

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

## Solid Tumor:

--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 on the 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 on the 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 on the 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 on the clinicaltrials.gov website**

## Breast:

### Neo 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)

**Sponsor: Merck**

**NCT # 03725059/ Please click the [LINK](#) for more information on the clinicaltrials.gov website**

### Adjuvant HR positive/HER2 negative Breast cancer (high risk):

**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

NCT # 03155997 Please click the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

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

**USON 17009/ODO-TE-B301:** A Multinational, Multicenter, Randomized, Phase 3 Study of Teseaxel 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 on the [clinicaltrials.gov](http://clinicaltrials.gov) website

### **Hematologic malignancies:**

#### **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

*MCL and FL are the only cohorts open.*

*The DLBCL, SLL, and MZL Cohorts are closed to accrual*

**Sponsor: TG Therapeutics**

NCT02793583/Please click the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

--USON 17195/ (062-HEM-102) A Phase 1b/2 Dose-Escalation and Cohort-Expansion Study of the Noncovalent, Reversible Bruton's Tyrosine Kinase Inhibitor, SNS-062, in Patients With B-Lymphoid Malignancies

**Sponsor: Sunesis Pharmaceuticals Inc.**

NCT03037645 / Please click the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

#### **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

**Sponsor: Abbvie**

NCT03406156/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

#### **Hodgkins Lymphoma:**

--USON 11282 (DB) (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 on the [clinicaltrials.gov](http://clinicaltrials.gov) website

## 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 on the [clinicaltrials.gov](#) website

--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 on the [clinicaltrials.gov](#) website

## 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 on the [clinicaltrials.gov](#) website

## Benign hematologic conditions:

### Autoimmune hemolytic anemia:

--Bioveritiv 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 Transfusion/ Opening at our site May 2018:

**Sponsor: Bioveritiv**

NCT03347422/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#) website

## 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 on the [clinicaltrials.gov](#) website

--USON 17160 (SM) PANOVA-3: Pivotal, randomized, open-label study of Tumor Treating Fields (TTFields, 150kHz) concomitant with gemcitabine and nab-paclitaxel for front-line treatment of locally-advanced pancreatic adenocarcinoma

**Sponsor: Novocure**

NCT 03377491/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#) website

## **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**

*Renal Cell Carcinoma.*

NCT# 02501096/ Please click this [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

### **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 on the [clinicaltrials.gov](http://clinicaltrials.gov) website

--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 on the [clinicaltrials.gov](http://clinicaltrials.gov) website

--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 on the [clinicaltrials.gov](http://clinicaltrials.gov) website

--USON 18095(CA017078) (CD): A Phase 3, Randomized, Open-Label Study of Neoadjuvant Chemotherapy alone versus Neoadjuvant Chemotherapy plus Nivolumab or Nivolumab and BMS-986205, Followed by Continued Post-Surgery Therapy with Nivolumab or Nivolumab and BMS-986205 in Participants with Muscle-Invasive Bladder Cancer

**Sponsor: Bristol Myers Squibb**

NCT03661320/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

## **Gynecologic:**

### **Ovarian cancer:**

--USON 17216/ Pfizer B9991030 (JB): 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 Advanced Ovarian Cancer

**Sponsor: Pfizer**

NCT03642132/ Please click on the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

--USON 17182(ATHENA): A Multicenter, RAndomized, Double-Blind, Placebo-ConTrolled PHAsE 3 Study of Nivolumab and RucAparib Combination Switch Maintenance following Front-Line Platinum-based Chemotherapy in Ovarian Cancer Patients

**Sponsor: Clovis Oncology and GOG Foundation**

NCT 03522246/ Please click on the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

--USON 17206/ (AVB500-OC-002) A Phase 1b/2 Randomized, Controlled Study of AVB-S6-500 in Combination with Pegylated Liposomal Doxorubicin or Paclitaxel in Patients with Platinum-resistant Recurrent Ovarian Cancer

Sponsor: Aravive Biologics Inc.

NCT03639246/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](http://clinicaltrials.gov) website

### **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 on the [clinicaltrials.gov](http://clinicaltrials.gov) website

## **Open and Pending Trials Listing For Arizona Oncology Associates SRO Division/ Tucson, Arizona**

(as of 02/21/19)

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

**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**  
Intermediate                      **Prostate**  
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>**

**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>**