Open and Pending Trials Listing For Arizona Oncology Associates
P.C. HOPE Division/ Tucson, Arizona

Solid Tumor:
USON 15180 / A Multicenter, Open-Label Phase 1b/2 Trial of Lenvatinib (E7080) Plus Pembrolizumab in Subjects With Selected Solid Tumors
Sponsor: Eisai Inc
Only Renal Cell Carcinoma Cohort is open to enrollment
NCT# 02501096/ Please click the link for more information: Link to 02501096 study on clinicaltrials.gov

USON 16041/BMS CA209-627 : An Open-label Phase 2 Multi-cohort Trial of Nivolumab in Advanced or Metastatic Malignancies
Sponsor: Bristol Myers Squibb
NCT# 02832167/ Please click the link for more information: Link to 02832167 on clinicaltrials.gov website

USON 17063/ 4020-01-001) A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-022, an anti-TIM-3 Monoclonal Antibody, in Patients with Advanced Solid Tumors (colon, melanoma, lung)
Sponsor: TESARO
NCT# 02817633/ Please click the link for more information: Link to 02817633 on clinicaltrials.gov website

Lung:
USON 16156/ CA209817: A Phase IIIb/IV Safety Trial of Flat Dose Nivolumab in Combination with Ipilimumab in Participants with Advanced Malignancies
ONLY COHORT C remains open: Cohort C will evaluate the clinical activity of nivolumab in combination with ipilimumab as first-line treatment in patients with NSCLC whose tumor harbors a high mutation burden (High TMB=>/=10mutations/MB)
Sponsor: Bristol Myers Squibb
NCT# 02869789/ Please click the link for more information: Link to 02869789 on clinicaltrials.gov website

USON 15079 Open at WILMOT location ONLY(Spinet) - A-US-52030-328 : A Phase 3, Prospective, Randomized, Double-Blind, Multi-Center, Study of the Efficacy and Safety of Lanreotide Autogel/ Depot 120 mg plus BSC vs. Placebo plus BSC for Tumour Control in Subjects with Well Differentiated, Metastatic and/or Unresectable Typical or Atypical Lung Neuroendocrine Tumours
Sponsor: Ipsen/Theradex
NCT# 02683941/ Please click the link for more information: Link to 02683941 on clinicaltrials.gov website

USON 17140 : A Phase III, Double-Blinded, Multicenter, Randomized Study Evaluating The Efficacy and Safety of Neo-adjuvant Treatment with Atezolizumab or Placebo in Combination with Platinum-Based Chemotherapy in Patients with Resectable Stage IB-III A Non-Small Cell Lung Cancer
Sponsor: Genentech
NCT# 03456063/ Please click the link for more information: Link to 03456063 on clinicaltrials.gov
Breast:

**Triple negative breast cancer:**

**USON 16208/ MK-3475-522 (RS) A Phase III Randomized, Double-blind Study to Evaluate Pembrolizumab plus Chemotherapy vs Placebo plus Chemotherapy as Neoadjuvant Therapy and Pembrolizumab vs Placebo as Adjuvant Therapy for Triple Negative Breast Cancer (TNBC)**

**Sponsor: Merck**

NCT# 03036488/ Please click the link for more information: Link to 03036488 on clinicaltrials.gov

**Adjuvant HR positive/HER2 negative Breast cancer:**

**USON 17188/ KEYNOTE 756: A Randomized, Double-Blind, Phase III Study of Pembrolizumab versus Placebo in Combination with Neoadjuvant Chemotherapy and Adjuvant Endocrine Therapy for the Treatment of High-Risk Early-Stage Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative (HR+/HER2−) Breast Cancer (KEYNOTE-756) Opening at our site August 2018**

**Sponsor: Merck**


**Sponsor: Eli Lilly and Company**

NCT03155997 Please click the link for more information: Link to 03155997 on clinicaltrials.gov

**Adv/Metastatic HR positive/HER2 negative breast cancer :**

**USON 17009/ODO-TE-B301: A Multinational, Multicenter, Randomized, Phase 3 Study of Tesetaxel plus a Reduced Dose of Capecitabine versus Capecitabine Alone in Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Previously Treated with a Taxane (ODO-TE-B301)**

**Sponsor: Odonate Therapeutics**

NCT03326674/ Please click the link for more information: Link to 03326674 on clinicaltrials.gov

**HER 2 Positive breast cancer:**

**USON 17043: A Phase 2, Multicenter, Open-Label Study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC) for HER2-Positive, Unresectable and/or Metastatic Breast Cancer Subjects Who are Resistant or Refractory to T-DM1**

**Sponsor: Daiichi Sankyo**

NCT# 03248492/ Please click the link for more information: Link to 03248492 on clinicaltrials.gov

**Hematologic malignancies:**

**Follicular/Marginal zone and Mantle Cell Lymphoma:**

**USON 13064 : A phase 3B randomized study of lenalidomide (CC-5013) plus rituximab maintenance therapy followed by lenalidomide single-agent maintenance versus rituximab maintenance in subjects with relapsed/refractory follicular, marginal zone or mantle cell lymphoma**

**Sponsor: Celgene**

NCT01996865/ Please click the link for more information: Link to 01996865 on clinicaltrials.gov
Diffuse Large B Cell /Small Lymphocytic/Follicular/Marginal Zone Lymphoma:
USON 16065/UTX-TGR-205 : A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 and TGR-1202 alone in Patients with Previously Treated Diffuse Large B-Cell Lymphoma DLBCL cohort is now closed. Cohorts for SLL/MCL/MZL and FL are still open and enrolling.
Sponsor: TG Therapeutics
NCT02793583/Please click the link for form information: Link to 02793583 on clinicaltrials.gov

Chronic Lymphocytic Lymphoma:
USON 17106/A phase 3b study in previously untreated Chronic Lymphocytic Leukemia (CLL) subjects, excluding those with the 17p deletion, to evaluate debulking regimens prior to initiating venetoclax combination therapy/ Opening at our site June 2018.
Sponsor: Abbvie
NCT03406156/ Please click the link for more information: Link to 03406156 on clinicaltrials.gov

Hodgkins Lymphoma:
USON 11282 (STAR TRIAL) SGN35-015: A phase 2 single-arm, open-label study of brentuximab vedotin plus bendamustine for front-line therapy of Hodgkin lymphoma (HL) in adults age 60 and above
ARM D NOW OPEN: Nivolumab plus brentuximab
Sponsor: Seattle Genentics
NCT01716806: Please click the link for more information: Link to 01716806 on clinicaltrials.gov

Multiple Myeloma:
USON 17081/C16038 : An Open-Label, Single-Arm, Multicenter Study to Evaluate the Effectiveness and Safety of Ixazomib (NINLARO®) in Combination with Lenalidomide and Dexamethasone (IRD) in Patients with Multiple Myeloma Previously Receiving a Bortezomib-Based Triplet Induction Regimen
Sponsor: Millennium Pharmaceuticals
NCT03173092/ Please click the link for more information: Link for 03173092 on clinicaltrials.gov

OP103 Ocean: A Randomized, Controlled, Open-Label, Phase 3 Study of Melflufen/Dexamethasone Compared with Pomalidomide/ Dexamethasone for Patients with Relapsed Refractory Multiple Myeloma who are Refractory to Lenalidomide
Sponsor: Oncopeptides
NCT 03151811/Please click the link for more information: Link to 03151811 on clinicaltrials.gov

Myelodysplastic syndrome/Acute Myelogenous Leukemia/Chronic Myelomonocytic Leukemia :
USON 17153/Pevonedistat-3001 : A Phase 3, Randomized, Controlled, Open-label, Clinical Study of Pevonedistat Plus Azacitidine Versus Single-Agent Azacitidine as First-Line Treatment for Patients With Higher-Risk Myelodysplastic Syndromes, Chronic Myelomonocytic Leukemia, or Low-Blast Acute Myelogenous Leukemia
Sponsor: Takeda/ Millennium Pharmaceuticals
NCT 03268954/ Please click the link for more information: Link to 03268954 on clinicaltrials.gov
Benign hematologic conditions:

Autoimmune hemolytic anemia (Warm):

**Rigel 053 SOAR**: Two-Stage Study to Evaluate the Safety and Efficacy of Fostamatinib Disodium in the Treatment of Warm Antibody Autoimmune Hemolytic Anemia
**Sponsor**: Rigel Pharmaceuticals
**NCT02612558** Please click the link for more information: Link to 02612558 on clinicaltrials.gov

Autoimmune hemolytic anemia (cold agglutinin)

**Bioverativ BIVV009-03 (Cardinal)**: A Pivotal, Open-Label, Multicenter Study to Assess the Efficacy and Safety of BIVV009 in Patients with Primary Cold Agglutinin Disease Who Have a Recent History of Blood Transfusion
**Sponsor**: Bioverativ Therapeutics Inc.
**NCT03347396** Please click the link for more information: Link to 03347396 on clinicaltrials.gov

**Bioverativ BIVV009-04 (Cadenza)**: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of BIVV009 in Patient with Primary Cold Agglutinin Disease Without a Recent History of Blood Tranfusion
**Sponsor**: Bioverativ Therapeutics Inc.
**NCT03347422** Please click the link for more information: Link to 03347422 on clinicaltrials.gov

Gastrointestinal:

**USON 16130/CanStem303C/BB608-303CRC (CD)**: A Phase III Study of BBI-608 in Combination with 5-Fluorouracil, Leucovorin, Irinotecan (FOLFIRI) in Adult Patients with Previously Treated Metastatic Colorectal Cancer
**Sponsor**: Boston Biomedical
**NCT02753127** Please click the link for more information: Link to 02753127 on clinicaltrials.gov

Genitourinary:

**Renal Cell Carcinoma**:

**USON 15180**: A Multicenter, Open-Label Phase 1b/2 Trial of Lenvatinib (E7080) Plus Pembrolizumab in Subjects With Selected Solid Tumors
**Sponsor**: Eisai Inc
*Only Renal Cell Carcinoma Cohort is open to enrollment*
**NCT 02501096** Please click the link for more information: Link to this study on clinicaltrials.gov

**Urothelial/Bladder**:

**USON 16052/CA209-274**: A Phase 3 Randomized, Double-blind, Multi-center Study of Adjuvant Nivolumab versus Placebo in Subjects with High Risk Muscle Invasive Urothelial Carcinoma
**Sponsor**: Bristol Myers Squibb
**NCT02632409** Please click the link for more information: Link to 02632409 on clinicaltrials.gov
USON 15228/ INCB 54828-201 : A Phase 2, Open-label, Single Agent, Multi-Center Study to Evaluate the Efficacy and Safety of a Pan-FGFR Tyrosine Kinase Inhibitor INCB054828 in Patients with Metastatic or Surgically Unresectable Urothelial Carcinoma Harboring FGF/FGFR Alterations (Open at Wilmot only)  
**Sponsor:** Incyte  
**NCT02872714/ Please click the link for more information:** [Link to 02872714 on the clinicaltrials.gov](#)

USON 17005/ SGN22E-001: Phase II study of enfortumab vedotin for treatment of patients with locally advanced or metastatic urothelial cancer.  
**Sponsor:** Seattle Genetics  
**NCT03219333/ Please click the link for more information:** [Link to 03219333 on clinicaltrials.gov](#)

**Gynecologic:**  
**Ovarian cancer:**  
USON 16233/GOG-3015/YO39523 (JB): A Phase III, Multicenter, Randomized Study of Atezolizumab versus Placebo Administered in Combination with Paclitaxel, Carboplatin and Bevacizumab to Patients with Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube or Primary Peritoneal Cancer  
**Neoadjuvant cohort is closed to enrollment. Primary debulking cohort is still enrolling.**  
**Sponsor:** Genentech and GOG Foundation  
**NCT03038100/ Please click the link for more information:** [Link to 03038100 on clinicaltrials.gov](#)

USON 17216/ (B9991030) A Randomized, Open-Label, Multicenter, Phase 3 Study To Evaluate the Efficacy and Safety of Avelumab in Combination with Chemotherapy Followed by Maintenance Therapy of Avelumab in Combination With The Poly (Adenosine Diphosphate [ADP]-Ribose) Polymerase (PARP) Inhibitor Talazoparib in Patients with Previously Untreated Advance Ovarian Cancer.  
**Opening at our site August 2018**  
**Sponsor:** Pfizer

I4D-MC-JTJN : A Phase 2 Study of Prexasertib in Platinum-Resistant or Refractory Recurrent Ovarian Cancer : **Cohorts 1,2,3 are closed Cohort 4 (for primary platinum refractory disease) is still enrolling**  
**Sponsor:** Eli Lilly and Company  
**NCT#03414047/ Please click the link for more information:** [Link to 03414047 on clinicaltrial.gov](#)

**Cervical cancer:**  
USON 17052/ R2810-ONC-1676: An Open-Label, Randomized, Phase 3 Clinical Trial of REGN2810 Versus Therapy of Investigator's Choice Chemotherapy in Recurrent or Metastatic Platinum-Refractory Cervical Carcinoma  
**Sponsor:** GOG Foundation and Regeneron  
**NCT03257267/Please click the link for more information:** [Link to 03257267 on clinicaltrials.gov](#)
ARIZONA ONCOLOGY
RADIATION CLINICAL TRIALS
(as of 06/18/18)

**13091**
1st Line
OPEN

NSABP B-51 / RTOG 1304  Post-Mastctomy/Lumpctmy XRT, Neoadj Chemo
A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy (NSABP B-51 / RTOG 1304)
For more information call: (520) 544-2919

Sponsor: NRG Oncology
Please click the link for more information: [https://clinicaltrials.gov/ct2/show/NCT01872975](https://clinicaltrials.gov/ct2/show/NCT01872975)

**14057**
High grade
OPEN

TOG 0924  Ph3Andro+HighRad +/- PelvicRad Prostate
Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial
For more information call: (520) 544-2919

Sponsor: NRG Oncology
Please click the link for more information: [https://clinicaltrials.gov/ct2/show/NCT01368588](https://clinicaltrials.gov/ct2/show/NCT01368588)

**14057**
Intermediate grade
OPEN

TOG 0924  Ph3Andro+HighRad +/- PelvicRad Prostate
Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial
For more information call: (520) 544-2919

Sponsor: NRG Oncology
Please click the link for more information: [https://clinicaltrials.gov/ct2/show/NCT01368588](https://clinicaltrials.gov/ct2/show/NCT01368588)

**18021**
OPEN

NRG-GU005  PHIII
IGRT/SBRTvsIGRT/HypoIMRT IntProst
Phase III IGRT and SBRT Vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer
For more information call: (520) 544-2919

Sponsor: NRG Oncology

Please click the link for more information: https://clinicaltrials.gov/ct2/show/NCT03367702