

# 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](https://clinicaltrials.gov/ct2/show/study/NCT02501096)

**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](https://clinicaltrials.gov/ct2/show/study/NCT02832167)

**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](https://clinicaltrials.gov/ct2/show/study/NCT02817633)

## 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](https://clinicaltrials.gov/ct2/show/study/NCT02869789)

**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](https://clinicaltrials.gov/ct2/show/study/NCT02683941)

**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](https://clinicaltrials.gov/ct2/show/study/NCT03456063)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT03036488)**

### **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<sup>-</sup>C) Breast Cancer (KEYNOTE-756) **Opening at our site August 2018**

**Sponsor: Merck**

**USON 17082 (I3Y-MC-JPCF) monarchE:** A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer

**Sponsor: Eli Lilly and Company**

**NCT03155997 Please click the link for more information: [Link to 03155997 on clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03155997)**

### **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](https://clinicaltrials.gov/ct2/show/study/NCT03326674)**

### **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](https://clinicaltrials.gov/ct2/show/study/NCT03248492)**

## **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](https://clinicaltrials.gov/ct2/show/study/NCT01996865)**

## **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](https://clinicaltrials.gov/ct2/show/study/NCT02793583)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT03406156)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT01716806)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT03173092)

**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](https://clinicaltrials.gov/ct2/show/study/NCT03151811)

## **Myelodysplastic syndrome/Acute Myelogenous Leukemia/Chronic Myelomonocytic Leukemia :**

**USON 17153/Pevedistat-3001** : A Phase 3, Randomized, Controlled, Open-label, Clinical Study of Pevedistat 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](https://clinicaltrials.gov/ct2/show/study/NCT03268954)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT02612558)

### **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](https://clinicaltrials.gov/ct2/show/study/NCT03347396)

**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 03347422on clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03347422)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT02753127)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT02501096)

### **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](https://clinicaltrials.gov/ct2/show/study/NCT02632409)

**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](https://clinicaltrials.gov/ct2/show/study/NCT02872714)

**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](https://clinicaltrials.gov/ct2/show/study/NCT03219333)

## **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](https://clinicaltrials.gov/ct2/show/study/NCT03038100)

**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](https://clinicaltrials.gov/ct2/show/study/NCT03414047)

### **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](https://clinicaltrials.gov/ct2/show/study/NCT03257267)

**ARIZONA ONCOLOGY  
RADIATION CLINICAL TRIALS  
(as of 06/18/18)**

**13091** NSABP B-51 / RTOG 1304 **Post-Mastctmy/Lumpctmy XRT, Neoadj Chemo**  
1st Line  
**OPEN** 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>**

**14057** TOG 0924 **Ph3Andro+HighRad +/- PelvicRad Prostate**  
High  
grade  
**OPEN** 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>**

**14057** TOG 0924 **Ph3Andro+HighRad +/- PelvicRad**  
Intermediat  
e grade  
**OPEN** **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>**

**18021** NRG-GU005 **PHIII**  
**OPEN** **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>**