

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

PHASE 1 studies:

- **USON 19081/** (MER-XMT-1536-1) (JB):A Phase 1b, First-in-Human, Dose Escalation and Expansion Study of XMT-1536 In Patients with Solid Tumors Likely to Express NaPi2b (Cohorts open: Platinum resistant ovarian cancer and Non small cell lung cancer)

Sponsor: Mersana

NCT03319628/ Please click on the [LINK](#) for more information on the clinicaltrials.gov website

This is also listed under Lung and Ovarian as this study is enrolling to these two diseases.

Pending USON 19082 A Phase 1/1b multicenter study to evaluate the humanized anti-CD73 antibody, CPI-006, as a single agent or in combination with ciforadenant, with pembrolizumab, and with ciforadenant plus pembrolizumab in adult subjects with advanced cancers

Sponsor: Corvus Pharmaceuticals Inc.

NCT03454451/ Please click on the [LINK](#) for more information on the clinicaltrials.gov website

Solid Tumor:

Lung:

--**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

- **USON 19081/** (MER-XMT-1536-1) (JB):A Phase 1b, First-in-Human, Dose Escalation and Expansion Study of XMT-1536 In Patients with Solid Tumors Likely to Express NaPi2b (Cohorts open: Platinum resistant ovarian cancer and Non small cell lung cancer)

Sponsor: Mersana

NCT03319628/ Please click on 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

Adv/Metastatic HR positive/HER2 negative breast cancer :

--**OPEN USON 18282**(IMMU-132-09) Phase 3 Study of Sacituzumab Govitecan (IMMU-132) Versus Treatment of Physician's Choice (TPC) in subjects with Hormonal Receptor-Positive (HR+) Human Epidermal Growth Factor Receptor 2 (HER2) Negative Metastatic Breast Cancer (MBC) who have failed at least two prior chemotherapy regimens

Sponsor: Immunomedics

NCT03901339/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#)

Metastatic Triple Negative

-- **NON USON Infinity IPI-549-03 (RS)** A Phase 2 Multi-arm, Multicenter, Open-label Study to evaluate the Efficacy and Safety of IPI-549 Administered in Combination with Front-Line Treatment regimens in patients with Locally Advanced and/or Metastatic Triple negative Breast Cancer or Renal Cell Carcinoma

Sponsor: Infinity Pharmaceuticals Inc.

NCT03961698/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#)

Advanced/Metastatic HR positive

-- **USON 19054**(SGNTUC-016): Randomized, double-blind, phase 3 study of tucatinib or placebo in combination with ado-trastuzumab emtansine (T-DM1) for subjects with unresectable locally-advanced or metastatic HER2+ breast cancer

Sponsor: Seattle Genetics

NCT 03975647 /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

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

--**USON 18263** (BGB-3111-215) :A Phase 2, Multicenter, Single-arm Study of Zanubrutinib (BGB-3111) in Patients with Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Intolerant of Prior Treatment with Ibrutinib

Sponsor: BeiGene USA Inc

NCT03206918/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#) website

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 Genetics

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

NCT 03173092/ 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

Acute Myelogenous Leukemia:

--USON 18168(M19-072) (SM): A Phase 3b, Single-Arm, Multicenter Open-Label Study of Venetoclax in Combination with Azacitidine or Decitabine in an Outpatient Setting in AML Patients Ineligible for Intensive Chemotherapy

Sponsor: Abbvie

NCT03941964 /Please click the [LINK](#) for more information on the [clinicaltrials.gov](#) website

Benign hematologic conditions:

Autoimmune hemolytic anemia:

--Bioerativ 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: Bioerativ

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

--Non USON **Rigel C-935788-057(Forward):** A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Warm Antibody Autoimmune Hemolytic Anemia

Sponsor: Rigel Pharmaceuticals, Inc.

NCT03764618/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#)

Gastrointestinal:

--USON 17160 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

--USON 19086/(CA209-9DX) : A Phase 3, Randomized, Double-blind Study of Adjuvant Nivolumab versus Placebo for Participants with Hepatocellular Carcinoma Who Are at High Risk of Recurrence after Curative Hepatic Resection or Ablation

Sponsor: Bristol Myers Squibb

NCT03383458/ Please click the [LINK](#) for more information on the clinicaltrials.gov website

Genitourinary:

Renal Cell Carcinoma:

--Infinity IPI-549-03 : A Phase 2 Multi-arm, Multicenter, Open-label Study to evaluate the Efficacy and Safety of IPI-549 Administered in Combination with Front-Line Treatment regimens in patients with Locally Advanced and/or Metastatic Triple negative Breast Cancer or Renal Cell Carcinoma

Sponsor: Infinity Pharmaceuticals Inc.

NCT03961698/ Please click the [LINK](#) for more information on the clinicaltrials.gov

Urothelial/Bladder:

--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 website

--USON 18095(CA017078): 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 website

--18-214-10 / CA045-012 Nektar : A Phase 2, single-arm study of bempegaldesleukin (NKTR-214) in combination with nivolumab in cisplatin ineligible, locally advanced or metastatic urothelial cancer patients

Sponsor: Nektar Therapeutics

NCT03785925/ Please click the [LINK](#) for more information on the clinicaltrials.gov website

--USON 19032(42756493BLC0002) : Biomarker Study to Identify Subjects with Advanced Urothelial Cancer and Fibroblast Growth Factor Receptor Gene Aberrations

Sponsor: Janssen

NCT03955913/ Please click the [LINK](#) for more information on the clinicaltrials.gov website

Prostate:

--USON 16238 CO-338-063 TRITON3 (DB): A Multicenter, Randomized, Open-label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency

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Sponsor: Clovis Oncology, Inc

NCT02975934/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#) website

--USON 19135 (CA209-650): A Phase 2 Trial of Nivolumab Plus Ipilimumab, Ipilimumab Alone, or Cabazitaxel in Men with Metastatic Castration-Resistant Prostate Cancer

Sponsor: Bristol Myers Squibb

NCT 02985957/ Please click the [LINK](#) for more information on the [clinicaltrials.gov](#) website

Gynecologic:

Ovarian cancer:

First line/initial diagnosis

--USON 17218 3000-03-005/ENGOT-OV44 :A Randomized, Double-Blind, phase 3 Comparison of Platinum- Based Therapy with TSR-042 and Niraparib Versus Standard of Care Platinum Based Therapy as First Line Treatment of Stage III or IV Non Mucinous Epithelial Ovarian Cancer.

Sponsor: Tesaro Inc

NCT03602859/ Please click on the [LINK](#) for more information on the [clinicaltrials.gov](#) website

1st line Maintenance:

--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](#) website

Platinum resistant:

--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

--USON 19046/(MOONSTONE): A Phase 2 Open-label, Single-arm Study to Evaluate the Efficacy and Safety of the Combination of Niraparib and TSR-042 in Patients with Platinum-Resistant Ovarian Cancer

Sponsor: Tesaro Inc/GOG Foundation

NCT03955471 Please click the [LINK](#) for more information on the [clinicaltrials.gov](#) website

--USON 19081/ (MER-XMT-1536-1) : A Phase 1b, First-in-Human, Dose Escalation and Expansion Study of XMT-1536 In Patients with Solid Tumors Likely to Express NaPi2b (Cohorts open: Platinum resistant ovarian cancer and Non small cell lung cancer)

Sponsor: Mersana

NCT03319628/ Please click on 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

--USON 18223 RaPiDS : A Two-arm, Randomized, Non-comparative, Phase 2 Trial of AGEN2034(anti-PD-1) as a Monotherapy or Combination Therapy with AGEN1884(anti-CTLA4) or with Placebo in Women with Recurrent Cervical Cancer (Second Line)

Sponsor: Agenus/ GOG Foundation

NCT 03894215 /Please click the [LINK](#) for more information on the clinicaltrials.gov website

Endometrial:

-- Non USON KCP-330-024 : A Randomized, Double Blind, Phase 3 Trial of Maintenance with Selinexor/Placebo After Combination Chemotherapy for Patients with Advanced or Recurrent Endometrial Cancer

Sponsor: Karyopharm

NCT 03555422/Please click the [LINK](#) for more information on the clinicaltrials.gov website

-- USON 18143/(LEAP-001)(MK-7902-001-00) : A Phase 3 Randomized, Open-Label, Study of Pembrolizumab (MK-3475) Plus Lenvatinib (E7080/MK-7902) Versus Chemotherapy for First-line Treatment of Advanced or Recurrent Endometrial Carcinoma

Sponsor: Merck

NCT 03884101 /Please click the [LINK](#) for more information on the clinicaltrials.gov website

--USON 19034 (RUBY): Phase 3, randomized, double-blind, multicenter study of dostarlimab (TSR-042) plus carboplatin-paclitaxel versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced endometrial cancer

Sponsor: Tesaro Inc/ GOG Foundation/ ENGOT

NCT 03981796/Please click the [LINK](#) for more information on the clinicaltrials.gov website