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-IIIA 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−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):
Sponsor: Eli Lilly and Company
NCT # 03155997 Please click the LINK for more information on the clinicaltrials.gov website

**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 on the 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 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.
NCT03073645 / Please click the LINK for more information on the 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 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 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/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 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 Tranfusion/ 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](https://clinicaltrials.gov) for more information on the 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](https://clinicaltrials.gov) for more information on the 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](https://clinicaltrials.gov) for more information on the 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](https://clinicaltrials.gov) for more information on the 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](https://clinicaltrials.gov) for more information on the 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](https://clinicaltrials.gov) for more information on the 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 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 website

Open and Pending Trials Listing For Arizona Oncology Associates
SRO Division/ Tucson, Arizona
(as of 02/21/19)

13091 1st Line OPEN
NSABP B-51 / RTOG 1304 Post-Mastctmy/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

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

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
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