - **h. ALX148003 (Aspen-03) Patients with metastatic or unresectable, recurrent HNSCC not yet trea** — **Closed 5/8/24**
     - i. Arm A: ALX148 (evropacept) 45mg/kg IV Q3W + Pembrolizumab 200mg IV Q3W
     - ii. Arm B: Pembrolizumab 200mg IV Q3W up to a maximum of 35 cycles (approx 24 months)
3. Previously Treated
   - **a. See Multiple Sites (NVS Signature Series PDR001)** — **Closed 3/2/15**
   - **b. ACORN LIL JFBF (Opened 8/10/11) Phase II, 2nd or 3rd line** — **Closed 10/15/12**
     - i. Arm S: LY2523355 IV d1,2,3 q21d until disease progression or toxicity — *Accrual* = 1; *Accrual Goal* = 3
   - **c. MK 7902-009 (LEAP 009) A Phase 2, randomized, open-label three-arm clinical study to evaluate** — **Closed 8/2/21**
     - i. Arm A: Pembrolizumab 200mg IV Q3W + Lenvatinib 20mg PO
     - ii. Arm B: SOC Investigators choice: paclitaxel, docetaxel, cetuximab, or capecitabine
     - iii. Arm C: Lenvatinib Monotherapy 24mg QD
     - iv. Arm D: Second Course Tx: Pembrolizumab 200mg IV Q3W +/- lenvatinib

Esophagus/Gastric (C15-C16)

1. Stage II- IV, Neo-adjuvant
   - **a. MPRN GI-57 Phase II, non-randomized. (Oxaliplatin provided)** — **Closed 3/1/08**
     - i. Oxaliplatin + Docetaxel weekly x 5; capecitabine + XRT — *Accrual* = 2; *Accrual Goal* = 5
   - **b. ACORN ARCHESO0611 (Opened 06/09/11) Phase II, (Panitumumab Provided)** — **Closed 11/14/11**
     - i. Arm S: Panitumumab, Paclitaxel, Carboplatin and Continuous 5FU — *Accrual* = 0; *Accrual Goal* = 10
2. First Line, Recurrent or Metastatic
   - **a. BMS CA209-649 Phs III, Open-Label, 3 Arm, Metastatic Gastric or Gastroesophageal Jun** — **Closed 4/11/19**
     - i. Nivolumab 360mg + Xelox q 3 weeks OR Nivo 240mg + Folfox q 2 weeks — *Accrual* = 11
     - ii. Arm is closed: Nivolumab 1mg/kg + Ipilumumab 3mg/kg q 3 weeks x 4 doses then Nivo 240mg q 2 weeks — *Accrual Goal* = 5
     - iii. Chemotherapy Arm: Xelox q 3 weeks or Folfox q 2 weeks
   - **b. BMS CA209-648 Esophageal, Open-Label, 3 Arm, Unresectable, Recurr,Metastatic Prev. U** — **Closed 11/22/19**
     - i. Nivolumab 3mg/kg + Ipilumumab 1 mg/kg — *Accrual* = 3
     - ii. Nivolumab 240mg + 5FU 800mg/m2/day D1-5 + Cisplatin 80mg/m2 on D1 — *Accrual Goal* = 2
     - iii. 5FU 800mg/m2/day D1-5 +Cisplatin 80mg/m2 on D1
   - **c. AZ D702AC00001 (Artemide-Gastric01) A Phase 3 Study of Rilvegostomig in Combination with Fluoropyrimidine** — **Open 8/12/25**
     - i. Arm A: Rilvegostomig + T-Dxd + Investigator's Choice: 5-FU or Capecitabine
     - ii. Arm B: Pembro + trastuzumab + Investigator's choice: Cisplatin+ 5FU or CAPOX+capecitabine
     - iii. Arm C: Rilvegostomic (750mg IV Q3w) + Trastuzumab + Investigator's Choice: Cisplatin+5FU OR CAPOX+Capecitabine
3. Previously Treated
   - **a. SWOG S0415 Phase II (Cetuximab provided)** — **Closed 4/25/05**
     - i. Cetuximab q1w — *Accrual* = 3; *Accrual Goal* = 3
   - **b. See Multiple Sites (EMD EMR 100070-001)** — **Closed 3/2/15**
   - **c. TORI GI-06 (Opened 5/4/10) Adenocarcinoma only; (RAD001 Provided)** — **Closed 5/9/12**
     - i. RAD001 10mg po daily — *Accrual* = 1; *Accrual Goal* = 2
   - **d. ACORN LIL JFBF (Opened 8/10/11) Phase II, 2nd or 3rd Line** — **Closed 10/15/12**
     - i. Arm S: LY2523355 IV d1,2,3 q21d until disease progression or toxicity — *Accrual* = 0; *Accrual Goal* = 3
   - **e. MK 2870-015 A Phase 3 Study to Evaluate MK-2870 in Advanced/Metastatic Gastroesoph** — **Closed 6/16/25**
     - i. Arm1:MK-2870 TROP2 ADC 4mg/kg IV q2w
     - ii. Arm 2: Treatment of Physician's Choice
   - **f. AZ D9802C00001 (Clarity) AZD0901 compared with Investigator's choice of therapy in participants** — **Closed 3/20/26**
     - i. Arm 1: AZD0901 2.2 mg/kg IV Q3W (selected as optimal biologic dose)
     - ii. CLOSED - Arm 2: AZD0901 1.8 mg/kg IV Q3W
     - iii. Arm 3: Investigator's choice of therapy (ramucirumab, paclitaxel, docetaxel, irinotecan, TAS-102, and apatinib)

Biliary (K83.9)

1. First Line Therapy
   - **a. MRK MK3475-966 A Phase 3 Randomized, Double Blind Study of Pembrolizumab Plus Gemcita** — **Closed 5/12/21**
     - i. Arm A: Pembrolizumab + Gemcitabine + Cisplatin q 3 weeks
     - ii. Arm B: Placebo + Gemcitabine + Cisplatin q 3 weeks
   - **b. AZ D702NC00001 A Global Phase III Study of Rilvegostomig Plus Chemotherapy for First-** — **Open 3/25/26**
     - i. Arm A: Rilvegostomig 750mg on D1 of each Q3W+ Gemcitabine 1000 mg/m2 IV Q3W plus cisplatin 25 mg/m2 IV Q3W will be administered on D1 and D8 of each cycle starting on C1D1 for up to 8 cycles
     - ii. Arm B:Durvalumab 1500mg on D1 of each Q4W cycle +Gemcitabine 1000 mg/m2 IV Q3W plus cisplatin 25 mg/m2 IV Q3W will be administered on D1 and D8 of each cycle starting on C1D1 for up to 8 cycles

Pancreas (C25)

1. Adjuvant / NeoAdjuvant
   - **a. CTSU E2204 Phase II, (Cetuximab and Bevacizumab Provided)** — **Closed 1/9/08**
     - i. ARM A: Cetuximab + Gemcitabine
     - ii. ARM B: Bevacizumab + Gemcitabine
     - iii. Both ARMS: Capecitabine + XRT
   - **b. TORI PA-01 (Opened 12/01/2010) Phase II, Randomized Stage I-III, Resected (Dasatinib Provided)** — **Closed 12/28/12**
     - i. ARM A: Gemcitabine x 6 cycles — *Accrual* = 4
     - ii. ARM B: Gemcitabine x 6 cycles + Dasatinib x 1 year — *Accrual Goal* = 4
2. 1st Line, Metastatic
   - **a. PCYC-1137-CA (RESOLVE) PhaseII/III -THE STUDY IS IN A MANUAL APPROVAL PROCESS THRU EOB 3/16/1** — **Closed 4/19/17**
     - i. ARM S: nab-P + Gem d1,8,15 q28d + daily oral study drug (1:1 Ibrutinib vs.Placebo) — *Accrual* = 3; *Accrual Goal* = 5
   - **b. ACORN LIL JMMC (LY618 Provided) (Opened 1/19/12) Phase I/II** — **Closed 5/8/12**
     - i. ARM A: Gemcitabine + LY618 — *Accrual* = 0
     - ii. ARM B: Gemcitabine — *Accrual Goal* = 2
   - **c. ACORN GSK MEK 113487 (Opened 12/17/10) Phase II, 1st Line, Metastatic** — **Closed 6/28/11**
     - i. ARM S: Gemcitabine Weekly + Study Drug p.o. daily (GSK1120212 vs. Placebo) — *Accrual* = 2; *Accrual Goal* = 3
   - **d. ACORN IMC CP02-0555 Phase II, Randomized (Cetuximab & Bevacizumab Provided)** — **Closed 9/3/08**
     - i. Cetuximab + Bevacizumab +FDR Gemcitabine — *Accrual* = 2
     - ii. Cetuximab + Bevacizumab — *Accrual Goal* = 5
   - **e. TORI AMG 20060323 Phase IB/II, Randomized (Study Drugs Provided) Marietta & Austell Only** — **Closed 4/1/09**
     - i. Gemcitabine + AMG 655 or Placebo — *Accrual* = 1
     - ii. Gemcitabine + AMG 479 — *Accrual Goal* = 5
   - **f. AbbVie M20-732 A Phase 1b/2, Randomized, Controlled, Open-Label Study Evaluating the** — **Closed 7/20/23**
     - i. Cohort A: mFFX
     - ii. Cohort B: mFFX + ABBV-927
     - iii. Cohort C: mFFX + ABBV-927 + budigalimab
   - **g. BMS CA240-0030 (MountainTAP) Study of BMS-986504 in Combination with Nab-p/Gem versus Placebo in Co** — **On Hold 5/5/26**
     - i. Phase 2 Dose Selection Arm A: BMS-986504 400mg + Nab-Pac + Gem
     - ii. Phase 2 Dose Selection Arm B: BMS-986504 600mg + Nab-Pac + Gem
     - iii. Phase 2 Dose Selection Arm C: BMS-986504 400mg Placebo + Nab-Pac + Gem
     - iv. Phase 2 Dose Selection Arm D: BMS-986504 600mg Placebo + Nab-Pac + Gem
     - v. NOT YET OPEN Phase 3 Arm E: BMS-986504 Optimal Dose + Nab-Pac + Gem
     - vi. NOT YET OPEN Phase 3 Arm F: BMS-986504 Optimal Dose Placebo + Nab-Pac + Gem
3. Previously Treated
   - **a. NGOC INC 18424-362 (JANUS-1) (Opened 04/16/14) Phase III PI: RCH** — **Closed 1/8/16**
     - i. ARM S: Study Drug (1:1 Ruxolitinib vs. Placebo) + Capecitabine — *Accrual* = 4; *Accrual Goal* = 5

Colon & Rectum (C18-C20)

1. Stage III, Resected Colon, Adjuvant
   - **a. NSABP C-08 Stage II and Stage III, Phase III** — **Closed 10/6/06**
     - i. ARM A: mFOLFOX6 q2w x 12 cycles — *Accrual* = 7
     - ii. ARM B: mFOLFOX6 q2w x 12 cycles + Bevacizumab 2qw x 24 cycles — *Accrual Goal* = 10
   - **b. TORI BO17920A (AVANT) Phase III (Bevacizumab Provided)** — **Closed 5/11/07**
     - i. ARM A: FOLFOX4 — *Accrual* = 9
     - ii. ARM B: FOLFOX4 + Bevacizumab — *Accrual Goal* = 10
     - iii. ARM C: XelOX + Bevacizumab
   - **c. CTSU N0147 Phase III, Randomized, (Cetuximab Provided)** — **Closed 12/27/07**
     - i. ARM A: mFOLFOX6 q2w x 12 — *Accrual* = 7
     - ii. ARM B: mFOLFOX6 q2w x12 + C225 q1w x 24 — *Accrual Goal* = 10
   - **d. GSK 219606 (AZUR -2) Phase 3 Study of Perioperative Dostarlimab in Participants with Untr** — **Closed 4/27/25**
     - i. Arm A: Dostarlimab 500mg IV Q3Wx 4 cycles,Surgery, Dostarlimab 1000mg IV Q6W x6 cycles
     - ii. Arm B: Surgery followed by SOC Folfox
     - iii. Arm B: Surgery followed by SOC Capeox
     - iv. Arm B: Surgery followed by SOC watch and wait
2. Stage IV, Metastatic, 1st Line, Colon or Rectum
   - **a. MK 3475-177 (Keynote-177) Phase III Randomized 1:1 (Pembrolizumab Provided) PI: McCune** — **Closed 1/25/18**
     - i. ARM A: Pembrolizumab
     - ii. ARM B: SOC (FOLFOX or FOLFIRI +/-Cetuximab or Bevacizumab)
   - **b. NGOC GNE MEF4982g (Opened 10/07/2011) Phase II (Study Drug Provided)** — **Closed 7/27/12**
     - i. ARM S: Study Drug (MEGF0444A vs. Placebo) + A-FOLFOX — *Accrual* = 3; *Accrual Goal* = 5
   - **c. NGOC GNE SHH4429g Phase II, Randomized (Study Drug Provided)** — **Closed 5/23/09**
     - i. GDC-0449 + FOLFOX or FOLFIRI + Bevacizumab — *Accrual* = 9
     - ii. Placebo + FOLFOX or FOLFIRI + Bevacizumab — *Accrual Goal* = 5
   - **d. ACORN AFMSMCRC0706 (NGOC DECLINED PARTICIPATION) Phase I, Marietta Site Only (Nexavar Provided)** — **Closed 4/25/08**
     - i. mFOLFOX6 + Nexavar (Dose Escalation) — *Accrual* = 0; *Accrual Goal* = 9
   - **e. ACORN Roche ML21567 (X-BIO) Phase II, Randomized** — **Closed 3/5/09**
     - i. XelOx + Bevacizumab q 2 w — *Accrual* = 0
     - ii. XelIri + Bevacizumab q 2 w — *Accrual Goal* = 5
   - **f. SWOG C80405 Phase III (Cetuximab Provided)** — **Closed 6/21/06**
     - i. ARM A: Bevacizumab + FOLFOX or FOLFIRI — *Accrual* = 14
     - ii. ARM B: Cetuximab + FOLFOX or FOLFIRI — *Accrual Goal* = 10
     - iii. ARM C: Cetuximab + Bevacizumab + FOLFOX or FOLFIRI
   - **g. TORI AMG 20040249 (PACCE) Phase III (Irinotecan Only)** — **Closed 9/14/06**
     - i. ARM A: Chemotherapy + Avastin + Panitumumab — *Accrual* = 3
     - ii. ARM B: Chemotherapy + Avastin — *Accrual Goal* = 10
3. Metastatic, 1st Line, Colorectal
   - **a. BMS CA266-0003 (ROSETTA CRC-203) Pumitamig in Combination with Chemotherapy Versus Bevacizumab in Combi** — **Pending 4/28/26**
     - i. Closed-Phase 2 Arm A1: pumitamig (BMS-986545) Dose Level 1, Day 1 + FOLFOX or FOLFIRI,Q2W
     - ii. Closed-Phase 2 Arm A2: pumitamig (BMS-986545) Dose Level 2, Day 1 + FOLFOX or FOLFIRI,Q2W
     - iii. Closed-Phase 2 Arm B:bevacizumab, Day 1 + FOLFOX or FOLFIRI, Q2W
     - iv. NOT OPEN Phase 3 Arm C: pumitamig RP3D, Day 1 + FOLFOX or FOLFIRI, Q2W; or pumitamig RP3D + CAPOX, Q3W
     - v. NOT OPEN Phase 3 Arm D:bevacizumab, Day 1 + FOLFOX or FOLFIRI, Q2W or bevacizumab + CAPOX, Q3W
4. Metastatic, 3rd Line, Colon
   - **a. ACORN LIL JVBB (Opened 06/09/11) Phase III (Ramucirumab + Leucovorin provided) PI: Hermann** — **Closed 7/31/13**
     - i. Arm S: FOLFIRI + Study Drug (Ramucirumab vs. Placebo) — *Accrual* = 2; *Accrual Goal* = 5
   - **b. ACORN AOI 211 Phase II, Randomized (Study Drug Provided)** — **Closed 8/24/07**
     - i. ARM A: Single Agent Chemotherapy + Perifosine 50mg/d — *Accrual* = 23
     - ii. ARM B: Single Agent Chemotherapy + Placebo — *Accrual Goal* = 10
   - **c. TORI AMG 20060141(SPIRITT) (Opened 02/05/08) Phase II, Randomized (K-ras wild-type only) (Panitumumab Provided)** — **Closed 12/15/10**
     - i. ARM A: Panitumamab + FOLFIRI — *Accrual* = 4
     - ii. ARM B: Bevacizumab + FOLFIRI — *Accrual Goal* = 5
   - **d. SWOG S0600 Phase III, Randomized (Bevacizumb & Cetuximab Provided)** — **Closed 11/13/07**
     - i. Arm 1: FOLFIRI (or Irinotecan) + Cetuximab — *Accrual* = 0
     - ii. Arm 2: FOLFIRI (or Irinotecan) + Cetuximab + lower-dose Bevacizumab — *Accrual Goal* = 5
     - iii. Arm 3: FOLFIRI (or Irinotecan) + Cetuximab + higher-dose Bevacizumab
   - **e. MK7902-017 A Phase 3 Randomized Study of Lenvatinib in Combination with Pembroliz** — **Closed 12/3/21**
   - **f. MK4280A-007 A Phase 3 study of MK-4280A (coformulated favezelimab [MK-4280] plus p** — **Closed 7/29/22**

i. Arm A: MK-4280A 800/200mg IVQ3W (800mg MK4280+ 200mg pembrolizumab)
ii. Arm B: Regorafenib 160mg PO QD Q4W (3WK on 1WK off) OR TAS-102 35/mg/m2 Q4W (twice daily on days 1-5 and 8-12)

g. AbbVie M24-064 Phase 3 comparing Abbv-400 Monotherapy vs Lonsurf+Bevacizumab in subj — **Closed 3/12/26**
i. CLOSED: Stage 1 Arm A: AbbV-400 2.0mg/kg IV Q3W
ii. CLOSED: Stage 1 Arm B: AbbV-400 2.4mg/kg IV Q3W
iii. NOT OPEN Stage 2 Arm A: AbbV-400 Optimal Dose IV Q3W
iv. NOT OPEN Stage 2 Arm B: LONSURF 35mg/m2 PO BID + Bevacizumab 5mg/kg IV q2w

5. Metastatic 2nd or 3rd Line, KRAS Mutated

a. TORI ABX 20030167 EGFR Positive, Phase II — **Closed 7/1/06**
i. ABX-EGF 6mg/kg q 2w — *Accrual* = 1

b. TORI ABX 20030250 EGFR Negative, Phase II — **Closed 7/1/06**
i. ABX-EGF 6mg/kg q2w — *Accrual* = 2

c. ACORN EZN 2208-04 Phase II, (EZN 2208 Provided) — **Closed 3/19/10**
i. Arm A: EZN 2208 d1,8,15 q 28d — *Accrual* = 3; *Accrual Goal* = 5

d. AMG 20190172 Sotorasib and Panitumumab Versus Investigator's Choice for Subjects wi — **Closed 2/10/23**
i. ARM A: Sotorasib 960mg PO QD + Panitumumab 6mg/kg IV Q2W
ii. ARM B: Sotorasib 240mg PO QD + Panitumumab 6mg/kg IV Q2W
iii. ARM C: Trifluridine & Tipiracil (35mg/m2 PO BID Days 1-5 & Days 8-12 up to a max of 80mg per dose) OR Regorafenib (160mg PO QD Days 1-21 of 28 Day cycle)

6. Metastatic 2nd or 3rd Line, KRAS Wild Type

a. ACORN EZN 2208-04 (Opened 8/14/09) Phase II, Randomized 2:1(EZN 2208 Provided) — **Closed 6/24/11**
i. Arm B: EZN 2208 d1,8,15 + Cetuximab — *Accrual* = 2
ii. Arm C: Irinotecan d1,8,15 + Cetuximab — *Accrual Goal* = 5

b. Exelixis XL092-303 (Stellar-303) Randomized Phase 3 study of XL092+Atexo vs Regorafenib in patients wi — **Closed 5/21/24**
i. Arm A: XL092 100mg PO QD + Atezolizumab 1200mg IV Q3W for 21 day cycles
ii. Arm B: Regorafenib (160mg PO QD Days 1-21 of 28 Day cycle)

7. Refractory

a. See Multiple Sites — **Closed 3/2/15**

b. ACORN KRX 343 (X-PECT) (Opened 11/06/10) Phase III, (Perifosine/Placebo Provided) — **Closed 7/22/11**
i. ARM S: Study Drug Daily p.o. + Xeloda d1-14 (Study drug = Perifosine vs. Placebo 1:1) — *Accrual* = 7; *Accrual Goal* = 4

c. ACORN LIL JFBF (Opened 3/31/11) Phase II, 2nd or 3rd line — **Closed 2/16/12**
i. Arm S: LY2523355 IV d 1,2,3 q 21d until disease progression or toxicity — *Accrual* = 0; *Accrual Goal* = 3

Lung, Squamous Cell (C34)

1. Stage IV, Metastatic

a. RGN GO29437 (IMPOWER150) Phase III Randomized (1:1:1) (Atezolizumab +nabPac Provided) PI:McCune — **Closed 3/6/17**
i. ARM A: Atezolizumab + Paclitaxel/Carboplatin — *Accrual* = 4
ii. ARM B: Atezolizumab + nabP/Carboplatin — *Accrual Goal* = 3
iii. ARM C: nabP/Carboplatin

b. ACORN LIL JFCL (Opened 05/13/13) Phase III (Necitumumab Provided) PI: Hermann — **Closed 1/28/14**
i. ARM A: Paclitaxel/Carbo + Necitumumab — *Accrual* = 3
ii. ARM B: Paclitaxel/Carbo — *Accrual Goal* = 4

c. NGOC RGN GO27820 (Opened 09/20/12) Phase II (Study Drug Provided) PI: Hermann — **Closed 9/25/13**
i. ARM S: Taxol/Carbo + Study Drug (MetMab vs. Placebo) — *Accrual* = 3; *Accrual Goal* = 5

2. Second Line

a. NGOC BMS CA209-017 (Opened 10/07/13) Phase III (Nivolumab Provided) PI: Hermann — **Closed 11/8/13**
i. ARM A: Nivolumab — *Accrual* = 0
ii. ARM B: Docetaxel — *Accrual Goal* = 3

Lung, Non-Small Cell (C34)

1. Stage IB, II, IIIA; Adjuvant

a. ACORN OSI-774-302 (RADIANT) Phase III (Study Drug Provided) — **Closed 3/1/10**
i. ARM S: Study Drug (Tarceva or Placebo) daily x 2 years — *Accrual* = 7; *Accrual Goal* = 5

b. RGN GO29527 (IMPOWER010) Phase III Randomized 1:1 PI: McCune — **Closed 7/24/18**
i. PDL-1 + Only: Induction Cisplatin Doublet x 4 cycles — *Accrual* = 0
ii. ARM A: Atezolizumab — *Accrual Goal* = 6
iii. ARM B: BSC

c. ACORN GSK MAGE3 NSC-003 (MAGRIT) (Opened 09/14/10) Phase III, Study Drug Provided — **Closed 12/31/11**
i. ARM S: MAGE3 NSC-003 (Vaccine) or Placebo — *Accrual* = 0; *Accrual Goal* = 5

d. WCR CTSU E1505 Randomized, Phase III — **Closed 7/25/08**
i. Arm A: Platinum Doublet x 4 cycles — *Accrual* = 0
ii. Arm B: Platinum Doublet x 4 cycles + Bevacizumab x 1 year — *Accrual Goal* = 5

e. AZ D5164C00001 (ADAURA) within 10 weeks following complete Surgical Resection, Phase III Rando — **Closed 11/30/18**
i. AZD 9291/Placebo 80mg PO QD for 3 years from date of first treatment — *Accrual* = 0; *Accrual Goal* = 5

2. Stage 1B, II, Resectable IIIA

a. BMS CA209-816 Phase 3-Nivolumab and Ipilimumab versus Platinum-Doublet Chemo — **Closed 5/16/18**
i. Arm A: Nivolumab 3mg/kg q 2 weeks x 3 doses; C1D1 only single dose of Ipilimumab 1mg/kg — *Accrual* = 4
ii. Arm B: Investigator Choice of Platinum Doublet x 3 cycles (Vinorelbine + Cisplatin); (Docetaxel + Cisplatin); (Gemcitabine + Cisplatin); (Pemetrexed _ Cisplatin)

3. Stage II-III Resectable or Resected

a. AZ D910LC00001 (MeRmaiD-1) A Phase III, Randomized, Multicenter, Double-blind, Placebo-controlled — **Closed 3/23/22**
i. Durvalumab + SOC Chemotherapy q3w x4 cycles followed by Durvaluamb q4w x 10 cycles
ii. Placebo + SOC Chemotherapy q3w x4 cycles followed by Placebo q4w x 10 cycles

b. AZ D910MC0001 (MeRmaiD-2) Stage II-III NSCLC Patients with MRD Following Surgery & Curative Inte — **Closed 5/10/22**
i. Durvalumab 1500mg IV q4W (maximum 24 months up to 26 doses/cycles)
ii. Placebo IV q4W (maximum 24 months up to 26 doses/cycles)
iii. MRD negative: Observation

c. MK V940-002 A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Co — **Closed 11/6/24**
i. Arm A:V940 (q3w x 9 doses) + pembrolizumab (q6w x9 cycles)
ii. Arm B: Placebo (q3w X 9 doses) + pembrolizumab (q6w x 9 cycles)

d. BI 1479-0032 (Beamion Lung-3) A Phase 3, Beamion LUNG-3: A study to test whether zongertinib helps — **Open 3/19/26**
i. Arm A: Zongertinib (BI 1810631) 120mg po qd
ii. Arm B: Physicians Choice(Nivolumab 480mg, pembrolizumab 200mg, atezolizumab 1200mg, or durvalumab 1500mg)

4. Stage IIIA-IIIB, Locally Advanced, Unresectable

a. AZ D4191C00001 (PACIFIC) Phase III Randomized (Blinded Study Drug Provided) PI: McCune — **Closed 3/11/16**
i. ARM S: Study Drug (2:1 Durvalumab vs. Placebo) IV q 2w x 12 months — *Accrual* = 2; *Accrual Goal* = 10

b. ACORN LIL H3E-MC-JMIG (Opened 05/14/2010) IIIA-IIIB Unresectable, Phase III — **Closed 9/4/12**
i. ARM A: Pemetrexed + Cisplatin q 21d x3 + XRT 66Gy — *Accrual* = 1
ii. Consolidation: Pemetrexed q 21d x3 — *Accrual Goal* = 5
iii. ARM B: Cisplatin + Etoposide q 28d x 2 + XRT 66Gy
iv. Consolidation: Doublet Choice

c. ACORN LIL S182 Randomized Phase II — **Closed 12/31/06**
i. Induction: Cisplatin + Etoposide + XRT — *Accrual* = 2
ii. Consolidation ARM A: Gemcitabine 1000mg/m2 d1, d8 q 21d — *Accrual Goal* = 5
iii. Consolidation ARM B: Gemcitabine 1000mg/m2 d1, d8 + Docetaxel 75/m2 q21d x 3

d. ACORN LIL H3E-US-S047 Phase II, Non-Squamous Randomized (Pemetrexed Provided) — **Closed 11/6/09**

i. ARM A: Pemetrexed + Carboplatin + XRT — *Accrual* = 8
ii. ARM B: Pemetrexed + Cisplatin + XRT — *Accrual Goal* = 5
iii. Consolidation: Pemetrexed q 21d x 3

e. SCRI LUN 134 Phase II (Pemetrexed and Bevacizumab Provided) — **Closed 1/17/08**
i. Chemoradiotherapy: Pemetrexed + Bevacizumab + Carboplatin + XRT — *Accrual* = 0
ii. Followed by Consolidation: Pemetrexed + Bevacizumab q21d x3 — *Accrual Goal* = 5
iii. Followed by Maintenance: Bevacizumab q3w x 9

f. RGN GO41854 A PHASE III, OPEN-LABEL, RANDOMIZED STUDY OF ATEZOLIZUMAB AND TIRAGOLU — **Closed 1/3/23**
i. Arm A: Atezolizumab 1680mg IV + Tiragolumab 840mg IV Q 4 weeks
ii. Arm B: Durvalumab 10 mg/kg IV Q 2 weeks

5. Stage IIB-IIIB Resected and Chemotherapy-Naive Stage IV

a. RGN MO43576 Phase II, randomized, multi-center, multinational, open-label, cross-o — **Closed 7/7/23**
i. Arm A:Atezolizumab SC 1875 mg Q3W
ii. Arm A:Atezolizumab IV 1200 mg Q3W

b. RGN GO45006 (Skyscaper-15) TIRAGOLUMAB/ATEZO COMPARED WITH PLACEBO/ATEZO IN PARTICIPANTS WITH COM — **Closed 7/24/24**
i. Arm A: Atezolizumab 1680mg + Tiragolumab 840mg IV coinfusion Q4w
ii. Arm B: Atezolizumab 1680mg + Placebo 840mg IV coinfusion Q4w

6. Stage IV, Metastatic

a. NGOC RGN BO28984 (ALEX) ALK + (Opened 10/14/14) Phase III PI: RCH — **Closed 8/26/15**
i. ARM A: Alectinib 600mg bid — *Accrual* = 0
ii. ARM B: Crizotinib 250mg bid — *Accrual Goal* = 2

b. AZ D5160C00007 (FLAURA) Phase III Randomized (Blinded Study Drugs Provided) PI: RCH — **Closed 2/12/16**
i. ARM S: Blinded Study Drugs (2:1 AZD vs. Erlotinib daily) — *Accrual* = 2
Accrual Goal = 4

c. NGOC BMS CA209-227 Phase III, Randomized (Nivolumab, Ipilimumab Provided) PI: RHO — **Closed 8/17/17**
i. PDL-1 POSITIVE COHORT RANDOMIZED (1:1:1) ARMS A, B,C (CLOSED) — *Accrual* = 0
ii. ARM A: Nivolumab 240mg q 2 weeks (CLOSED) — *Accrual Goal* = 10
iii. ARM B: Nivolumab q2w + Ipilimumab q6w (CLOSED)
iv. ARM C: Gem/Platin q3wx4 (Squamous) OR Pem Platin q3wx4, optional Pem Maintenance (Non-Squamous) CLOSED
v. PDL-1 NEGATIVE COHORT RANDOMIZED (1:1:1) ARMS D,F,G (CLOSED)
vi. ARM D: Nivolumab q2w + Ipilimumab q6w (CLOSED)
vii. ARM F: Platin Doublet Chemo q3wx4 (CLOSED)
viii. ARM G: Nivolumab + Platin Doublet Chemo (CLOSED)
ix. PDL-1 Squamous vs non Squamous Randomized (1:1) ARMS H, I
x. ARM H: Nivolumab 360mg + Platin Doublet Chemo q3 weeks
xi. ARM I: Platin Doublet Chemo q3wx4

d. NGOC RGN GO29537 (Non Squamous)IMPower 130 Phase III, Randomized (1:1:1) Atezolizumab and nab Paclitaxel Provided — **Closed 1/16/17**
i. ARM A: Atezolizumab + nabP/Carbo — *Accrual* = 7
ii. ARM B: nabP/Carbo — *Accrual Goal* = 10
iii. ARM X: Crossover Atezolizumab @ Progression of ARM B

e. NGOC AZ D4191C00011 (OCEANS 11) (Opened 10/03/14) Phase II PI: RCH — **Closed 1/31/15**
i. EGFR mt+ : Iressa followed by MEDI4736 — *Accrual* = 2
ii. No Mutation: Tremelimumab followed by MEDI4736

f. NGOC BMS CA209026 (Checkmate 026) (Opened 05/19/14) Phase III PI: RO — **Closed 2/17/15**
i. ARM A: Nivolumab — *Accrual* = 8
ii. ARM B: Physician's Choice — *Accrual Goal* = 5

g. NGOC EMR 100070-001 Phase I — **Closed 3/17/14**

h. NGOC RGN GO28625 (FIR) (Opened 08/21/2013) Phase II PI: Hermann — **Closed 4/29/14**
i. Cohort 1: 1st Line (Opened to Enrollment 10/04/13)(On Hold 04/07/14) — *Accrual* = 1
ii. Cohort 2: Greater than or Equal to 2nd Line (Re-Opened to Enrollment 02/18/14)) — *Accrual Goal* = 9
iii. Cohort 3: Brain Mets (Closed to accrual Oct. 3, 2013)
iv. ARM S: MPDL3280A 1200mg IV q3w x 16

i. NGOC RGN GO28754 (BIRCH) (Opened 12 16 2013) Phase II (Study Drug Provided) PI: McCune — **Closed 10/8/14**
i. ARM S: MPDL3280A 1200mg IV q3w x 16 — *Accrual* = 6
ii. Cohort 1: 1st Line — *Accrual Goal* = 5
iii. Cohort 2: 2nd Line
iv. Cohort 3: 3rd line or greater

j. NGOC RGN GO27821 (Opened 09/20/12) Phase II (Study Drug Provided) PI: Hermann — **Closed 5/23/13**
i. ARM S1: Taxol/Carbo/Bev + Study Drug (MetMab vs. Placebo) — *Accrual* = 4
Accrual Goal = 5

k. BMS CA225099 Phase IIB — **Closed 9/20/06**
i. ARM A: Taxol 200/m2 d1; Carboplatin AUC=6 d1; Cetuximab 250mg/m2/wk; q21d — *Accrual* = 20
ii. ARM B: Taxol 200/m2 d1; Carboplatin AUC=6 d1; q21d

l. ACORN BAY 11961 Phase III, (Study drug provided) — **Closed 4/25/07**
i. Initial: Paclitaxel + Carboplatin q21d + Sorafenib (or Placebo) d2-19 q21d — *Accrual* = 3
ii. Maintenance: Continue Sorafenib or Placebo continuously until disease progression. — *Accrual Goal* = 5

m. ACORN AMG 20060136 Phase II, (Bevacizumab and AMG 706 Provided) — **Closed 8/30/07**
i. ARM A: AMG 706 125mg/d + Taxol/Carbo AUC =6 q21d x 4 — *Accrual* = 0
ii. ARM B: AMG 706 75mg/d bid (5 days on 2 days off) + Taxol /Carbo q21d x 4 — *Accrual Goal* = 5
iii. ARM C: Bevacizumab 15mg/kg + Taxol/Carbo q21d x 4

n. TORI GNE AVF3671g (ATLAS) Phase IIIB, Randomized (Bevacizumab & Erlotinib Provided) — **Closed 4/11/08**
i. Induction Choice + Bevacizumab q21d x 4 cycles — *Accrual* = 7
ii. Maintenance: Bevacizumab + Study Drug (Erlotinib vs. Placebo) daily x 2yrs (or until progression) — *Accrual Goal* = 5
iii. Post-progression Bevacizumab and/or Erlotinib provided.

o. ACORN NOV ASA404A2301 Phase III, Randomized (Study Drug Provided) — **Closed 7/25/08**
i. Paclitaxel + Carboplatin + Study Drug — *Accrual* = 0
Accrual Goal = 10

p. ACORN LIL H3E-MC-JMHD Phase III, Non-Squamous Only, (Pemetrexed & Bevacizumab Provided) — **Closed 9/10/10**
i. ARM A: Pemetrexed + Carbo + Bevacizumab x 4 cycles followed by Pemetrexed + Bevacizumab Maintenance Therapy — *Accrual* = 19
ii. ARM B: Paclitaxel + Carbo + Bevacizumab x 4 cycles followed by Bevacizumab Maintenance Therapy — *Accrual Goal* = 6

q. SWOG S0536 Phase II (Cetuximab & Bevacizumab Provided) — **Closed 9/15/07**
i. Cetuximab + Bevacizumab + Paclitaxel + Carboplatin

r. ACORN ALJBNSCLC0602 Phase II, Age >/= 65 (Pemetrexed, Gemcitabine & Bevacizumab Provided) — **Closed 7/10/09**
i. Pemetrexed & Gemcitabine + Bevacizumab IV q 2w — *Accrual* = 3
Accrual Goal = 5

s. NGOC GNE MEF4984g (Opened 8/23/11) Phase II, Non-Squamous Only (Study Drug Provided) — **Closed 6/22/12**
i. ARM S: Paclitaxel, Carboplatin, Bevacizumab + Study Drug (MEGF0444A/Placebo) — *Accrual* = 2
Accrual Goal = 10

t. ACORN LIL S130 (Opened 11/10/10) Phase III, Non-Squamous Only (Pemetrexed Provided) — **Closed 3/26/12**
i. ARM A: Pemetrexed + Carboplatin x 4, Maintenance Pemetrexed — *Accrual* = 2
ii. ARM B: Paclitaxel + Carboplatin + Bevacizumab x 4, Maintenance Bevacizumab — *Accrual Goal* = 5

u. ACORN AC01L08 (Opened 8/14/2009) Phase IIb Randomized, Stratified (Cetuximab Provided) (Non-Squamous On — **Closed 5/9/11**
i. ARM A: Paclitaxel + Carboplatin + Cetuximab — *Accrual* = 8
ii. ARM B: Gemcitabine + Carboplatin + Cetuximab — *Accrual Goal* = 10
iii. ARM C: Pemetrexed + Carboplatin + Cetuximab (Non-Squamous)

v. SCRI BPR LUN 201 (Opened 6/15/10) Phase III, Squamous Only (BSI 201 Provided) — **Closed 5/10/12**
i. ARM A: Gemcitabine d1& d8 + Carboplatin d1+ BSI-201 d1,4,8,11 — *Accrual* = 7
ii. ARM B: Gemcitabine d1& d8 + Carboplatin d1 — *Accrual Goal* = 5

w. WCR SWOG S0635 Phase II, (BAC or Adeno BAC only) — **Closed 5/9/08**
i. Erlotinib + Bevacizumab — *Accrual* = 0
Accrual Goal = 3

x. WCR SWOG S0636 Phase II, IIIB/IV (Adeno, Never Smoker) — **Closed 6/4/08**
i. Erlotinib + Bevacizumab — *Accrual* = 1
Accrual Goal = 3

y. NGOC BMS CA209-384 (Opened 12/06/16) Phase IIIb/IV (Nivolumab provided) — **Closed 5/18/18**
- i. ARM 1: Nivolumab 240mg q 2 weeks
- ii. ARM 2: Nivolumab 480mg q 4 weeks — *Accrual Goal* = 8

z. BMS CA209-9LA Phase III, First Line in Stage IV NSCLC, Nivo plus Ipi in Combination — **Closed 11/26/18**
- i. Arm 1: Induction 2 cycles Nivolumab + Ipilumumab in Combination with Chemo — *Accrual* = 8
- ii. Arm 2: Platnium Doublet x 4 cycles — *Accrual Goal* = 5

aa. RGN BO39633 (IMBRELLA) Extension Study Previously Enrolled Patients — **Closed 8/5/17**

ab. MK 7902-007 (LEAP 007) Phase III, Double-Blind Trial of Pemb without Lenvatinib in sujbects with treatment naive metastatic NSCLC — **Closed 12/31/20**
- i. Pembrolizumab 200mg IV Q3W (up to 35 cycles) + Lenvatinib/Placebo 20mg PO QD (until meeting DC Criteria) — *Accrual* = 3
- ii. Second Course re-treatment available for Subjects who receive 35 administrations of Pembro or Subjects who have been on study intervention for at least 24 weeks and attain a confirmed CR — *Accrual Goal* = 4

ac. CLT CX-839-014 A Phase 2 Randomized, Multicenter, Double-Blind Study of the Glutamina — **Closed 11/5/21**
- i. Pembrolizumab+Carboplatin+Pemetrexed+Telaglenastat
- ii. Pembroluzumab+Carboplatin+Pemetrexed+Placebo

ad. RGN BO42592 A PHASE II, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF TIRA — **Closed 8/25/23**
- i. Arm A: Induction of 4 cycles of Carboplatin/Cisplatin + Pemetrexed+Tiragolumab 600mg IV q 3 weeks + Atezolizumab 1200mg IV q 3 weeks followed by maintenance with Tiragolumab+Atezolizumab+pemetrexed q
- ii. Arm B:Induction of 4 cycles of Carboplatin/Cisplatin + Pemetrexed+Placebo 600mg IV q 3 weeks + Atezolizumab 1200mg IV q 3 weeks followed by maintenance with Placebo 600mg IV+Atezolizumab+pemetrexed q

ae. AMG 20190288 (CodeBreaK 201) Phase 2 Sotorasib (AMG 510) in Subjects with NSCLC with KRASG12C Mutat — **Closed 11/18/22**
- i. Arm A: Sotorasib (AMG 510) 960mg Oral Daily x21days
- ii. Arm B: Sotorasib (AMG 510) 240mg Oral Daily x21days

7. First Line- Metastatic

a. MK 3475-D46 An Open-label, Multicenter, Phase 3 Randomized, Active-Comparator- Con — **Closed 5/21/24**
- i. Arm A: Sacituzumab Govitecan 180mg or 200mg Q3 weeks IV (10mg/kg D1 and D8 until PD) + Pembrolizumab 25mg/mL Q3 weeks (200mg D1 up to 35 cycles)
- ii. Arm B: Pembrolizumab 25mg/mL Q3 weeks IV (200mg D1 up to 35 cycles)

b. MK 2870-007 Phase 3 Study of MK-2870 in Combination With Pembro VS Pembro Monother — **Closed 5/20/25**
- i. Arm A: MK-2870 4mg/kg Q2w until PD + Pembrolizumab 400mg IV Q6W upto 18cycles
- ii. Arm B: Pembrolizumab 400mg IV Q6W upto 18 cycles

c. MK2870-023 A Phase 3 Study of Pembrolizumab in Combination With Carboplatin/Taxa — **Closed 5/20/25**
- i. Arm A: MK-2870 4mg/kg Q2w + Pembrolizumab 400 mg Q6w up to 16 cycles
- ii. Arm B: Pembrolizumab 400mg Q6w up to 16 cycles

d. MRT 849-007 (Krystal-7) Phase 3 Trial of Adagrasib+Pembrolizumab vs Pembro Patients w Adv NSCL — **Closed 6/27/25**
- i. Cohort 3: Adagrasib (MRTX849) 400 mg BID (until PD) + pembrolizumab 200mg IV Q3W (up to 35 cycles)
- ii. Cohort 4: Pembrolizumab 200mg IV Q3W (up to 35 cycles)

e. AZ D702GC00001 Artemide Lung-04 A Global Phase III Study of Rilvegostomig or Pembrolizumab Monotherapy — **Open 1/7/26**
- i. Arm A: Rilvegostomig 750 mg IV Q3W
- ii. ArmB: Pembrolizumab 200 mg IV Q3W

f. BMS CA266-0002(ROSETTA Lung-202) A Study of Pumitamig Versus Pembrolizumab in Participants With Previou — **Open 4/15/26**
- i. Arm A: Pumitamig 1200 mg (if body weight < 50 kg) or 1500 mg (if body weight ≥ 50 kg) as a 60-minute IV infusion every 3 weeks (Q3W)
- ii. Arm B: Pembrolizumab 200 mg as a 60-minute IV infusion every 3 weeks (Q3W)

g. BMS CA239-0004 (KRYSTAL-4) Adagrasib plus Pembrolizumab plus Chemotherapy vs. Placebo plus Pembro — **Open 5/19/26**
- i. Arm A: Adagrasib 400mg BID + pemetrexed 500mg/m2 Q3W (until PD or unacceptable toxicity) + [cisplatin 75mg/m2 OR carboplatin AUC 5mg/mL/min Q3W (4 cycles)] + pembrolizumab 200mg Q3W (up to 24 months)
- ii. Arm B: Placebo + pemetrexed 500 mg/m2 Q3W (until PD or unacceptable toxicity) + [cisplatin 75 mg/m2 OR carboplatin AUC 5 mg/mL/min Q3W (4 cycles)] + pembrolizumab 200 mg Q3W (up to 24 months)

8. 2nd or 3rd Line

a. USOR 10090 ARQ U302 (Opened 2/23/11) Phase III, (Study Drug Provided) — **Closed 5/15/12**
- i. ARM S: Erlotinib + Study Drug Daily (Study Drug = 1:1 ARQ197:Placebo) — *Accrual* = 9; *Accrual Goal* = 7

b. NGOC PFZ 1009 ARCHER (Opened 06/25/12) Phase III (Study Drug Provided) PI: Hermann — **Closed 2/15/13**
- i. ARM S: Dacomitinib/Plbo vs. Erlotinib/Plbo daily — *Accrual* = 8; *Accrual Goal* = 5

c. NGOC BMS CA209-057 (Opened 05/30/13) Phase III (Nivolumab Provided) PI: Hermann — **Closed 11/8/13**
- i. ARM A: Nivolumab — *Accrual* = 3
- ii. ARM B: Docetaxel — *Accrual Goal* = 5

d. ACORN LIL JFBF (Opened 8/10/11) Phase II, 2nd or 3rd line — **Closed 5/8/12**
- i. Arm S: LY2523355 IV d 1,2,3 q21d until disease progression or toxicity — *Accrual* = 0; *Accrual Goal* = 3

e. SWOG S0424 Epidemiology Case Study — **Closed 5/18/06**
- i. Submission of Lung Cancer Epidemiology Questionnaire, blood specimen, and tumor blocks or slides. — *Accrual* = 6; *Accrual Goal* = 10

f. NGOC SCRI LUN 160 Phase II, (No Prior Erlotinib) (Erlotinib & Study Drug Provided) — **Closed 2/3/09**
- i. Erlotinib + Study Drug (Sorafenib or Placebo 2:1) — *Accrual* = 3; *Accrual Goal* = 3

g. ACORN PFZ A7471028 Phase II, Randomized, Open Label, Drugs Provided — **Closed 5/8/09**
- i. Arm A: Erlotinib 150mg daily — *Accrual* = 3
- ii. Arm B: PF-00299804 45mg daily — *Accrual Goal* = 5

h. MIRATI 516-005 Phase 3 Study of Sitravatinib in Combination with Nivolumab Versus Doc — **Closed 4/29/22**
- i. Arm A: Sitravatinib (MGCD516) 120mg PO QD + Nivolumab (Investigators discretion 240mg IV Q2W or 480mg Q4W)
- ii. Arm B: Docetaxel 75 mg/m2 IV Q3W until Progressive Disease

i. RGN GO41892 A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL, CONTROLLED STUDY TO — **Closed 10/11/21**
- i. Arm A: Atezolizumab (1200 mg IV q3 weeks + Cabozantinib 40 mg po QD
- ii. Arm B: Docetaxel 75 mg/m2 IV Q3 weeks

j. WCR SCRI LUN 162 Phase II (Progression on Erlotinib) (Nexavar and Erlotinib Provided) — **Closed 7/23/08**
- i. Nexavar + Erlotinib — *Accrual* = 1
- ii. Nexavar — *Accrual Goal* = 5

k. MRT 849-012 (Krystal-12) Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously — **Closed 10/11/23**
- i. Arm A: MRTX849 (600mg PO BID q3 weeks)
- ii. Arm B: Docetaxel 75 mg/m2 IV Q3 weeks

l. AZ D533BC00001 (LATIFY) A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib — **Closed 2/16/24**
- i. Arm A: Ceralasertib 240mg BID D1-D7 followed by durvalumab 1500 mg IV on Day 8
- ii. Arm B: Docetaxal 75mg/m2 Day 1 of 21 day cycle

m. MK 2870-009 (TroFuse 009) MK-2870 vs Platinum & Pemetrexed in TKI-treated Advanced EGFRm NSCLC — **Closed 5/9/25**
- i. Arm A: MK-2870 4mg/kg Q2 weeks
- ii. Arm B: Pemetrexed 500 mg/m2 IV q3w + Carboplatin AUC5 IV q3w for 4 doses followed by Pemetrexed 500 mg/m2 IV q3w

9. Metastatic, Previously Treated

a. See Multiple Sites (NVS Signature Series INC280) — **Closed 2/19/20**

b. SYNTA 9090-14 (GALAXY-2) (Opened 05/12/15) Phase III PI: RO — **Closed 10/21/15**
- i. ARM A: Docetaxel d1 q21d — *Accrual* = 0
- ii. ARM B: Ganetespib IV d1, d15 + Docetaxel d1 q 21d — *Accrual Goal* = 3

c. NGOC AZ A4191C00011 (OCEANS 11) (Opened 10/03/14) Phase II PI: Hermann — **Closed 1/31/15**
- i. T790m mt+ : AZD9293 followed by MEDI4736
- ii. Kras mt +: Selumetinib + Docetaxel followed by MEDI4736
- iii. No Mutation : Tremelimumab followed by MEDI4736

d. EMD EMR100070-001 Phase 1 PI: Robert Hermann, MD — **Closed 6/18/14**
- i. ARM S: Study Drug IV q 2 weeks — *Accrual* = 0; *Accrual Goal* = 7

e. NGOC PPH 0902 (Opened 11/10/10) Phase II, Non Squamous NSCLC (Study Drug Provided - Bavituximab) — **Closed 10/12/11**
- i. ARM S: Docetaxel 75mg/m2 d1 + Study Drug Weekly q21d x6; Maintenance Study Drug Weekly (Study Drug = 1:1:1 Placebo:Bavituximab 1mg/kg:Bavituximab 3mg/kg) — *Accrual* = 1; *Accrual Goal* = 4

f. TORI AZ 6474IL0032 Phase III (Study Drug Provided) — **Closed 2/27/08**

i. Initial: Docetaxel d1 q21d x 6 cycles + Zactima daily (vs. Placebo) — *Accrual* = 6
ii. Maintenance: Continue Zactima/Placebo until progression. — *Accrual Goal* = 3

g. NGOC SAV EFC10261 (VITAL) Phase III Non-Squamous Only (Study Drug Provided) — **Closed 2/2/10**
i. ARM S: Docetaxel + Study Drug (Aflibercept vs. Placebo) — *Accrual* = 4
Accrual Goal = 3

h. ACORN LIL H3E-US-B001 Non-Caucasian — **Closed 3/2/10**
i. Pemetrexed Registry: 2nd Line Lung Ca — *Accrual* = 15

i. ACORN NOV CASA404A2302 Phase III, Randomized — **Closed 8/1/08**
i. Docetaxel + Study Drug (ASA404 or Placebo) — *Accrual* = 0
Accrual Goal = 5

j. ACORN AOI 211 Phase II, Randomized (Study Drug Provided) — **Closed 8/24/07**
i. ARM A: Single Agent Chemotherapy + Perifosine 50mg/d — *Accrual* = 23
ii. ARM B: Single Agent Chemotherapy + Placebo — *Accrual Goal* = 10

k. ACORN LIL H6Q-MC-JCBT (Study Drug Provided) — **Closed 4/16/08**
i. Pemetrexed + Study Drug (Enzastaurin vs. Placebo) — *Accrual* = 0
Accrual Goal = 5

l. BMS CA116-003 Phase 2 Study of MORAb-202 in Previously Treated Metastatic NSCLC AC — **Closed 11/21/23**
i. CLOSED(SAFETY)Arm A: MORAb-202 33mg/m2 IV Q3W
ii. Arm B: MORAb-202 25mg/m2 IV Q3W

m. MK 2870-004 Phase 3 Study of MK-2870 vs Chemo Previously Treated Advanced or Metas — **Closed 4/27/26**
i. Arm A: MK-2870 4mg/KG IV Days 1,15, & 29 every 6 week cycle
ii. Arm B: Investigator's choice of Docetaxel 75mg/m2 IV or Pemetrexed 500mg/m2 IV on Days 1 and 22 of 6 week cycle

n. AbbV M25-274 (TELImet NSCLC-04) A Phase 2, Open-Label, Randomized, Global Study of Three Telisotuzumab — **Open 10/20/25**
i. Arm A: Telisotuzumab vedotin 1.9 mg/kg Q2W
ii. Arm B: Telisotuzumab vedotin 1.6 mg/kg Q2W
iii. Arm C: Telisotuzumab vedotin 1.6 mg/kg Q2W x 4 cycles then 1.9 mg/kg Q2W

o. AZ D763QC00001 (TROPION-Lung17) Datopotamab Deruxtecan or Docetaxel in Previously Treated TROP2-posit — **Open 11/13/25**
i. Arm A: Dato-DXd 6mg/kg IV q3w
ii. Arm B: Docetaxel 75mg/m2 IV q3w

Mesothelioma (C45)

1.

a. See Multiple Sites — **Closed 4/21/15**

Lung, Small Cell (C34)

1. Extensive Stage, Small Cell Lung Ca

a. RGN GO30081 (IMPOWER133) Phase III, Randomized — **Closed 6/1/17**
i. ARM S: Study Drug (Atezolizumab vs. Placebo) + Carbo/Etop q 21d x 4 — *Accrual* = 4
ii. Maintenance Study drug q 21 d — *Accrual Goal* = 5

b. ACORN LIL H3E-MC-JMHO (GALES) Phase III, (Alimta Provided) — **Closed 12/19/07**
i. ARM A: Alimta + Carboplatin d1 q 21d — *Accrual* = 3
ii. ARM B: Etoposide d1,2,3 + Carboplatin d1 q 21d — *Accrual Goal* = 5

c. ACORN GMX GEM 017 Phase I/II (Obatoclax Provided) Marietta Only — **Closed 11/25/09**
i. ARM A: Carbo + Etoposide + Obatoclax (3hr infusion d1,2,3) — *Accrual* = 3
ii. ARM B: Carbo + Etoposide — *Accrual Goal* = 5

d. RGN GO41767 A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF ATE — **Closed 3/11/20**
i. Arm A: Tiragolumab + Atezolizumab + 4 cycles of Carboplatin + Etoposide
ii. Arm B: Placebo + Atezolizumab + 4 cycles of Carboplatin + Etoposide

e. RGN GO43104 (IMforte) A PHASE III, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY OF LURBINECTEDI — **Closed 12/26/23**
i. Arm A: Atezolizumab 1200mg IV + Lurbinectedin 3.2 mg/m2 Q3 weeks
ii. Arm B: Atezolizumab 1200 mg IV Q3 weeks

f. BMS CA245-0001 A Randomized, Double-Blind, Multicenter Phase 3 Trial — **Open 1/24/25**
i. Arm A:BMS-986489 420mg/nivolumab 360 mg IV+carboplatin+etoposide
ii. Arm B: atezolizumab 1200mg IV+carboplatin+etoposide

2. Previously Treated

a. CRX ALDOXORUBICIN P2-SCLC-01 Phase II, Randomized (1:1:1) (Aldoxorubicin Provided) PI: McCune — **Closed 8/26/16**
i. ARM A: Aldoxorubicin 230 mg/m2 — *Accrual* = 7
ii. ARM B: Topotecan (q 3 wk or q 1 wk schedule) — *Accrual Goal* = 4

b. NGOC GSK HYT111127 Phase II (Topotecan + Bevacizumab Provided) — **Closed 4/29/09**
i. Topotecan d1-5 + Bevacizumab d1 q 21days x 8 cycles — *Accrual* = 2
Accrual Goal = 3

c. ACORN LIL L1Y-MC-JFBD (Opened on 02/09/2011) Relapsed, Phase II — **Closed 7/23/12**
i. ARM S: Study Drug (LY2523355) IV d1,2,3 q 21d — *Accrual* = 3
Accrual Goal = 5

d. UTC DIV-SCLC-301 Phase II/III, Dinutuximab+Irinotecan versus Irinotecan, Relpased or Re — **Closed 10/4/18**
i. Group A: Irinotecan 350mg/m2 D1 — *Accrual* = 4
ii. Group B: Dinutuximab 16mg/m2 (fluctuating doses) + Irinotecan 350mg/m2 D1
iii. Group C: Topotecan 1.5mg/m1 D1-5

e. AZ D933QC00001(ADRIATIC) Phase III, Randomized,Dbl-Blind, Placebo Controlled with Durvalumab or Durvalumab — **Closed 8/18/21**
i. Durvalumab 1500mg IV Q4W +Placebo 75mg IV Q4W up to 4 doses, followed by Durvalumab 1500mg Q4W
ii. Durvalumab 1500mg IV Q4W+ Tremelimumab 75mg IV Q4W up to 4 doses, followed by Durvalumab 1500mg Q4W
iii. Placebo Q4W in Combination with a Second Placebo Q4W up to 4 doses, followed by single Placebo solution Q4W

f. IPSEN MM-398-01-03-04 (RESILIENT) RESILIENT: A Randomized, Open Label Phase 3 Study of Irinotecan Liposo — **Closed 2/1/21**
i. Onivyde 70 mg/m2 q2 weeks — *Accrual* = 1
ii. Topotecan initial dose: 1.5mg/m2 daily x 5 days q 3 weeks in a 6 week cycle — *Accrual Goal* = 4

g. KRT-232-112 Phase 2 Study of KRT-232 in Relapsed/Refractory SCLC — **Closed 6/30/22**
i. Arm A: KRT-232 administered at 240 mg PO QD on Days 1–7 with 14 days off on a 21-day treatment cycle.
ii. Arm B:KRT-232 administered at 180 mg PO QD on Days 1–7 with 14 days off on a 21-day treatment cycle.

Breast, Adjuvant (C50)

1. NeoAdjuvant, Stage I, II, III

a. TORI B-02 Randomized, Phase II (Avastin Provided) — **Closed 8/28/08**
i. TAC + Bevacizumab 7.5mg/kg — *Accrual* = 3
ii. TAC + Bevacizumab 15mg/kg — *Accrual Goal* = 5
iii. TAC + Placebo

b. WCR EU822-03 Randomized, Phase II — **Closed 6/25/07**
i. Docetaxel x 4 cycles; Capecitabine x 4 cycles — *Accrual* = 3
ii. Docetaxel + Capecitabine x 8 cycles — *Accrual Goal* = 5

c. RGN WO39392 (Impassion031) Phase III, Double-Blind, Randomized 1:1, Placebo-controlled — **Closed 5/9/18**
i. Arm A: Atezolizumab 840mg+ Nab-Paclitaxel x 12 wks followed by Atezolizumab 840mg + Doxorubicin + Cyclophosphamide x 4 cycles; Post surgery receive unblinded Atezolizumab 1200mg x 11 cycles — *Accrual* = 3
ii. Arm B: Placebo + Nab-Paclitaxel x 12 weeks followed by Placebo + Doxorubicin + Cyclophosphamide x 4 cycles — *Accrual Goal* = 2

2. Adjuvant

a. USOR NSABP B-46-I (TC TAC TOE) (Opened 05/04/10) Phase III (Bevacizumab Provided) PI: Oyola — **Closed 1/11/12**
i. ARM A: TAC x 6 — *Accrual* = 10
ii. ARM B: TC x 6 — *Accrual Goal* = 10
iii. ARM C: TC x 6 + Bevacizumab q 21d x 17 (one year)

b. USOR 10065 / ESI 212 (Opened 9/16/11) Phase II (Eribulin and Capecitabine Provided) — **Closed 3/6/12**
i. ARM S: Eribulin d1,8 + Capecitabine d1-14 q 21d x 4 cycles — *Accrual* = 0
Accrual Goal = 5

c. TORI DOCET_L_00713 Phase II (Bevacizumab Provided) — **Closed 4/6/07**
i. Stratum 1 (Her-2 Negative): TAC + Bevacizumab q3w x 6; Bevacizumab continued for 52 wks total. — *Accrual* = 3
Accrual Goal = 10

d. TORI USO 06900 (TC-TAC) Phase III, Randomized PI: Oyola — **Closed 5/8/09**

i. Docetaxel + Cyclophosphamide (TC) — *Accrual* = 15
ii. Docetaxel + Doxorubicin + Cyclophosphamide (TAC) — *Accrual Goal* = 20

e. WCR CTSU E5103 Phase III (Bevacizumab Provided) — **Closed 7/9/08**
i. AC x 4 then Taxol weekly x 12 + Bevacizumab or Placebo q 21d x 4 (Arm A) — *Accrual* = 2
ii. Patient assigned to Bevacizumab will be randomized to discontinue at cycle 8 (Arm B) or continue for total of one year (Arm C) — *Accrual Goal* = 5

f. SWOG S0307 Phase III — **Closed 6/13/07**
i. ARM A: Zolendronic Acid 4mg IV q4wk x6; q 3 mo x 2.5 yrs — *Accrual* = 2
ii. ARM B: Clodronate 1600mg po qd x 3 years — *Accrual Goal* = 5

g. LIL I3Y-MC-JPCF (MonarchE) Phase III, Open-Label, Active Control, Randomized 1:1 (Drug Provided) — **Closed 2/15/19**
i. Arm A: Abemaciclib(for 2 years) -Std. Adj. Endocrine therapy(at least 5 years) — *Accrual* = 5
ii. Arm B: Std. Adj. Endocrine Therapy Alone (at least 5 years in duration) — *Accrual Goal* = 5

h. RGN WO39391 Phase III Open-Label Comparing Atezo in Combo wth Adj. Taxane Chemo versus Chemo Alone — **Closed 11/15/19**
i. Arm A: Atezolizumab 840mg+Pacliatxel 80mg/m2 x 12 weekly doses followed by ddAC q 2 weeks x 4 doses then Atezolizumab 1200mg maintenance for total of 1 year — *Accrual* = 0
ii. Arm B: Paclitaxel 80mg/m2 x 12 weekly doses followed by ddAC q 2 weeks x 4 doses — *Accrual Goal* = 2

i. GS-US-595-6184 (ASCENT-05) A Randomized, Open-label, Phase 3 Study of Adjuvant Sacituzumab Govite — **Open 1/31/23**
i. Arm A: Sacituzumab Govitecan 10mg/kg IV Days 1 and 8 + Pembrolizumab 200mg IV Day 1 Q3W X 8 cycles
ii. Arm B: Treatment of Physician's Choice: Pembrolizumab 200mg IV Day 1 Q3 weeks X 8 cycles OR Pembrolizumab 200 mg IV Day 1 and Capecitabine 1000 mg/m2 PO BID D1-D14 Q3 Weeks X 8 cycles

j. AZ D926XC00001 (TROPION-Breast03) Dato-DXd With/Without Durva Vs Investigator's Choice Stage I-III TNBC — **Closed 10/2/24**
i. Arm 1: Dato-DXd (6.0 mg/kg IV on Day 1, Q3W) for 8 cycles + durvalumab (1120mg IV on Day 1, Q3W) for 9 cycles
ii. Arm 2: Dato-DXd (6.0 mg/kg IV on Day 1, Q3W) for 8 cycles
iii. Arm 3: Investigator's Choice: Capecitabine (1000 or 1250 mg/m2 oral BID on Days 1 to 14, Q3W) for 8 cycles
iv. Arm 3: Investigator's Choice: Pembrolizumab (200 mg IV on Day 1, Q3W) for 9 cycles
v. Arm 3: Investigator's Choice: Capecitabine (1000 or 1250 mg/m2 oral BID on Days 1 to 14, Q3W) for 8 cycles + pembrolizumab (200mg IV on Day 1, Q3W) for 9 cycles

Breast, Her-2 Positive (C50)

1. NeoAdjuvant HER-2 Positive

a. RGN WO29217 (BERENICE) Phase II — **Closed 8/14/15**
i. Cohort A: AC-T+ Pertuzumab and Trastuzumab Maintenance PH — *Accrual* = 4; *Accrual Goal* = 7

b. ACORN ALSSNBC1006 (Opened 01/17/12) Phase I/II (Erubulin Provided) PI: Hermann — **Closed 11/26/13**
i. ARM S: Eribulin, Carboplatin, Herceptin q21d x 4 — *Accrual* = 3; *Accrual Goal* = 7

c. ACORN ALSSNBC0401 Phase II — **Closed 10/6/08**
i. EC q2w x 4, Docetaxel + Trastuzumab q2w x 4 — *Accrual* = 6; *Accrual Goal* = 5

d. WCR GA-CORE ABX-018 Phase II, Neoadjuvant — **Closed 8/21/08**
i. Trastuzumab weekly x 12w + Abraxane q 2w x8w, then Vinorelbine q 1w x 12w — *Accrual* = 0; *Accrual Goal* = 3

2. Adjuvant, HER-2 Positive

a. RGN TOC4939g (APHINITY) Phase III — **Closed 6/28/13**
i. ARM S: TCH + SD (Pertuzumab vs. Placebo) — *Accrual* = 10; *Accrual Goal* = 10

b. NGOC CIRG 011 (BETH) Phase III, (Bevacizumab Provided) — **Closed 9/24/10**
i. ARM A: TCH + Bevacizumab — *Accrual* = 9
ii. ARM B: TCH — *Accrual Goal* = 10

c. ACORN GSK EGF 105485 (TEACH) Phase III, Randomized (Study Drug Provided) — **Closed 4/4/08**
i. Lapatinib 1500mg or matching placebo daily x 1 year. — *Accrual* = 1; *Accrual Goal* = 5

d. TORI DOCET_L_00713 Phase II (Bevacizumab Provided) — **Closed 11/26/08**
i. Stratum 2 : TCH + Bevacizumab — *Accrual* = 3
ii. Stratum 3: AC then TH+Bevacizumab — *Accrual Goal* = 10

e. RGN WO42633 A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRI — **Closed 7/13/21**
i. ARM A: Atezolizumab placebo 1200 mg IV Q3W and trastuzumab emtansine 3.6 mg/kg IV Q3W for 14 cycles
ii. Arm B: Atezolizumab 1200 mg IV Q3W and trastuzumab emtansine 3.6 mg/kg IV Q3W for 14 cycles

3. Metastatic, HER-2 Positive, 1st Line

a. RGN MO27775 (PERTAIN) Phase II (Pertuzumab Provided) — **Closed 11/3/14**
i. ARM A: Pertuzumab + Trastuzumab + AI — *Accrual* = 5
ii. ARM B: Trastuzumab + AI — *Accrual Goal* = 5

b. NGOC RGN MO27782 (VELVET) (Opened 8/06/12) Phase II (Pertuzumab & Vinorelbine Provided) PI: Oyola — **Closed 8/14/12**
i. ARM S: Pertuzumab, Trastuzumab and Vinorelbine — *Accrual* = 4; *Accrual Goal* = 5

c. USOR 10037 ESI 208 (Opened 08/06/12) Phase II (Eribulin Provided) — **Closed 11/6/12**
i. ARM S: Eribulin d1, d8; Trastuzumab d1 q 21 days — *Accrual* = 5; *Accrual Goal* = 3

d. TORI B-03 Single Arm, Phase II (Avastin Provided) — **Closed 4/17/07**
i. Herceptin weekly + Avastin q2w — *Accrual* = 3; *Accrual Goal* = 3

e. NGOC GNE TOC 4129g (CLEOPATRA) Phase III (Study Drug Provided) PI: Oyola — **Closed 6/14/10**
i. ARM S: Docetaxel + Trastuzumab + Study Drug (Pertuzumab vs. Placebo) q3w — *Accrual* = 4; *Accrual Goal* = 5

f. ACORN SAV DOCET_L_00712 Phase II, (Bevacizumab provided) — **Closed 3/3/09**
i. Stratum 2: Docetaxel + Bevacizumab + Trastuzumab IV q 3w — *Accrual* = 9; *Accrual Goal* = 5

g. WCR CTSU E1105 Phase III (Study Drug Provided) — **Closed 2/4/09**
i. Paclitaxel (or Paclitaxel/Carboplatin) + Trastuzumab + Study Drug (Bevacizumab or Placebo) — *Accrual* = 0
ii. Maintenance: Trastuzumab + Study Drug — *Accrual Goal* = 5

4. Metastatic, Previously Treated, Her-2 Positive

a. MG CP-MGAH 22-04 (SOPHIA) Phase III, (Margetuximab Provided) — **Closed 4/23/19**
i. ARM A: MGAH22 (Margetuximab) IV q 3w + TPC-CLOSED — *Accrual* = 6
ii. ARM B: Trastuzumab IV q 3w + TPC- CLOSED — *Accrual Goal* = 5
iii. TPC= Capecitabine, Eribulin, Gemctiabine or Vinorelbine-CLOSED
iv. Sub-Study- OPEN

b. RGN MO42319 A RANDOMIZED, MULTICENTER, DOUBLEBLIND, PLACEBO-CONTROLLED PHASE III S — **Closed 3/1/22**
i. Arm A: kadcyla (trastuzumab emtansine) 3.6 mg/kg and placebo, q3w
ii. Arm B: Kadcyla (Trastuzumab Emtansine) 3.6 mg/kg and atezolizumab 1200 mg, q3w

c. NGOC GNE TDM4997g (TH3RESA) (Opened 12/05/11) — **Closed 10/12/12**
i. ARM A: TDM-1 — *Accrual* = 1
ii. ARM B: Tx of Physician's Choice (TPC) — *Accrual Goal* = 8

d. NGOC GNE TDM4370g (EMILIA) (Opened 09/01/09) Phase III (All drugs provided) — **Closed 9/6/11**
i. ARM A: TDM-1 3.6mg/kg IV d1 q 21d — *Accrual* = 5
ii. ARM B: Lapatinib 1250mg q d + Capecitabine 1000mg/m2 bid d1-14 — *Accrual Goal* = 5

e. NGOC ESI 399 (Opened 10/12/10) Metastatic, Refractory Compassionate Use (Erubulin Provided) — **Closed 11/18/10**
i. Eribulin 1.4mg/m2 d1, d8 q 21 days — *Accrual* = 2

f. ACORN AOI 211 Phase II, Randomized (Study Drug Provided) — **Closed 8/24/07**
i. ARM A: Single Agent Chemotherapy + Perifosine 50mg/d — *Accrual* = 23
ii. ARM B: Single Agent Chemotherapy + Placebo — *Accrual Goal* = 10

g. NGOC GNE TDM 4258g Phase II (trastuzumab-MCC-DM1 Provided) — **Closed 6/12/08**
i. T-DM1 3.6mg/kg IV q21d — *Accrual* = 1; *Accrual Goal* = 5

h. RGN BO25430-TDM4529g (Opened 09/14/2009) Open-Label Extension Study — **Closed 9/14/14**
i. ARM S: T-DM1 — *Accrual* = 2

Accrual Goal = 2

i. NGOC GNE TDM 4374g Phase II, Single Arm — **Closed 2/20/09**
- i. T-DM1 3.6mg/kg IV every 21 days — *Accrual* = 1
- *Accrual Goal* = 3

j. GSK EGF 103659 (Expanded Access, Lapatinib Provided) — **Closed 3/1/07**
- i. Lapatinib + Xeloda — *Accrual* = 8

Breast, Advanced (C50)

1. Stage IV, Metastatic, 1st Line

a. USOR 11027 / NVS CBKM120F2202 (BELLE-4) (Opened 01/21/13) PI: Oyola — **Closed 8/28/14**
- i. ARM S: Taxol d1,8,15 + Study Drug — *Accrual* = 8
- *Accrual Goal* = 4

b. RGN WO29522 (Impassion130) Phase III Randomized (1:1) — **Closed 5/4/17**
- i. ARM S: Nab-Paclitaxel + Study Drug (Atezolizumab vs Placebo) — *Accrual* = 4
- *Accrual Goal* = 3

c. USOR 10026 ESI 206 (Opened 1/10/11) Phase II (Eribulin Provided) — **Closed 10/28/11**
- i. Arm S: Eribulin d1, d8 q 21 days — *Accrual* = 6
- *Accrual Goal* = 5

d. TORI B-01 Phase II — **Closed 9/14/06**
- i. ARM B: Taxotere 75mg/m2 + Bevacizumab 15mg/kg q3w — *Accrual* = 4
- *Accrual Goal* = 5

e. TORI CIRG 010 Phase II, Randomized, (Study drug provided) — **Closed 8/30/07**
- i. ARM A: Paclitaxel weekly (3/4) + AMG 706
- ii. ARM B: Paclitaxel weekly (3/4) + Placebo (AMG 706 at Progression)
- iii. ARM C: Paclitaxel weekly (3/4) + Bevacizumab q 2w

f. ACORN CA 023 Randomized, Phase II, (Abraxane and Bevacizumab provided) — **Closed 6/27/08**
- i. ARM A: ABI-007 260mg/m2 + Bevacizumab 15mg/kg q3w — *Accrual* = 5
- ii. ARM C: ABI-007 130mg/m2 weekly + Bevacizumab 10mg/kg q2w — *Accrual Goal* = 5

g. ACORN SAV DOCET L 00712 Phase II, (Bevacizumab provided) — **Closed 3/3/09**
- i. Stratum 1: Docetaxel + Bevacizumab IV q3w — *Accrual* = 9
- *Accrual Goal* = 5

h. NGOC GNE AVF4349n (VIRGO) Registry (Opened 08/01/08) — **Closed 12/31/10**
- i. ARM C: Chemotherapy Stratum — *Accrual* = 14
- *Accrual Goal* = 5

i. ACORN LIL B9E-US-S377 Phase III, (Gemcitabine and Bevacizumab provided) — **Closed 2/8/08**
- i. ARM A: Paclitaxel weekly (3/4) + Bevacizumab q 2w — *Accrual* = 1
- ii. ARM B: Paclitaxel weekly (3/4) ; Gemcitabine + Bevacizumab q 2w — *Accrual Goal* = 5

j. RGN MO39196 (Impassion131) -Phase III Placebo Controlled, Double-Blind, Atezo in Combo with Pacli — **Closed 7/10/19**
- i. Arm A: Atezolizumab IV 840mg, D1 & 15+ Paclitaxel IV 90mg/m2, D1, 8 & 15 — *Accrual* = 1
- ii. Arm B: Placebo IV D1 & 15 + Paclitaxel IV 90mg/m2, D1, 8 & 15 — *Accrual Goal* = 5

k. RGN WO45654 (INAVO123) A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED — **Open 5/23/25**
- i. Arm A: Inavolisib 9mg tablet PO QD days 1-28 of 28 day cycle + + letrozole 2.5mg PO QD + Investigator's choice - palbociclib 125mg PO QD D1-21 of 28 or ribociclib 600mg D1-21 of 28d cycle
- ii. Arm B: Placebo tablet PO QD days 1-28 of 28 day cycle + + letrozole 2.5mg PO QD + Investigator's choice - palbociclib 125mg PO QD D1-21 of 28 or ribociclib 600mg D1-21 of 28d cycle

2. Stage IV, Metastatic, ER -

a. CDX011-04 (METRIC) Phase III Randomized (2:1) — **Closed 8/21/17**
- i. ARM A: Study Drug CDX011 q 3 weeks — *Accrual* = 2
- ii. ARM B: Capecitabine bid x 14d q 3 weeks — *Accrual Goal* = 4

b. ACORN BPR 2010 EAP (Opened 08/23/10) Phase: EAP (Iniparib Provided) — **Closed 8/15/11**
- i. ARM S: Gemcitabine + Carboplatin + Iniparib d1,8 q 21d — *Accrual* = 4
- *Accrual Goal* = 6

c. ACORN BiPar 20090301 Phase III Open Label (BSI-201 provided) — **Closed 2/19/10**
- i. ARM A: Gemcitabine + Carboplatin d1,8 q 21d — *Accrual* = 9
- ii. ARM B: Gemcitabine + Carboplatin d1,8 + BSI-201 d1,4,8,11 — *Accrual Goal* = 5
- iii. ARM X: Subjects in ARM A may crossover to Gem + Carbo + BSI-201 at progression

3. Stage IV, Metastatic, Previously Treated

a. NGOC INCB 18424-268 (Opened 09/04/14) Phase II (Study Drug: Ruxolitinib vs. Placebo Provided) PI: RCH — **Closed 8/4/15**
- i. ARM S: Study drug bid d1-21 + Capecitabine bid d1-14 q21d — *Accrual* = 1
- *Accrual Goal* = 4

b. NGOC AZ D081900003 (BRCA mt+) (OYLMPIAD) (Opened 03/11/15) Phase III Randomized (2:1) (Olaparib Provided) PI: RHO — **Closed 11/30/15**
- i. ARM A: Olaparib 300mg p.o. bid — *Accrual* = 1
- ii. ARM B: TPC (Capecitabine, Vinorelbine or Eribulin) — *Accrual Goal* = 2

c. EMD EMR100070-001 Phase I — **Closed 6/26/14**
- i. ARM S: Study Drug IV q 2 weeks — *Accrual* = 1
- *Accrual Goal* = 7

d. USOR 11086 / NKR 11-PIR-11(Opened 04/11/12) Phase III, Previously Treated (2-5) PI: Oyola — **Closed 7/23/13**
- i. ARM A: NKR-102 q 21d — *Accrual* = 4
- ii. ARM B: TPC — *Accrual Goal* = 4

e. ACORN ALSSMBC0804 (Opened 10/28/2009) Phase II (Dasatinib & Ixabepilone Provided) — **Closed 5/25/12**
- i. Arm S: Dasatinib p.o. daily + Ixabepilone IV d1,8,15 q 28d — *Accrual* = 6
- *Accrual Goal* = 4

f. NGOC ESI 399 (Opened 10/12/10) Metastatic, Refractory Compassionate Use (Eribulin Provided) — **Closed 11/18/10**
- i. Eribulin 1.4mg/m2 d1, d8 q 21 days — *Accrual* = 2

g. ACORN ONX AC01B07 Phase IIb (Study Drug Provided) Non-Randomized, Investigator Choice — **Closed 8/31/10**
- i. ARM A: Gemcitabine d,1 8 + Study Drug (Sorafenib vs. Placebo) — *Accrual* = 8
- ii. ARM B: Capecitabine d1-14 + Study Drug (Sorafenib vs. Placebo) — *Accrual Goal* = 2

h. ACORN AOI 211 Phase II, Randomized (Study Drug Provided) — **Closed 8/24/07**
- i. ARM A: Single Agent Chemotherapy + Perifosine 50mg/d — *Accrual* = 23
- ii. ARM B: Single Agent Chemotherapy + Placebo — *Accrual Goal* = 10

i. RGN MO39193 (Impassion132) Phase III (All Drugs Provided by Sponsor) Relapsing Recurrent (inopera — **Closed 3/26/19**
- i. Atezolizumab/Placebo + Chemotherapy (Gem/Carbo or Capecitabine) — *Accrual* = 0
- *Accrual Goal* = 3

j. AZ D5336C00001 (VIOLETTE) Phase II Randomized 1:1:1, Olaparib versus Olaparib Monotherapy — **Closed 4/29/19**
- i. Olaparib 300mg bid continuous (28-day cycle) — *Accrual* = 0
- ii. Olaparib 300mg bid continuous + AZD6738 160mg qd D1-7 (28-day cycle) — *Accrual Goal* = 5
- iii. Olaparib 200mg bid continuous + AZD1775 175mg bid D1-3 and 8-10 (21-day cycle)

4. Stage IV, Metastatic, Triple Negative Breast Cancer

a. CLT Calithera CX-839-007 A Multicenter Phase 2, Open-Label — **Closed 10/4/18**
- i. CB-839 800mg PO BID + Paclitaxel 80mg/m2 D1, 8, 15 — *Accrual* = 0
- *Accrual Goal* = 5

b. GS-US-592-6238 (ASCENT-03) Phase III Sacituzumab Govitecan VS Physician's Choice Triple Negative — **Closed 5/31/24**
- i. Arm A: Sacituzumab Govitecan 10 mg/kg IV on Day 1 & Day 8 of a 21-day cycle
- ii. Arm B: Treatment of Physician's Choice: Gemcitabine (1000 mg/m2 IV) + Carboplatin (AUC 2) IV on Days 1 & 8 of a 21-day cycle
- iii. Arm B: Treatment of Physician's Choice: Paclitaxel 90 mg/m2 IV on Days 1, 8, & 15 of a 28-day cycle
- iv. Arm B: Treatment of Physician's Choice: nab-Paclitaxel 100 mg/m2 IV on Days 1, 8, & 15 of a 28-day cycle

Breast, ER Positive (C50)

1. Adjuvant

a. AZ D8535C00001 (Cambria-2) Adjuvant Endocrine-based Therapy Study of Camizestrant (AZD9833) in ER — **Closed 6/2/26**
- i. Arm A: Standard ET (AI or tamoxifen)+/-abemaciclib (+/-LHRH agonist*)
- ii. Arm B: Camizestrant 75 mg/daily +/- abemaciclib (+/- LHRH agonist*)

2. Metastatic, First Line

a. NVS CLEE011E2301 (Monaleesa-7) Phase III — **Closed 6/17/16**

i. Cohort A: Tam + Goserelin + SD (1:1 LEE011 : Plbo) — *Accrual* = 1
ii. Cohort B: NSAI + Goserelin + SD (1:1 LEE011 : Plbo) — *Accrual Goal* = 3

b. PFZ A5481008 (PALOMA 2) (Study Drug Provided 2:1) — **Closed 5/23/14**
i. ARM S: Letrozole + Study Drug (d1-21) (PD-0332991 vs Placebo) — *Accrual* = 3, *Accrual Goal* = 4

c. RGN BO41843 A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER — **Closed 4/26/22**
i. Arm A: GDC-9545 combined with palbociclib
ii. Arm B: letrozole combined with palbociclib

d. RGN WO41554 A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUA — **Closed 9/2/22**
i. Arm A: GDC-0077 (Inavolisib) plus palbociclib and fulvestrant
ii. Arm B: Placebo + plus palbociclib and fulvestrant

3. Metastatic, Prior Hormonal Therapy

a. NGOC RGN GO29058 (SANDPIPER) Phase III — **Closed 7/10/17**
i. ARM S: Fulvestrant + Oral Study Drug (2:1 Taselisib vs. Placebo — *Accrual* = 2, *Accrual Goal* = 4

b. NGOC GNE GDC4950g (FERGI) Part 1 — **Closed 9/7/11**
i. ARM SA: Fulvestrant + study drug (GDC0941 or GDC0980 vs. Placebo) Randomized before 7/10-12

c. NGOC PFZ A5481023 (PALOMA 3) Phase III — **Closed 7/15/14**
i. ARM S: Fulvestrant + Study Drug (2:1 PD-0332991 vs. Placebo) — *Accrual* = 3, *Accrual Goal* = 4

d. NGOC GNE GDC4950g (FERGI) Part 2 — **Closed 12/30/13**
i. ARM S: Fulvestrant +Study Drug (GDC0941 vs. Placebo) — *Accrual* = 3, *Accrual Goal* = 4

e. RGN WO42312 A PHASE II, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY EVALUATING THE E — **Closed 9/15/21**
i. Arm A: GDC-9545 30mg PO QD
ii. Arm B: Physician's Choice of Endocrine Monotherapy

f. RGN WO40181 Phase II: Post CDK4/6 Inhibitor using Venetoclax plus Fulves — **Closed 2/4/20**
i. Arm A: ABT-199 + Fulvestrant
ii. Arm B: Fulvestrant

g. USO BMS CA187016 Phase II, 1st line — **Closed 11/12/10**
i. ARM A: BMS 690514 + Letrozole — *Accrual* = 0
ii. ARM B: Laptinib + Letrozole — *Accrual Goal* = 3

h. NGOC GNE AVF4349n (VIRGO) Registry — **Closed 12/31/10**
i. Arm H: Hormonal Therapy Stratum — *Accrual* = 14, *Accrual Goal* = 5

i. RGN CO39611 (MORPHEUS) Phase Ib/II Open Label, Multicenter, Randomized Umbrella — **Closed 5/7/19**
i. Safety Run-In Arm: Ipatasertib +Atezo- CLOSED
ii. Arm 2: Atezolizumab + Entinostat
iii. Arm 3: Atezolizumab + Fulvestrant
iv. Arm 4: Atezolizumab + Ipatasertib- CLOSED
v. Arm 5: Atezolizumab + Ipatasertib + Fulvestrant
vi. Arm 1 Control: Fulvestrant

j. AZ D3615C00001 (CAPItello) A Phase III Double-blind Randomised Study Assessing the Efficacy and S — **Closed 9/1/21**
i. Arm A: Capivasertib 400mg BD (4 days on, 3 days off per week) + Fulvestrant 500 mg Day 1 of Weeks 1 and 3 of Cycle 1, and then Day 1 of each cycle thereafter)
ii. Arm B: Placebo + Fulvestrant 500 mg Day 1 of Weeks 1 and 3 of Cycle 1, and then Day 1 of each cycle thereafter)

k. MK 3475-B49 (Keynote-B49) HR+/HER2- Locally Recurrent Inoperable or Metastatic Breast Cancer — **Closed 10/25/23**
i. Arm A: Pembro 200 mg IV Q3W + Chemotherapy Investigator's Choice (Paclitaxel,Nab-Paclitaxel, Liposomal Doxorubicin, or Capecitabine)
ii. Arm B: Placebo IV Q3W + Chemotherapy Investigator's Choice (Paclitaxel,Nab-Paclitaxel, Liposomal Doxorubicin, or Capecitabine)

l. RGN ML43171- (Non-ESR1 mutation is CAPPED, MUST HAVE ESR1 Mu A PHASE III, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY EVALUATING THE — **Closed 9/17/24**
i. Arm A: Giredestrant 30mg + Everolimus 10mg PO QD x 28 Days
ii. Arm B: Exemestane 25mg + Everolimus 10mg PO QD x 28 Days

m. GS-US-598-6168 (ASCENT-07) A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan Versu — **Closed 7/16/24**
i. Arm A: Sacituzumab Govitecan 10mg/kg Days 1 and 8 Q 21 days
ii. Arm B: Treatment of Physician's Choice: (capecitabine, paclitaxel, nab-paclitaxel)

n. MK 6482-029 (Litespark-029) Phase 2 study of belzutifan for ER+/HER2- metastatic breast cancer — **Closed 6/24/25**
i. Arm A: Belzutifan 120mg oral qd + Fulvestrant 500mg IM C1D1, C1D15, D2+D1
ii. Arm B: Everolimus + Endocrine therapy of physician's choice (Fulvestrant or Exemestane)

Melanoma (C43)

1. Adjuvant

a. WCR SWOG E1697 Randomized, Phase III (Interferon Provided) — **Closed 9/1/05**
i. ARM A: Observation, no placebo used — *Accrual* = 0
ii. ARM B: Interferon alfa-2b 20MU/m2/d IV x 5; weekly x 4 weeks — *Accrual Goal* = 3

b. NGOC MK V940-001 Phase 3 Study of Adjuvant V940 and Pembrolizumab in Resected Melanoma — **Closed 9/18/24**
i. Arm A: V940 (q3w x 9doses) +Pembrolizumab (Q6w x 9cycles)
ii. Arm B: Placebo (q3w x 9doses) +Pembrolizumab (Q6w x 9cycles)

2. Locally advanced or Metastatic

a. CTSU E2603 Phase III, blinded (Study Drug Provided) — **Closed 4/22/08**
i. Taxol 225 mg/m2 d1 + Carboplatin AUC=6 q 21d x 4 cycles — *Accrual* = 0
ii. Then, Taxol 175 mg/m2 + Carboplatin AUC=5 d1, q21d x 6 cycles — *Accrual Goal* = 5
iii. Study drug (BAY 43-9006 or Placebo) will be taken 2 tablets bid days 2-19 of each chemo cycle, then 2 tablets bid continuously upon completion of chemotherapy

b. ACORN GSK MEK114267 (Opened 2/17/11) Phase III, 2:1 Randomization (Study Drug Provided) — **Closed 5/16/11**
i. ARM A: Study Drug (GSK 1120212) 2mg p.o. daily — *Accrual* = 0
ii. ARM B: Investigator Choice: DTIC or Paclitaxel (Crossover allowed at progression) — *Accrual Goal* = 2

c. WCR CTSU N0775 Phase II, Randomized — **Closed 3/4/09**
i. ARM A: Temozolomide (TMZ) 200mg/m2 PO days 1-5; Avastin 10mg/kg IV days 1 and 15 — *Accrual* = 1
ii. ARM B: Avastin 10mg/kg IV days 1 and 15; ABI-007 (Abraxane) 100mg/m2 IV days 1,8 and 15; Carboplatin AUC 6 IV day 1 — *Accrual Goal* = 5

d. MK 3475-029 (KEYNOTE-029) Open-Label, Phase 1/2, 3 part, Part 1 C only, Randomized 1:1 — **Closed 10/10/17**
i. Arm A: Pembrolizumab 200mg q 3 weeks (max 24 mnths) + Ipilumumab 50 mg q 6 weeks (max 4 doses)
ii. Arm B: Pembrolizumab 200mg q 3 weeks (max 24 mnths) + Ipilumumab 100mg q 12 weeks (max 4 doses) — *Accrual Goal* = 2

e. MK 3475-587 (see Multiple Sites) — **Closed 9/22/21**

3. Previously Treated

a. See Multiple Sites — **Closed 4/21/15**

b. BMS CA027-002 A Phase 1/2 Study of BMS-986253 in Combination with Nivolumab or Nivol — **Closed 1/19/24**
i. Cohort 2A: BMS-986253 3600mg Q2W + Nivo 1mg/kg Q3W x4 doses followed by 480mg Q4W + Ipi 3mg/kg Q3W x4 doses
ii. Cohort 2B: Placebo + Nivo 1mg/kg Q3W x4 doses followed by 480mg Q4W + Ipi 3mg/kg Q3W (Ipi x4 doses)

Ovarian (C56)

1. Previously Treated

a. PFZ B9991009 (JAVELIN) Phase 3(Avelumab Provided)-Screening form required effective 4/11/17 — **Closed 4/19/17**
i. ARM A: Avelumab d1,15 q 28d — *Accrual* = 4
ii. ARM B: Avelumab d1, 8 + Doxil d1 q 28d — *Accrual Goal* = 4
iii. ARM C: Doxil d1 q 28d

b. See Multiple Sites Incyte Trial — **Closed 4/15/20**

c. ACORN LIL JFBF (Opened 8/10/11) Phase II, 2nd or 3rd line — **Closed 10/15/12**
i. Arm S: LY2523355 IV d 1,2,3 q21d until disease progression or toxicity — *Accrual* = 0, *Accrual Goal* = 3

d. MRK MK3475-B96 A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Plac — **Closed 5/25/23**
i. Arm A: Pembrolizumab 400mg q 6 weeks (18 cycles) + paclitaxel 80 mg/m2 D1, 8, 15 Q 3 weeks (+/- bevacizumab 10mg/kg q2 weeks(optional per eligible participants at investigator discretion)

ii. Arm B: Placebo q 6 weeks (18 cycles) + paclitaxel 80 mg/m2 D1, 8, 15 Q 3 weeks (+/- bevacizumab 10mg/kg q2 weeks(optional per eligible participants at investigator discretion)

Bladder (C67)

1.
   - **a. See Multiple Sites (EMD EMR 100070-001)** — **Closed 12/3/14**

2. Urothelial
   - **a. MK 7902-011 Phase 3 First Line for Locally Advanced or Metastatic Urothelial** — **Closed 8/25/21**
     - i. Arm 1: Pembrolizumab 200mg (IV Q3W) + Lenvatinib 20mg (QD PO)
     - ii. Arm 2: Pembrolizumab 200mg (IV Q3W) + Placebo (QD PO)
   - **b. SEAGEN RC48G001 A Phase 2 Multi-Cohort, Open-Label, Multi-Center Clinical Study Evalua** — **Closed 6/11/25**
     - i. CLOSED:Cohort A: Disitamab Vedotin monotherapy (IHC3+, or IHC2+ and ISH +)
     - ii. CLOSED: Cohort B: Disitamab Vedotin monotherapy (IHC 2+ and ISH-negative, or IHC 1+)
     - iii. Cohort C: Disitamab Vedotin + Pembrolizumab (Treatment Naive subjects with LA/mUC that expresses HER2 (HER2- positive and HER2-low) (Randomized Portion Open)

Renal (C64)

1. Adjuvant, Phase III
   - **a. WCR CTSU E2805 (ASSURE) Phase III, (Study Drug Provided)** — **Closed 3/21/07**
     - i. ARM A: Sunitinib x 54 weeks — *Accrual* = 1
     - ii. ARM B: Sorafenib x 54 weeks — *Accrual Goal* = 5
     - iii. ARM C: Placebo x 54 weeks
   - **b. MK 3475-564 Phase III, Placebo-Controlled, Double-Blind, Randomized 1:1** — **Closed 7/12/19**
     - i. Pembrolizumab/Placebo 200mg IV q 3 weeks (max 17 cycles) — *Accrual* = 7; *Accrual Goal* = 5
   - **c. MK 6482-022 A Multicenter, Double-blind, Randomized Phase 3 Study to Compare the E** — **Closed 6/28/23**
     - i. Arm A: PT2977 (Belzutifan) 120mg PO qd (54 weeks) + Pembrolizumab 400mg Q6W x 9 cycles
     - ii. Arm B: Placebo oral qd (54 weeks) + Pembrolizumab 400mg Q6W x 9 cycles

2. First Line Treatment, Advanced or Metastatic
   - **a. NGOC MERCK MK3475-679 Phase III, Unblinded Open-Label** — **Closed 5/1/18**
     - i. Arm A: Pembrolizumab + Epacadostat
     - ii. Arm B: Sunitinib or Pazopanib — *Accrual Goal* = 5

3. Advanced, Metastatic
   - **a. NGOC AGS-003-007 (ADAPT) (Immune Product Provided) Phase III PI: Oyola (Opened 03/04/15)** — **Closed 6/25/15**
     - i. ARM S: — *Accrual* = 0; *Accrual Goal* = 3
   - **b. NGOC RGN WO29637 (Opened 10/21/15) Phase III Randomized (1:1) (Atezolizumab +Bev Provided) PI: RCH** — **Closed 11/16/15**
     - i. ARM A: Atezolizumaqb + Bevacizumab q3w IV — *Accrual* = 0
     - ii. ARM B: Sunitinib d1-28 po q 6w — *Accrual Goal* = 5
   - **c. MPRN GU 32 Phase II, (Bevacizumab and RAD 001 Provided)** — **Closed 11/8/07**
     - i. Bevacizumab 10 mg/kg q2w + RAD001 10mg orally daily — *Accrual* = 0; *Accrual Goal* = 5
   - **d. See Other/ Observational Registries** — **Closed 12/21/16**
     - i.
   - **e. ACORN AVJARCC0702 Phase IIb, Randomized (Sorafenib Provided)** — **Closed 8/11/08**
     - i. Sorafenib Dose Escalation — *Accrual* = 1
     - ii. Standard Dose Sorafenib — *Accrual Goal* = 3
   - **f. MK 3475-426 (KEYNOTE-426) Phase III, Open-Label, Active Control, Randomized 1:1 (Drug Provided)** — **Closed 12/22/17**
     - i. Pembrolizumab 200mg q 3 weeks IV + Inlyta 5mg PO BIOD — *Accrual* = 6
     - ii. Sutent 50mg PO QD x 4 weeks then 2 weeks off — *Accrual Goal* = 840
   - **g. WCR SCRI GU 44 Phase II (RAD 001Provided)** — **Closed 3/19/08**
     - i. Sorafenib daily + RAD 001 weekly — *Accrual* = 3; *Accrual Goal* = 5
   - **h. CLT CX-839-005 (ENTRATA) Phase II, Placebo Controlled, Double-Blind** — **Closed 1/25/19**
     - i. Everolimus 10mg PO QD + CB-839 (800mg) PO BID — *Accrual* = 2
     - ii. Everolimus 10mg PO QD + CB-839 (placebo) PO BID — *Accrual Goal* = 3
   - **i. CLT CX-839-008 (CANTATA) Phase II, Randomized, Double-Blinded, Placebo-Controlled** — **Closed 8/30/19**
     - i. Arm A: CB-839 + Cabozantinib — *Accrual* = 2
     - ii. Arm B: Placebo + Cabozantinib — *Accrual Goal* = 4
   - **j. MK 6482-005 An Open-label, Randomized Phase 3 Study of PT2977 (MK-6482) Versus Eve** — **Closed 12/27/21**
     - i. Arm A: PT2977 (MK-6482) 120 mg oral QD
     - ii. Arm B: Everolimus 10 mg oral QD
   - **k. MK 6482-034 A Phase 3, Randomized, Double-blind, Study of Belzutifan + Zanzalintin** — **Pending 5/29/26**
     - i. Arm 1: Belzutifan 120 mg qd+ Zanzalintinib 60 mg qd — *Accrual* = 3
     - ii. Arm 2: Belzutifan 120 mg qd+Placebo

4. Previously Treated
   - **a. See Multiple Sites** — **Closed 7/31/15**

Prostate (C61)

1. Hormone Refractory, 1st Line
   - **a. USOR 11167 / DND P10-3 Provenge Registry (Opened 10/03/11) PI: Oyola** — **Closed 10/31/13**
     - i. Observational Registry — *Accrual* = 9
   - **b. ACORN NVS CEP0906A2229 Phase II, Randomized (Patupilone Provided)** — **Closed 10/5/09**
     - i. Arm A: Patupilone + Prednisone (3 Schedules) — *Accrual* = 3
     - ii. ARM B: Taxotere + Prednisone — *Accrual Goal* = 3
   - **c. CTSU CALGB-90401 Phase III (Bevacizumab Provided)** — **Closed 12/15/07**
     - i. Docetaxel + Prednisone — *Accrual* = 7
     - ii. Docetaxel + Prednisone + Bevacizumab — *Accrual Goal* = 10
   - **d. SWOG S0421 Phase III (Study Drug Provided)** — **Closed 5/30/07**
     - i. Taxotere + Prednisone + Study Drug (Atrasentan or Placebo) — *Accrual* = 1; *Accrual Goal* = 10

2. 1st line Metastatic
   - **a. PFZ C3441052 (TALAPRO-3) A PHASE 3, RANDOMIZED, DOUBLE-BLIND, STUDY OF TALAZOPARIB WITH ENZALUT** — **Closed 7/12/22**
     - i. TALAZOPARIB 0.5 mg QD + ENZALUTAMIDE 160 mg QD
     - ii. PLACEBO WITH ENZALUTAMIDE 160 mg QD

3. Metastatic, 2nd Line Prostate
   - **a. NGOC AST 0401 (MDV3100 EAP) (Opened 6/21/2012) Expanded Access (MDV3100 Provided)** — **Closed 9/14/12**
     - i. ARM S: MDV3100 180mg/daily — *Accrual* = 3; *Accrual Goal* = 6
   - **b. ACORN AVAHRPC0607 (MPNEXT) Phase II (Sorafenib Provided)** — **Closed 7/3/08**
     - i. Mitoxantrone + Prednisone + Sorafenib — *Accrual* = 2; *Accrual Goal* = 5
   - **c. ACORN AOI 211 Phase II, Randomized (Study Drug Provided)** — **Closed 8/24/07**
     - i. ARM A: Single Agent Chemotherapy + Perifosine 50mg/d — *Accrual* = 23
     - ii. ARM B: Single Agent Chemotherapy + Placebo — *Accrual Goal* = 10
   - **d. ACORN LIL JFBF (Opened 8/10/11) Phase II, 2nd or 3rd line** — **Closed 10/15/11**
     - i. Arm S: LY2523355 IV d 1,2,3 q21d until disease progression or toxicity — *Accrual* = 0; *Accrual Goal* = 3
   - **e. BMS CA209-9KD Phase II study, Nivo in combo with Rucaparib, Enzalutamide, docetaxel** — **Closed 12/20/19**
     - i. Arm A: Nivo 480mg IV Q4W + Rucaparib 600mg PO BID — *Accrual* = 8
     - ii. Arm C: Nivo 480mg IV Q4W + Enzalutamide 160mg PO QD — *Accrual Goal* = 5
     - iii. Arm B: Nivo 360mg IV Q3W + Docetaxel 75mg/m2 IV Q3W +Prednisone -ON HOLD
   - **f. BMS CA209-650 A Phase 2 Trial of Nivolumab Plus Ipilimumab, Ipilimumab Alone, or Cab** — **Closed 9/8/21**
     - i. Arm D1: Nivolumab 3 mg/kg Q3W + ipilimumab 1 mg/kg Q3W up to 4 cycles, then nivolumab 480 mg Q4W

ii. Arm D2: Nivolumab 1 mg/kg Q3W (8 doses)+ ipilimumab 3 mg/kg Q6W (4 doses), then nivolumab 480 mg Q4W
iii. Arm D3: Ipilimumab 3 mg/kg Q3W up to 4 cycles
iv. Arm D4: Cabazitaxel 25mg/m2 Q3W + prednisone 10mg PO D1-D21 up to 10 cycles

g. BMS CA209-7DX (CheckMate 7DX: CHECKpoint pathway and nivoluM Phase 3 Trial of Nivolumab or Placebo with Docetaxel in Men with Metas — **Closed 6/13/22**
i. Arm A: Docetaxel 75 mg/m2 IV Q3W + Prednisone 5mg PO BID + Nivolumab 360mg IV Q3W
ii. Arm B: Docetaxel 75mg/m2 IV Q3W + Prednisone 5mg PO BID + Placebo IV Q3W

h. BMS CA022-009 A Phase 2 Trial of BMS-986218 or BMS-986218/Nivolumab in Combination w — **Closed 1/3/23**
i. Screening -Slot Process FULL-Safety Lead-in - Part 1A: BMS-986218 50mg IV Q3W (dose escalation & de-escalation available) for 2 years or until PD + Docetaxel 75mg/m2 IV Q3W for Maximum of 1
ii. Not Yet Available Safety Lead-in - Part 1B: BMS-986218 15mg IV Q3W (dose escalation & de-escalation available) + Nivolmab 360 mg IV Q3W for up to 2 years or PD + Docetaxel 75mg/m2 IV Q3W for Maximum o

4. Hormone Refractory; Bone Predominant 3rd Line or Greater

a. See Multiple Sites — **Closed 12/3/14**

b. NGOC XL184-307 (COMET) (Opened 12/14/12) Phase III, 3rd Line or Greater (Study Drug and Prednisone Provided) PI — **Closed 9/18/13**
i. ARM S: Cabozantinib (XL184) vs. Prednisone — *Accrual* = 3, *Accrual Goal* = 4

Sarcoma (C46-C49)

1. Sarcoma, Previously Treated

a. Refer to Steve Attia, DO, Mayo Clinic 904-953-7292 — **Closed 3/2/15**

b. See Multiple Sites — **Closed 4/21/15**

c. ACORN AOI 211 Phase II, Randomized, Placebo Controlled — **Closed 8/28/07**
i. Perifosine vs. Placebo — *Accrual* = 23, *Accrual Goal* = 10

Adrenal (C74)

1. Previously Treated

a. See Multiple Sites — **Closed 12/3/14**

Lymphoma (C82-C88)

1. Indolent, previously treated

a. ACORN GSK OMB113676 (HOMER) (Opened 02/07/11) Phase III, Relapsed (Ofatumumab Provided) PI: RCH — **Closed 11/24/15**
i. ARM A: Ofatumumab d1,8,15,22 Induction; d1 q 2 mths x 4 Maintenance — *Accrual* = 5
ii. ARM B: Rituximab d1,8,15,22 Induction; d1 q 2 mths x 4 Maintenance — *Accrual Goal* = 4

b. TORI JNJ LYM 3001 Phase III, (Velcade and Rituxan Provided) PI: Kirkel — **Closed 7/18/08**
i. ARM A: Velcade 1.6mg/m2 + Rituxan 375mg/m2 — *Accrual* = 4
ii. ARM B: Rituxan 375mg/m2 Alone — *Accrual Goal* = 3

c. NGOC MLN C05012 Phase II, Velcade Provided — **Closed 4/30/10**
i. Stratum A: Velcade d1,8 + R-CAP — *Accrual* = 2
ii. Stratum B: Velcade d1,8 + R-CP (CLOSED) — *Accrual Goal* = 6

d. WCR SCRI LYM 37 Phase II, (Bevacizumab provided.) — **Closed 9/29/06**
i. Rituximab days 1,8,15,22; months 3,5,7,9. — *Accrual* = 1
ii. Rituximab days 1,8,15,22; months 3,5,7,9 + Bevacizumab days 3, 15; then q 2w x16. — *Accrual Goal* = 3

2. Follicular, First Line

a. GNE U2963n (Lymphocare) Observation Study — **Closed 3/7/07**
i. Observation Study — *Accrual* = 13, *Accrual Goal* = 20

b. NGOC GNE U4391g (RATE) (Opened 11/17/08) — **Closed 11/19/10**
i. ARM A: R-CVP, Rituxan Faster Infusion — *Accrual* = 6, *Accrual Goal* = 6

c. NGOC CPH 2048 (Opened 07/26/10) Phase II, (Bendamustine & Ofatumumab Provided) — **Closed 12/30/10**
i. ARM S: Bendamustine d1&2 + Ofatumumab d1 q28d x6-8 — *Accrual* = 1, *Accrual Goal* = 5

d. ACORN LIL H6Q-MC-S011 Phase II (Enzastaurin Provided) — **Closed 12/2/08**
i. Enzastaurin daily — *Accrual* = 6, *Accrual Goal* = 3

3. Indolent, Relapsed

a. NGOC GS313-0125 (Opened 04/02/13) Phase III (Study Drug Provided) PI: Kirkel — **Closed 3/27/15**
i. ARM S: BR + Study Drug (2:1 Idelalisib vs Placebo) — *Accrual* = 3, *Accrual Goal* = 4

b. CLG CC 5013-NHL-008 (MAGNIFY) Phase IIIb (Lenalidomide Provided) — **Closed 8/15/18**
i. Induction: Rituximab + Lenalidomide (Revlimid) (12 months) — *Accrual* = 7
ii. ARM A: Rituximab + Lenalidomide (Revlimid) Maintenance — *Accrual Goal* = 6
iii. ARM B: Rituximab Maintenance

4. Relapsed or Refractory; DLBCL, FL

a. NGOC GS339-0102 (Opened 07/19/13) Phase II (Study Drug Provided) PI: Kirkel — **Closed 7/19/13**
i. Cohort 4: MCL, Previously Treated — *Accrual* = 1
ii. Cohort 6: CLL, Prior BTK Exposure — *Accrual Goal* = 4
iii. Cohort 7: CLL, Prior PI3k Exposure
iv. Cohort 8: CLL, New Formulation

b. TG UTX-TGR-205 (UNITY) Phase IIb PI: McCune — **Closed 4/12/18**
i. Arm A: Ublituximab 900mg IV+TGR-1202 800mg PO-Temporarily suspended
ii. Arm B: TGR-1202 800mg PO

c. NGOC RGN GO29834 (HARMONY) Phase Ib/II (All drugs supplied) PI: Kirkel — **Closed 3/14/18**
i. ARM S: Obinutuzumab + Polatuzumab + Lenalidomide — *Accrual Goal* = 3

d. ADCT-402-201 Phase II, Open-Label Single Arm Study — **Closed 8/23/19**
i. Arm S: Loncastuximab tesirine — *Accrual* = 0, *Accrual Goal* = 2

5. Large Cell Lymphoma, Relapsed/Refractory

a. NGOC CLG CC-5013-NHL-005 Phase II, (Lenalidomide Provided) — **Closed 11/4/08**
i. Lenalidomide + Dexamethasone — *Accrual* = 3, *Accrual Goal* = 3

6. Relapsed and Refractory Folllicular Lymphoma

a. RGN BO29337 (CONTRALTO) Phase II,(GDC0199 Provided) — **Closed 2/1/16**
i. ARM A: GDC-0199 + Rituximab (CLOSED) — *Accrual* = 2
ii. ARM B: BR + GDC 0199 — *Accrual Goal* = 4
iii. ARM C: BR

b. BMS CA073-1003 A Phase 3, Multicenter, Randomized, Open Label Study to Compare the Ef — **Open 8/13/25**
i. Arm A: R-Golca 0.4mg D1-14/48 days+Rituximab x5cycles followed by golcadomide monotherapy for up to 12 cycles of toral therapy
ii. Arm B: R-Len 20mg, Days 1-21, cycles 1-12,rituximab 375mg/m2, Days 1,8,15,and 22 in cycle 1; Day 1 in cycles 2-5 — *Accrual Goal* = 3
iii. Arm C: Inv. Choice for 6 cycles: R-CHOP or Rituximab-Bendamustine

7. Relapsed and Refractory Follicular or Marginal Zone Lymphoma

a. NGOC INC MOR0208-301 A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter S — **Closed 1/23/23**
i. Arm A: Tafasitamab 12mg/kg IV for 12 cycles (weekly x3 Cycles then Q2W) + Rituximab 375mg/m2 IV x5 Cycles + Lenalidomide (Sponsor provided) 20mg/day PO Days 1-21 x12 Cycles
ii. Arm B: Tafasitamab Placebo 12mg/kg IV for 12 cycles (weekly x3 Cycles then Q2W) + Rituximab 375mg/m2 IV x5 Cycles + Lenalidomide(Sponsor Provided) 20mg/day PO Days 1-21 x12 Cycles

b. BGB-3111-308 R/R Follicular or Marginal Zone Lymphoma — **Closed 6/19/25**
i. CLOSED Arm A: R/R FL Zanubrutinib (BGB-3111) 160mg BID or 320mg QD + Obinutuzumab 1000mg weekly in C1, then Day 1 C2-C6
ii. CLOSED Arm B: R/R FL: Lenalidomide 10 or 20mg PO C1-12 q21d 7d rest + Rituximab 375mg/m2 C1 weekly then day 1 C2-C5
iii. CLOSED Arm C: R/R MZL: Zanubrutinib (BGB-3111) 160mg BID or 320mg QD + Rituximab 375mg/m2 C1 weekly then day 1 C2-C5
iv. CLOSED Arm D: R/R MZL: Lenalidomide 10 or 20mg PO C1-12 q21d 7d rest + Rituximab 375mg/m2 C1 weekly then day 1 C2-C5

8. Diffuse Large Cell, First Line

a. JNJ PCI-32765DBL3001 (PHOENIX) Non-GCB, Phase III, (Study Drug Provided) PI: Kirkel — **Closed 8/14/15**
- i. ARM S: R-CHOP + Study Drug 1:1 (Ibrutinib vs. Placebo) — *Accrual* = 3
Accrual Goal = 4

b. NGOC GNE GAO4915g (GATHER) (Opened 9/8/11) Phase II, (Study Drug Provided) PI: Kirkel — **Closed 9/14/12**
- i. ARM S: GA101 plus CHOP q21d x 6 — *Accrual* = 3
Accrual Goal = 3

c. NGOC GNE U4391g (RATE) (Opened 11/17/2008) — **Closed 11/19/10**
- i. ARM B: R-CHOP, Rituxan Faster Infusion — *Accrual* = 9
Accrual Goal = 6

d. ACORN RHH BO20603 Phase III (IPI= 2-5 or Bulky) (Bevacizumab Provided) — **Closed 3/9/09**
- i. R-CHOP + Bevacizumab — *Accrual* = 0
- ii. R-CHOP — *Accrual Goal* = 5

e. ACORN LIL H6Q-MC-JCBJ (PRELUDE) Phase III, (IPI = 3-5) (Study Drug Provided) — **Closed 4/1/10**
- i. ARM S: (Enzastaurin vs. Placebo) x 2 years — *Accrual* = 1
Accrual Goal = 5

f. SWOG S0515 Phase II, (Bevacizumab provided) — **Closed 7/1/06**
- i. R-CHOP + Bevacizumab x 8 cycles — *Accrual* = 0
Accrual Goal = 3

g. NGOC MOR208C310 (frontMIND) A phase 3, multicenter, randomized, double-blind, placebo-controlled t — **Closed 2/14/23**
- i. Arm A: Tafasitamab 12mg/kg IV (Days 1, 8, 15) + Lenalidomide (Revlimid) 25mg PO QD (Days 1-10) + R-CHOP (Day 1 for 6 Cycles) + Prednisone 100 mg/day PO (days 1-5) for 21 day cycles
- ii. Arm B: Tafasitamab Placebo Saline IV (Days 1, 8, 15) + Lenalidomide (Revlimid) 25mg PO QD (Days 1-10) + R-CHOP (Day 1 for 6 Cycles) + Prednisone 100 mg/day PO (days 1-5) for 21 day cycles

h. CC-220-DLBCL-001 First line of Therapy — **Closed 6/5/26**
- i. Single arm extension cohort of CC-99282 with the Polatuzumab R-CHP regimen. CC-99282 dose will be determined upon completion of Part 2A and 2B.

9. Mantle Cell Lymphoma

a. ACE-LY-308 Phase 3, Randomized 1:1, Double-Blind, Placebo-Controlled — **Closed 5/1/20**
- i. Arm 1: ACP-196 (Acalabrutinib) 100mgPO BID + Bendamustine Hydrochloride + Rituximab — *Accrual* = 2
- ii. Arm 2: Placebo PO BID + Bendamustine Hydrochloride + Rituximab- Crossover over allowed for Arm 2 to receive Acalabrutinib monotherapy at PD — *Accrual Goal* = 3

CNS (C71)

1. Glioblastoma Multiforme

a. See Multiple Sites — **Closed 4/21/15**

b. WCR MDACC 2004-0662 Phase II (Temozolomide Provided) — **Closed 12/5/07**
- i. Temozolomide + Study Drug — *Accrual* = 2
Accrual Goal = 3

Leukemia (C91-C92)

1. CLL, First Line

a. NGOC GSK OMB110911 Phase III PI: Kirkel — **Closed 4/26/12**
- i. ARM A: Ofatumumab + Chlorambucil q 28 days — *Accrual* = 3

b. RGN ML295838 (Opened 04/14/15) Phase II (Obinutuzumab Provided) PI: Kirkel — **Closed 3/1/16**
- i. ARM S: Obinutuzumab + Bendamustine — *Accrual* = 5
Accrual Goal = 4

c. BGB-11417-204 A Phase 2 Study to Investigate Sonrotoclax Combined With Zanubrutinib — **Closed 9/11/25**
- i. Arm A: Zanubrutinib 320mg PO QD for 3 cycles followed by Sonrotoclax (BGB-11417)Ramp up to Target 320mg QD PO + Zanbrutinib (BGB-3111) 320mg PO for 12 Cycles
- ii. Arm B: Zanubrutinib (BGB-3111) orally at 320 mg daily dose 28d Cycle Until Intolerance or PD

2. CLL, Relapsed or Refractory

a. NGOC GS339-0102 Phase II (Study Drug Provided) PI: Kirkel — **Closed 5/2/17**
- i. Cohort 6: CLL, Prior BTK Exposure — *Accrual* = 3
- ii. Cohort 7: CLL, Prior PI3k Exposure — *Accrual Goal* = 4
- iii. Cohort 8: CLL, New Formulation - Dose Ranging Cohort CLOSED 04/28/16

b. JNJ PCI-32765CLL3001 (HELIOS) Phase III, (Ibrutinib Provided) PI: Kirkel — **Closed 12/1/13**
- i. ARM S: Study Drug + Bendamustine + Rituximab — *Accrual* = 3
Accrual Goal = 4

c. PCYC-1112-CA (RESONATE) Phase III (Ibrutinib Provided) PI: Kirkel — **Closed 1/29/13**
- i. ARM A: Ofatumumab — *Accrual* = 2
- ii. ARM B: Ibrutinib

d. NGOC CLG CC-5013-CLL-001 Phase II, Blinded (Lenalidomide Provided) — **Closed 6/22/07**
- i. ARM A: Lenalidomide 25mg daily x 21d, q28d
- ii. ARM B: Lenalidomide 10mg daily x 28d, q28d

e. NGOC PCI-32765CAN3001 Phase IIIb, Multicenter, Open-Label Long-term Extension Study — **Closed 11/29/18**
- i. Arm A: Ibrutinib daily x 28 days

f. AZ D8220C00008 (ASSURE) Phase IIIb, Open-Label, Single-Arm Study of Acalabrutinib (ACP-196) in — **Closed 9/15/20**
- i. Treatment-naive: acalabrutinib 100 mg bid x 28d — *Accrual* = 4
- ii. Cohort closed 8/14/2020:Relapsed/refractory: acalabrutinib 100 mg bid x 28d — *Accrual Goal* = 4

3. CML

a. NGOC NOV CAMN107A2303 Phase III — **Closed 8/11/08**
- i. Nilotinib 400mg bid — *Accrual* = 0
- ii. Nilotinib 300mg bid — *Accrual Goal* = 2
- iii. Imatinib 400mg qd

b. NGOC NVS WORLD Registry (Opened 3/21/08) — **Closed 5/31/11**
- i. ARM A: Observational (Register < 6mths of dx.) — *Accrual* = 27
Accrual Goal = 18

c. NVS CABL001AUS08 (ASC2ESCALATE) 2nd & 1st line Chronic CML — **Closed 8/21/24**
- i. 2L Asciminib (ABL001) 80mg PO QD for 24 months (Dose escalation possible 6 & 12 months)
- ii. 1L Cohort: Asciminib (ABL001) 80mg PO QD for 24 months (Dose escalation possible 6 & 12 months)

Myeloma (C90)

1. 1st Line

a. — **Closed 11/17/16**

b. NGOC MLM C05009 (UPFRONT) Randomized, IIIb — **Closed 3/29/10**
- i. ARM A: Induction VD x 8 cycles followed by Velcade x 5 cycles — *Accrual* = 4
- ii. ARM B: Induction VTD x 8 cycles followed by Vecade x 5 cycles — *Accrual Goal* = 5
- iii. ARM C: Induction VMP x 8 cycles followed by Velcade x 5 cycles

c. MLN C16014 (Opened 08/14/13) Phase III PI: Kirkel — **Closed 9/17/15**
- i. ARM S: Rev-Dex + Study Drug(MLN9708 (Ixazomib)) vs Placebo) — *Accrual* = 3
Accrual Goal = 4

d. NGOC JNJ MMY-3008 (MAIA) Phase III Randomized (1:1) (Daratumumab Provided) PI: Kirkel — **Closed 11/17/15**
- i. ARM A: Len d1-21 + Dex q1w (q28d) — *Accrual* = 0
- ii. ARM B: Len d1-21 + Dex q1w (q28d x 2yrs) + Daratumumab IV — *Accrual Goal* = 4

2. Relapsed / Refractory 1-3 Lines

a. ACORN ALJBMM0502 Open Label, Phase II, (Velcade provided) — **Closed 12/31/08**
- i. Bortezomib + Dexamethasone d1,4,15,18 + Doxil d4 q 28d — *Accrual* = 5
Accrual Goal = 5

b. MLN C16010 (Opened 08/27/12) Phase III, (Study Drug Provided) PI: Kirkel — **Closed 11/22/13**
- i. ARM S: Study Drug (MLN 9708 vs. Placebo) + Dexamethasone d1,8,15; Lenalidomide d1-21 q 28d — *Accrual* = 3
Accrual Goal = 4

c. CLG CC-4047-MM-007 Pomalidomide Provided PI: Kirkel — **Closed 4/14/17**
- i. ARM A: Pomalidomide + BTZ + LD Dex — *Accrual* = 5

ii. ARM B: BTZ + LD Dex — *Accrual Goal* = 4

d. NVS CLBH589C2308 (Opened 06/15/10) Phase III (Study Drug Provided) — **Closed 2/15/12**
i. ARM S: Study Drug + Dexamethasone + Bortezomib — *Accrual* = 1
Accrual Goal = 5

e. AbbVie M13-494 A Phase 3, Multicenter, Randomized, Open Label Study of Venetoclax and — **Closed 6/13/23**
i. Venetoclax 800mg QD + Dexamethasone 40 mg Q1W

3. Relapsed / Refractory > or equal to 2 Lines

a. MK 3475-183 (KEYNOTE-183) Phase III, Open Label (Pembrolizumab Provided) PI: Kirkel — **Closed 6/12/17**
i. ARM A: Pembrolizumab + Pomalidomide + Dexamethasone — *Accrual* = 0
ii. ARM B: Pomalidomide + Dexamethasone

b. NGOC CLG CC-4047-MM-009 (Opened 01/04/13) (Pomalidomide Provided) PI: Hermann — **Closed 2/13/13**
i. ARM S: Pom d1-21 + Dex Weekly q 28d — *Accrual* = 1
Accrual Goal = 3

MDS (D46)

1. 1st Line

a. ACORN GEM 013 Phase II, (Obatoclax Provided) — **Closed 11/7/08**
i. Obatoclax 24 hr infusion, q2w — *Accrual* = 0
Accrual Goal = 3

b. NGOC CLG CC-5013-MDS-009 — **Closed 4/7/10**

c. NGOC CLG Vidaza Registry (First Line Vidaza Treatment) — **Closed 12/31/09**
i. ARM A: Observational — *Accrual* = 5

2. Observational Registry

a. See Other, Observational Registry — **Closed 5/5/14**

b. NGOC NVS MORE Registry (Low Risk MDS with Iron Overload) — **Closed 5/4/10**
i. ARM A: Observational Registry — *Accrual* = 9
Accrual Goal = 5

Unknown Primary (199)

1. 1st Line

a. NGOC SCRI UNK PRI 21 (Opened 08/14/09) Randomized, Phase II (Belinostat Provided) — **Closed 12/22/10**
i. ARM A: Belinostat + Paclitaxel + Carboplatin — *Accrual* = 2
ii. ARM B: Paclitaxel + Carboplatin — *Accrual Goal* = 5

b. WCR SCRI UNK PRI 12 (Iressa Provided) — **Closed 7/21/08**
i. ARM A: Paclitaxel, Carboplatin, Etoposide — *Accrual* = 12
ii. ARM B: Irinotecan, Gemcitabine — *Accrual Goal* = 15
iii. All patients will receive maintenance Iressa (Provided)

c. WCR SCRI UNK PRI 20 Phase II (Molecular Profiling Provided) — **Closed 2/4/09**
i. Chemotherapy assigned by molecular profile. — *Accrual* = 2
Accrual Goal = 5

Other

1. Tissue Studies

a. NCI Exceptional Responders Initiative — **Closed 8/7/15**
i. Case Report / Tissue Submission — *Accrual* = 0

b. ADB BLSSASHT0803 (Opened 8/30/11) — **Closed 2/27/12**
i. NSCLC Blood Collection — *Accrual* = 26

c. ADB BLSSASHT0803 (Opened 2/23/12) — **Closed 6/27/12**
i. Bladder Cancer Biospecimen Collection — *Accrual* = 4

d. ADB BLSSASHT0803 (Opened 06/18/2012) PI: Hermann — **Closed 1/10/13**
i. NSCLC TKI Blood Collection — *Accrual* = 12

e. NGOC ALX P-06-001 (EXPLORE) (Aplastic Anemia Only) — **Closed 3/16/10**
i. Blood Draw for CD 55, 59 — *Accrual* = 35

f. ACORN ALSSTIS0501 (Tarceva, Erbitux Recipients) — **Closed 7/1/08**
i. Tissue for EGFR — *Accrual* = 24

g. NGOC MTG-016 (Biobank) — **Closed 10/20/06**
i. Bone Marrow for AML, Multiple Myeloma Cells — *Accrual* = 6

2. Observational Studies

a. ALX 1399 PNH Patient Registry Trial PI: Kirkel — **Closed 1/9/11**
i. PNH Registry

b. CLG CLL CONNECT (Opened 08/09/11) CLL(Any Line) PI: Kirkel — **Closed 1/22/14**
i. ARM S: Observational Registry — *Accrual* = 21

c. NGOC GNE ML28257 (Opened 11/09/12) HER-2 Breast Registry PI: Oyola — **Closed 5/31/16**
i. Registry — *Accrual* = 23

d. BMS CA180-330 (SIMPLICITY) (Opened 06/03/12) PI: Kirkel — **Closed 2/27/15**
i. ARM S: Observational Registry — *Accrual* = 25

e. GNE AVF3991n (ARIES) — **Closed 6/4/09**
i. Avastin Registry: Lung, Colon — *Accrual* = 42

f. BMS CA209-118 Observational Registry — **Closed 1/25/17**
i. ARM S: Observational Registry — *Accrual* = 78
Accrual Goal = 70

g. CLG CONNECT MF, MDS, & AML Disease Registry Observational Registry PI: Kirkel — **Closed 9/3/24**
i. Observational Registry-Newly Diagnosed ICUS(CLOSED), LR-MDS, HR-MDS(CLOSED)
ii. CLOSED: Observational Registry-Newly Diagnosed AML cohorts
iii. Observational Registry-MF Cohort (subjects with a diagnosis of MDS/MPN, excluding JMML)
iv. Luspatercept Treated Cohort - NOT PARTICIPATING

h. ACORN SLSSETP0601 — **Closed 4/12/06**
i. ETP: NSCLC, Colon, Prostate — *Accrual* = 73

i. NGOC CST 15721BUS227 (reGISTry) — **Closed 9/1/06**
i. GIST Tumor Registry — *Accrual* = 12

j. PFZ A4061070 MaRCC Registry Non-Interventional PI: McCune — **Closed 12/21/16**
i. ARM S: Observational Registry — *Accrual* = 4

k. INC MA-PV-401 (REVEAL) PI: Kirkel — **Closed 6/10/16**
i. Polycythemia Vera Registry — *Accrual* = 13
Accrual Goal = 40

l. INC MA-MF-401 (MOST) — **Closed 3/29/19**
i. MF Cohort — *Accrual* = 21
ii. ET Cohort: CLOSED TO ACCRUAL as of 12/31/18 — *Accrual Goal* = 5

m. PFZ A5481082 (POLARIS) - Adv Breast CA Non-Interventional — **Closed 9/30/19**

Multiple Sites

1. Phase I

a. EMD EMR100070-001 (Study Drug Provided) Phase I — **Closed 10/31/17**
i. ARM S: AVELUMAB IV Q 2 WEEKS — *Accrual* = 10
ii. Cohort: Renal Cell 1st Line-CLOSED 10/25/16 — *Accrual Goal* = 7

2. EMD MS100070-0176 (EMR100070-001 Rollover)

a. EMD MS100070-0176 An Open-Label, Multicenter Follow-up Study to Collect Long-term Data o — **Closed 11/25/19**
i. Cohort: Renal Cell
ii. Cohort: Melanoma

3. Novartis Signature Series

a. Molecular Markers and Compounds — **Closed 4/18/14**
i. Molecular Markers and Compounds References Sheet

b. NGOC NVS CBKM120ZUS40 (Opened 07/24/14) — **Closed 12/15/14**
i. Module 1: BKM120 (P13K-Activated)

c. NGOC NVS CTKI258AUS26 (Opened 07/24/14) — **Closed 12/15/14**

i. Module 2: Dovitinib (FGFR)

d. NGOC NVS CMEK162AUS11 (Opened 07/24/14) — **Closed 12/15/14**
i. Module 3: MEK162 (MEK)

e. NGOC NVS CLGX818AUS03 (Opened 07/24/14) — **Closed 12/15/14**
i. Module 4: LGX818 (RAF)

f. NGOC NVS CLDE225XUS20 (Opened 07/24/14) — **Closed 12/15/14**
i. Module 5: LDE225 (SMO)

g. NGOC NVS CLDK378AUS23 (Opened 07/24/14) — **Closed 11/4/15**
i. Module 6: LDK378 (ALK) — *Accrual* = 0

h. NGOC NVS CLEE011XUS03 (Opened 07/24/14) — **Closed 6/10/15**
i. Module 7: LEE011 (CDK4/6) — *Accrual* = 0

i. NVS CBGJ398XUS04 (Operned 07/24/14) — **Closed 5/13/16**
i. Module 8: BGJ398 (FGFR) — *Accrual* = 2

j. NGOC NVS LDK 378 ALK or ROS Positive — **Closed 8/15/16**
i.

k. NVS CPDR001X2201 Nasopharyngeal Carcinoma, Previously Treated — **Closed 10/11/17**
i. NCT02605967 — *Accrual* = 1

l. NVS INC280A2201 cMET Amplification or Mutation — **Closed 2/19/20**
i. NCT02414139 — *Accrual* = 1

4. Solid Tumors, Refractory

a. CDX1127-02 Cohort Expansion Study of Varlilumab and Nivolumab — **Closed 1/10/18**
i. RCC- Phase II will receive 3.0 mk/kg of varlilumab in combination with 240 mg of nivolumab every 2 weeks
ii. SCCHN or Ovarian will receive varlilumab at a dose of either 3mg/kg every 2 weeks, 3mg/kg every 12 weeks, or 0.3 mg/kg every 4 weeks, in combination with 240mg of nivolumab every 2 weeks — *Accrual Goal* = 4

5. Solid Tumors, Advanced or Metastatic

a. EPC RRx-001-33 REPLATINUM: A Phase 3, Controlled, Open-label, Randomized Study of RRx — **Closed 3/19/19**
i. Arm A: RRx-001 + Platinum Rechallenge + Stacking Phase — *Accrual* = 0
ii. Arm B: Platinum + Etopside — *Accrual Goal* = 0

b. INCB 01158-203 Phase I/II Study to Evaluate Safety Tolerability and Efficacy of INCB00158 in Combo with Chemotherapy — **Closed 4/15/20**
i. Arm A1(MSS-CRC): Stage 1:Closed INCB001158 100mg PO BID +FOLFOX; 28 day cycle — *Accrual* = 5
ii. Arm B1(BTC): Stage 1 & Stage 2: Closed: INCB001158 100mg PO BID+Gemcitabine/Cisplatin; 21day cycle — *Accrual Goal* = 4
iii. Arm B2(OC): Stage 1:Closed INCB001158 100mg PO BID + Gemcitabine/Cisplatin; 21 day cycle
iv. ArmC1(GC): Stage 1: Closed INCB001158 100mg PO BID + Pacliatxel 80mg/m2 IV D1,8,15; 28 day cycle
v. Arm C2(EC): Stage 1: CLOSED INCB001158 100mg PO BID + Paclitaxel 80mg/m2 IV D1, 8, 15; 28 day cycle
vi. Arm C3(OC): Stage 1 & 2:Closed INCB001158 100mg PO BID + Paclitaxel 80mg/m2 IV D1,8,15; 28 day cycle

c. MK 3475-587 (Rollover Trial limited to MK3475-029, 7339-007 Open-label, Phase III Extension Trial to Study the Long-term Safety an — **Closed 9/22/21**
i. effective 2/12/2026 Second Course Discontinued: Pembrolizumab 200mg IV q3w (or 400mg IV q6w) +/- combination drug(s)
ii. Not Applicable: Lenvatinib Dose as per parent study PO QD
iii. Olaparib Dose as per parent study PO BID
iv. Not Applicable: MK-4280 800mg IV Q3W
v. Not Applicable: MK-4280A IV Q3W (fixed dose combo of 800mg MK-4280+200mg of pembro)
vi. Not Applicable: MK-3475A 395mg Q3W or 790mg Q6W IV

d. MRK MK7339-007 (LYNK-007) A Phase 2 Study of Olaparib in Combination with Pembrolizumab in Parti — **Closed 5/12/23**
i. Olaparib 300 mg BID + Pembrolizumab 200 mg IV Q3W

e. MRT 849-001 Phase 1/2 Multi Expansion Cohort Trial of MRTX849 in Advanced Solid Tu — **Closed 7/3/25**
i. A. CLOSED: NSCLC with KRAS G12C mutation detected in Tumor Tissue (MRTX849 600mg Oral BID)
ii. B. CLOSED:NSCLC with KRAS G12C mutation detected in blood (i.e. ctDNA) (MRTX849 600mg Oral BID)
iii. C. CLOSED: Colorectal Cancer (CRC) with KRAS G12C mutation detected in tumor tissue and/or blood (MRTX849 600mg Oral BID)
iv. D. Other solid tumors (other than NSCLC and CRC; no further appendiceal patients) with KRAS G12C mutation detected in tumor tissue and/or blood (MRTX849 600mg Oral BID)
v. CLOSED: E. NSCLC with KRAS G12C & STK11 mutations in 1st line systemic treatment (MRTX849 600mg Oral BID)
vi. CLOSED F. CRC with KRAS G12C mutation detected in tumor tissue (MRTX849 600mg Oral BID)
vii. CLOSED: G. CRC with KRAS G12C mutation detected in tumor tissue (MRTX849 600mg PO BID + Cetuximab 500mg/m2 IV on days 1 & 15 of every 28-day cycle)
viii. CLOSED: Sub-Study Cohort(Appendix 7): NSCLC with KRAS G12C mutation MRTX849 (600mg PO BID) + Pembrolizumab (200mg IV Q3W)
ix. CLOSED: Sub-Study Cohort(Appendix 8): Advanced CRC with KRAS G12C mutation MRTX849 (600mg PO BID) + Cetuximab (500mg/m2 IV Q 2 weeks)
x. CLOSED: Sub-Study Cohort(Appendix 10): Advanced NSCLC with KRAS G12C Mutation (MRTX849 400mg PO BID + Cetuximab 500mg/m2 IV on days 1 & 15 of every 28-day cycle)
xi. CLOSED: Sub-Study Cohort(Appendix 11): Advanced PDAC with KRAS G12C Mutation (MRTX849 400mg PO BID + Cetuximab 500mg/m2 IV on days 1 & 15 of every 28-day cycle)
xii. CLOSED: Sub-Study: Phase 1B Dose Optimization CRC cohort (MRTX849 400mg PO BID + Cetuximab 500mg/m2 IV Q2W on days 1 & 15 of every 28-day cycle)
xiii. CLOSED Sub Study: Phase 1B:NSCLC with KRAS G12C mutation previously treated (MRTX849 400 mg Oral BID)

f. MRT 849-EAP-001 Expanded use of MRTX849 for advanced solid tumors with KRAS G12C — **Closed 5/10/23**
i. MRTX849 600mg PO BID Monotherapy in 28-day cycles

g. MK 3475A-F11 A Phase 2 Study to Evaluate Patient Reported Preference for Subcutaneo — **Closed 11/22/24**
i. Arm A: MK-3475A SC Q3W for 3 cycles followed by pembrolizumab IV Q3W for 3 cycles followed by Continuation Period of Participants Choice
ii. Arm B: pembrolizumab IV Q3W for 3 cycles followed by MK-3475A SC Q3W for 3 cycles followed by Continuation Period of Participants Choice

h. MK 9999-02A (LIGHTBEAM) Phase 1/2 Study to Evaluate the Safety & Efficacy of MK-2870 Monothera — **Closed 4/4/25**
i. Closed Cohort 1: 2L CRC MK2870 4mg/kg q2w + 5FU/LV q2w
ii. CLOSED Cohort 2: 2L Pancreatic Ductal Adenocarcinoma MK2870 4mg/kg IV q2w monotherapy
iii. CLOSED Cohort 3: 2L+ Biliary Tract Cancer MK2870 4mg/kg IV q2w monotherapy

i. MK 1022-011 (HERTHENA-PanTumor02) A Phase 1/2 Study to Evaluate the Safety and Efficacy of Patritumab D — **Closed 6/3/25**
i. CLOSED-Cohort 1: 2L CRC: HER3-DXd Monotherapy 5.6mg/kg IV q3w
ii. CLOSED-Cohort 2: 2L BTC: HER3-DXd Monotherapy 5.6mg/kg IV q3w
iii. NOT PARTICIPATING SITE Cohort 3: 2L HCC: HER3-DXd Monotherapy DOSE ESCALATION 4.8mg/kg IV q3w
iv. NOT YET OPEN - Cohort 3: 2L HCC: HER3-DXd Monotherapy Efficacy Phase 5.6mg/kg IV q3w

Supportive Care

1. Bone Mets

a. ACORN AMG 20050244 Phase III, Blinded (Denosumab & Zometa Provided) — **Closed 4/9/08**
i. ARM A: Denosumab + IV Placebo q 4 weeks — *Accrual* = 2
ii. ARM B: Placebo + Zometa q 4 weeks — *Accrual Goal* = 6

b. TORI AMG20040114 Randomized, Phase III — **Closed 6/15/05**
i. ARM A: AMG 162 180mg sc q4w — *Accrual* = 0
ii. ARM B: AMG 162 180mg sc q12w
iii. ARM C: Standard IV Bisphosphonate

2. Anemia

a. ACORN ALSSCIA0401 Randomized, Phase II — **Closed 4/5/05**
i. Group 1: Darbepoetin 200mcg q2w, initiate when Hgb <11.5 — *Accrual* = 1
ii. Group 2: Darbepoetin 200mcg q2w, initiate when Hgb <10

3. Thrombocytopenia

a. ACORN AMG 20050144 Dose Finding, Lymphoma (AMG 531 & Neulasta Provided) — **Closed 5/28/08**
i. AMG 531/Cohort 4 1000ug dose level — *Accrual* = 0
Accrual Goal = 5

b. NGOC AMG 20040209 (Study Drug Provided) ITP — **Closed 9/12/08**
i. AMG 531 weekly — *Accrual* = 1
Accrual Goal = 1

c. NGOC AMG 20030213 Extension Study (Study Drug Provided) ITP — **Closed 12/10/07**
i. AMG 531 weekly — *Accrual* = 1