UCI Chao Family Comprehensive Cancer Center

Malignant Hematology

Myeloproliferative Neoplasm					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Fleischman	Blake Johnson	UCI 20-50: Ph II Trial of N-Acetylcysteine in Myeloproliferative Neoplasm to Improve Disease Markers & Symptoms	Mucolytic agent, cysteine and GSH precursor	Confirmed diagnosis of essential thrombocythemia (ET), polycythemia vera (PV), or myelofibrosis (MF) according to the 2016 WHO criteria. Must have peripheral blast count <10% during Screening. Has not taken interferon-alpha or a JAK inhibitor for treatment of MPN, N-Acetylcysteine (N-AC) or preparations containing N-AC in the past 28 days before enrollment. Free of other active or metastatic malignancies other than localized skin cancer.	Pending activation
Myelodysplastic Syndrome					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Jeyakumar	Stephanie Osorio	UCI 16-13: A Phase I Dose Escalation with Two Disease Specific Expansions, Multicenter, Open-label, Safety, Pharmacokinetic and Pharmacodynamic Study of APTO-253 in Patients with Relapsed or Refractory Hematologic Malignancies	MYC inhibitor	High-risk myelodysplasia (MDS): Patients must have a score of > 4.5 on the Revised International Prognostic Scoring System (IPSS-R) for whom all standard therapy options have failed or which are considered inappropriate	Suspended
O'Brien	Veronica De Santiago	UCI 17-19: A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Ascending Doses of AZD5991 in Subjects with Relapsed or Refractory Haematologic Malignancies	MCL-1 inhibitor	Must have received at least 2 prior lines of therapy Recurrence of disease after response to prior line(s) of therapy Or progressive disease after completion of the treatment regimen preceding entry into the study There are no treatment options available known to provide clinical benefit	Suspended
Jeyakumar	Veronica De Santiago	UCI 20-48: A Randomized, Double-blind, Multicenter Study Comparing Magrolimab in Combination with Azacitidine versus Azacitidine Plus Placebo in Treatment-naïve Patients with Higher Risk Myelodysplastic Syndrome	Anti-CD47 monoclonal antibody	Confirmed intermediate, high, or very high risk MDS that is previously untreated or relapsed, refractory or intolerant to conventional therapy WBC count <20k	Open to accrual
Jeyakumar	Veronica De Santiago	ETCTN-10264: The PRIME Trial: PARP Inhibition in IDH Mutant Effectiveness Trial. A Phase II Study of Olaparib in Isocitrate Dehydrogenase (IDH) Mutant Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome	PARP Inhibitor	IDH1/2 mutation with R/R AML	Open to accrual
Jeyakumar	Stephanie Osorio	UCI 19-79: A Phase Ib Trial of Hu5F9-G4 Monotherapy or Hu5F9-G4 in Combination with Azacitidine in Patients with Hematological Malignancies	Anti-CD47 monoclonal antibody	Confirmed intermediate, high, or very high risk MDS that is previously untreated or relapsed, refractory or intolerant to conventional therapy WBC count <20k	Open to accrual
Jeyakumar	Kelsey McAbee	UCI 21-17: A Randomized, Double-Blind, Placebo-Controlled Phase III Study of SY-1425 Plus Azacitidine Versus Placebo Plus Azacitidine in Newly Diagnosed, RARA-Positive Adult Patients with Higher-Risk Myelodysplastic Syndrome	RARα agonist	Newly diagnosed Myelodysplstic patients aged ≥18 years. Patients must be RARA-positive based on investigataional assay. Must have bone marrow blasts >5% at screening. Patients must have <20% blasts in peripheral blood or bone marrow. Patients must not have received prior treatment for MDS with any hypomethylating agent, chemotherapy (including lenalidomide), or allogenic HSCT, with the exception of prior treatment with growth factors or hydroxyurea.	Open to accrual

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Malignant Hematology

Newly Diagnosed Acute Myeloid Leukemia					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Jeyakumar	Kelsey McAbee	ETCTN-10300: Blockade of PD-1 Added to Standard Therapy to Target Measurable Residual Disease in Acute Myeloid Leukemia 1 (BLAST MRD AML-1): A Randomized Phase II Study of the Anti-PD-1 Antibody Pembrolizumab in Combination with Conventional Intensive Chemotherapy as Frontline Therapy in Patients with Acute Myeloid Leukemia	PDL-1 inhibitor + SOC chemo	Must have untreated AML and be a candidate for intensive chemo therapy	Open to accrual
Jeyakumar	Kelsey McAbee	UCI 18-76: Randomized Trial of Gilteritinib vs Midostaurin in FLT3 Mutated Acute Myeloid Leukemia (AML)	FLT3 inhibitor	Subjects with untreated FLT3 mutated Non M3 AML (FLT3-TKD or FLT3-ITD allowed). Patients may not have hypomethylating agent within 21 days.	Open to accrual
Brem	Stephanie Osorio	UCI 18-128 A Phase I/IB Study of Pitavastatin in Combination with Venetoclax for Chronic Lymphocytic Leukemia (CLL) and Acute Myeloid Leukemia (AML)	HMA+BCL2 inhibitor+Statin	Newly diagnosed AML not eligible for intensive induction. Must reach stable dose of venetoclax prior to starting Pitavastatin	Open to accrual
Jeyakumar	Stephanie Osorio	UCI 19-138: A Phase Ib/II Study of IMGN632 as Monotherapy or Combination with Venetoclax and/or Azacitidine for Patients with CD123-Positive Acute Myeloid Leukemia	CD123 antibody	Must have CD123+ AML	Open to accrual
Jeyakumar	Kelsey McAbee	UCI 18-105: Phase II study of the combination of CPX-351 and Glasdegib in previously untreated patients with Acute Myelogenous Leukemia with MDS related changes or therapy-related Acute myeloid leukemia	Combination of hedgehog signaling pathway inhibitor and lipsomal formulation of cytotoxic chemotherapy Daunorubicin and Cytarabine	Previously untreated therapy-related AML or AML with myelodysplastic related changes as described by WHO a. AML arising in MDS (including CMML) or MDS/MPN syndrome b. AML with MDS-related cytogenetic abnormalities (metaphase FISH allowable as surrogate for cytogenetics) c. AML with multilineage dysplasia involving the presence of 50% or more dysplastic cells in at least two cell lines and in the absence of mutation in NPM1 or CEBPA (as per WHO 2016)	Open to accrual
Jeyakumar	Stephanie Osorio	UCI 19-79: A Phase Ib Trial of Hu5F9-G4 Monotherapy or Hu5F9-G4 in Combination with Azacitidine in Patients with Hematological Malignancies	Anti-CD47 monoclonal antibody	Previously untreated patients with histological confirmation of AML who are ineligible for treatment with a standard cytarabine and anthracycline induction regimen WBC < 20k	Open to accrual
Jeyakumar	Kelsey McAbee	UCI 20-33: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Dociparstat Sodium in Combination with Standard Chemotherapy for the Treatment of Newly-Diagnosed Acute Myeloid Leukemia	Protein binding inhibitor (CXCL12, P-selectin, HMGB1, PF4, HLE)	Newly-diagnosed patients aged ≥18 years with previously untreated AML with at least 20% blasts in the peripheral blood or bone marrow. Must have adverse genetic risk (according to ELN criteria) or Intermediate genetic risk (≥60 years only).	Open to accrual
Jeyakumar	Kelsey McAbee	UCI 20-167: A Phase III, Randomized, Open-Label Study Evaluating the Safety and Efficacy of Magrolimab in Combination With Azacitidine versus Venetoclax Plus Azacitidine in Previously Untreated Patients with TP53 Mutant Acute Myeloid Leukemia who are Ineligible for Intensive Induction Chemotherapy	Anti-CD47 monoclonal antibody	Patients aged ≤ 8 years with previously untreated AML as defined by WHO criteria. Must have presence of at least 1 TP53 gene mutation that is not benign or likley benign. WBC ≤ 20k. Patients can be treated w/hydroxyurea throughout study and prior to randomization. Hgb must be ≤ 9.5g/dL prior to first dose of study drug for patients w/prior cardiac history. Prior treatment w/CD47, signal regulatory protein alpha targeting agents, or antileukemic therapy for AML, HMA, low dose cytarabine and/or venetoclax are excluded.	Open to accrual
Jeyakumar	Blake Johnson	UCI 20-100: A Phase II Trial of Fludarabine in Combination with Daunorubicin and Cytarabine Liposome for Adults with Newly-Diagnosed Acute Myeloid Leukemia	Combination of purine antimetabolite with lipsomal formulation of cytoxic chemotherapy Daunorubicin and Cytarabine	Newly diagnosed de novo or secondary AML as defined by WHO criteria. Aged ≥18 years. Patients w/history of second malignancies must be in complete remission and without history of metastasis confirmed via clinical evidence of disease stability for >6 months off cytotoxic chemotherapy at screening. Organ function requirements: -creatinine clearance > 60ml/min -serum bilirubin ≤ 2mg/dL -ALT/AST ≤ 3 times upper limit of normal -LVEF ≥ 50% by echo or MUGA	Pending activation

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Malignant Hematology

Relapsed/Refractory Acute Myeloid Leukemia					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Jeyakumar	Stephanie Osorio	UCI 20-51: A Phase 1, Multicenter, Open-Label, Dose-Escalation and Expansion, Safety, Pharmacokinetic, Pharmacodynamic, and Clinical Activity Study of Intravenously Administered IO-202 in Relapsed/Refractory Acute Myeloid Leukemia (AML) Patients with Monocytic Differentiation and in Relapsed/Refractory Chronic Myelomonocytic Leukemia (CMML) Patients	LILRB4 antibody	AML with myelomonocytic or monoblastic/monocytic differentiation according to the World Health Organization 2016 criteria	Open to accrual
Jeyakumar	Stephanie Osorio	UCI 16-13: A Phase I Dose Escalation with Two Disease Specific Expansions, Multicenter, Open-label, Safety, Pharmacokinetic and Pharmacodynamic Study of APTO-253 in Patients with Relapsed or Refractory Hematologic Malignancies	MYC inhibitor	Acute myelogenous leukemia: Patients with any subtype of refractory or relapsed AML are eligible as are patients with AML who have relapsed after a stem cell transplant unless they have active graft versus host disease (GVHD) requiring systemic immunosuppresant	Suspended
O'Brien	Veronica De Santiago	UCI 17-19: A Phase 1/1b/2a, 3-Part, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Ascending Doses of AZD5991 Monotherapy and in Combination with Venetoclax in Subjects with Relapse	MCL-1 inhibitor, MCL-1 inhibitor + BCL-2 inhibitor	Must have received at least 2 prior lines of therapy Recurrence of disease after response to prior line(s) of therapy Or progressive disease after completion of the treatment regimen preceding entry into the study There are no treatment options available known to provide clinical benefit	Suspended
Jeyakumar	Veronica De Santiago	UCI 18-38: A Phase 1b Trial with Dose Expansion CPX-351 (Vyxeos) Plus Gemtuzumab Ozogamicin (Mylotarg) for Relapsed Acute Myelogenous Leukemia	Combination of anti-CD33 monoclonal antibody with lipsomal formulation of cytoxic chemotherapy Daunorubicin and Cytarabine	Bone marrow blasts >=5% that develops after remission, no restriction on prior number of relapses or regimens, including relapse after HSCT At least a 3 month duration of remission prior to relapse Continued use of FLT3, IDH1, IDH2 targeted therapies are excluded	Open to accrual
Jeyakumar	Stephanie Osorio	UCI 19-93: Phase III Randomized Trial of DFP-10917 vs. Non-Intensive Reinduction (LoDAC, Azacitidine, Decitabine) or Intensive Reinduction (High and Intermediate Dose Cytarabine Regimens) for Acute Myelogenous Leukemia Patients in Second or Third Salvage	Nucleoside Analog	R/R AML to at least 2-3 regimens Two week wash out for previous cytotoxic agents Previous HSCT allowed	Open to accrual
Jeyakumar	Veronica De Santiago	ETCTN-10264: The PRIME Trial: PARP Inhibition in IDH Mutant Effectiveness Trial. A Phase II Study of Olaparib in Isocitrate Dehydrogenase (IDH) Mutant Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome	PARP Inhibitor	IDH1/2 mutation with R/R AML	Open to accrual
Jeyakumar	Stephanie Osorio	UCI 19-79: A Phase Ib Trial of Hu5F9-G4 Monotherapy or Hu5F9-G4 in Combination with Azacitidine in Patients with Hematological Malignancies	Anti-CD47 monoclonal antibody	R/R AML or confirmed intermediate, high, or very high risk MDS that is relapsed, refractory or intolerant to conventional therapy WBC count <20k	Open to accrual
Jeyakumar	Emiri Matsuda	UCI 21-118: A First in Human Study of the Menin-KMT2A (MLL1) Inhibitor JNJ-75276617 in Participants with Acute Leukemia	Menin-KMT2A inhibitor	Relapsed or refractory acute leukemia and has exhausted, or is ineligible for, available therapeutic options. Acute leukemia harboring KMT2A or NPM1 alternations. Patients with acute promyelocytic leukemia according to WHO 2016 criteria are excluded.	Pending activation
Jeyakumar	Stephanie Osorio	UCI 20-177: An Open-Label, Multicenter, Phase Ib/II Study of the Safety and Efficacy of TL-895 Combined with KRT-232 in Subjects with Relapsed/Refractory (R/R) FLT3+ Acute Myeloid Leukemia (AML)	BTK + MDM2 ihibitor	Must have primary TP53wt AML or TP53wt AML secondary to MDS. -At least one prior therapy with a FLT3 inhibitor (unless contraindicated or not available in country where treated) -Must have presence of FLT3 activating mutation TKD or FLT3-ITD in bone marrow or peripheral blood	Open to accrual

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Newly Diagnosed Acute Lymphoblastic Leukemia					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Jeyakumar	Kristen Mueller	A041501: A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin to Frontline Therapy in Young Adults with Newly Diagnosed Precursor B-Cell ALL	Conjugated Anti-CD22 Monoclonal Antibody	Subjects with untreated FLT3 mutated Non M3 AML (FLT3-TKD or FLT3-ITD allowed). Patients may not have hypomethylating agent within 21 days.	Open to accrual
Brem	Kristen Mueller	EA9181: A Phase III Randomized Trial of Steroids + Tyrosine Kinase Inhibitor Induction with Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-Positive Acute Lymphoblastic Leukemia in Adults	Bispecific T-cell engager (BiTE) which binds to CD19 expressed on B-cells and CD3 expressed on T-cells and PD-1 inhibitor	Newly diagnosed patients 18-75 years old with B-ALL or suspected to have ALL. Must have BCR-ABL1 positive disease. Must not have received prior chemotherapy for B-ALL. Must not have unstable epilepsy that requires treatment.	Open to accrual
Jeyakumar	Elizabeth Chin	UCI 21-98: Phase III Randomized, Controlled Study of Blinatumomab Alternating with Low-Intensity Chemotherapy Versus Standard of Care for Older Adults with Newly Diagnosed Philadelphia-Negative B-Cell Precursor Acute Lymphoblastic Leukemia with Safety Run-In	Bispecific T-cell engager (BiTE) which binds to CD19 expressed on B-cells and CD3 expressed on T-cells and PD-1 inhibitor	Age ≥ 55 years or if age 40<55 years, must have at least one of the following comobidities at time of consent: history of grade 3 or 4 pacreatitis, diabetes mellitus with end-organ damage, severe liver diease, BMI≥40 with relevant comobidities. Must have newly diagnosed Ph- B-cell precursor ALL.	Pending activation
Relapsed/Refractory Acute Lymphoblastic Leukemia					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Jeyakumar	Elizabeth Chin	UCI 20-34: A Phase IV, Multi-Center Open-Label Feasibility Study to Evaluate Outpatient Blinatumomab Administration in Adult Subjects with Minimal Residual Disease (MRD) of B-Precursor Acute Lymphoblastic Leukemia (ALL) in Complete Hematologic Remission	bispecific T-cell engager (BiTE) which binds to CD19 expressed on B-cells and CD3 expressed on T-cells and PD-1 inhibitor	MRD positive disease in a complete remission.	Open to accrual
Jeyakumar	Kristen Mueller	UCI 14-95: A Phase I/II Study of the Blinatumomab in Combination with the PD-1 Inhibitor Pembrolizumab (MK-3475) for the Treatment of Adults with Relapsed or Refractory B-Lineage Acute Lymphoblastic Leukemia	bispecific T-cell engager (BiTE) which binds to CD19 expressed on B-cells and CD3 expressed on T-cells and PD-1 inhibitor	R/R CD19-positive B-lineage acute lymphoblastic leukemia having received at least 1 prior line of therapy Philadelphia chromosome/BCR-ABL1-positive B-lineage ALL must have failed at least 1 2nd or 3rd generation TKI or be intolerant to TKIs Greater than 50% lymphoblasts on screening bone marrow aspirate or biopsy	Suspended
O'Brien	Veronica De Santiago	UCI 17-19: A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Ascending Doses of AZD5991 in Subjects with Relapsed or Refractory Haematologic Malignancies	MCL-1 inhibitor	Must have received at least 2 prior lines of therapy Recurrence of disease after response to prior line(s) of therapy Or progressive disease after completion of the treatment regimen preceding entry into the study Presence of superficial lymphadenopathy for the lymph node biopsy (applies only to CLL, lymphoma and ALL) There are no treatment options available known to provide clinical benefit	Suspended
Jeyakumar	Emiri Matsuda	UCI 21-118: A First in Human Study of the Menin-KMT2A (MLL1) Inhibitor JNJ-75276617 in Participants with Acute Leukemia	Menin-KMT2A inhibitor	Relapsed or refractory acute leukemia and has exhausted, or is ineligible for, available therapeutic options. Acute leukemia harboring KMT2A or NPM1 alternations. Patients with acute promyelocytic leukemia according to WHO 2016 criteria are excluded.	Pending activation

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Newly Diagnosed Chronic Lymphocytic Leukemia					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Brem	Kristen Mueller	UCI 18-128 A Phase I/IB Study of Pitavastatin in Combination with Venetoclax for Chronic Lymphocytic Leukemia (CLL) and Acute Myeloid Leukemia (AML)	HMA+BCL2 inhibitor+Statin(HMG-CoA reductase inhibitor)	Newly diagnosed CLL eligible for venetoclax therapy (combination with obinutuzumab) as per FDA indication. Must reach stable dose of venetoclax prior to starting Pitavastatin.	Open to accrual
O'Brien	Kristen Mueller	A041702: A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (>/= 70 years of age) With Chronic Lymphocytic Leukeumia (CLL)	BTK + BCL2 + CD20 antibody	Must have newly diagnosed CLL to be eligible. Age ≥ 70 years.	Open to accrual
Brem	Kristen Mueller	SWOG-S1925: Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therpay with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study	BCL2 inhibitor + anti-CD20 monoclonal antibody	Newly diagnosed CLL or SLL within 12 months of registration. Age ≥ 18 years. Participants must have CLL-International Prognostic Index (CLL-IPI) Score ≥ 4 and/or complex cytogenetics (defined as 3+ chromosomal abnormalities). Prior therapy with anti CD20 monoclonal antibodies is not allowed.	Open to accrual
Relapsed/Refractory Chronic Lymphocytic Leukemia					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Brem	Kristen Mueller	UCI 18-128 A Phase I/IB Study of Pitavastatin in Combination with Venetoclax for Chronic Lymphocytic Leukemia (CLL) and Acute Myeloid Leukemia (AML)	HMA+BCL2 inhibitor+Statin(HMG-CoA reductase inhibitor)	Relapsed/refractory CLL eligible for venetoclax therapy (with or without Rituxan) as per FDA indication. Must reach stable dose of venetoclax prior to starting Pitavastatin.	Open to accrual
Jeyakumar	Emiri Matsuda	UCI 21-118: A First in Human Study of the Menin-KMT2A (MLL1) Inhibitor JNJ-75276617 in Participants with Acute Leukemia	Menin-KMT2A inhibitor	Relapsed or refractory acute leukemia and has exhausted, or is ineligible for, available therapeutic options. Acute leukemia harboring KMT2A or NPM1 alternations. Patients with acute promyelocytic leukemia according to WHO 2016 criteria are excluded.	Pending activation

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Multiple Myeloma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
O'Brien	Veronica De Santiago	UCI 17-19: A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Ascending Doses of AZD5991 in Subjects with Relapsed or Refractory Haematologic Malignancies	MCL-1 inhibitor	Must have received at least 2 prior lines of therapy Recurrence of disease after response to prior line(s) of therapy Or progressive disease after completion of the treatment regimen preceding entry into the study There are no treatment options available known to provide clinical benefit	Suspended
Ciurea	Emiri Matsuda	UCI 21-02: Phase II Study of Descartes-08 Consolidation Treatment in Patients with High-Risk Multiple Myeloma who Have Residual Disease After Induction Therapy	Autologous CD8+ T-cell product modified to express an anti-BCMA CAR	Patients with high-risk multiple myeloma (defined as: 1) plasma cell leukemia; 2) R-ISS Stage III10; or 3) high-risk CA as defined by IMWG consensus) who have completed pre-transplant induction treatment anti-myeloma drug combination (minimum 2 drugs). Following pre-transplant induction regimen, patients must have redisual disease.	Open to accrual
Lee	Emiri Matsuda	SWOG S1803: Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)	Anti-CD38 monoclonal antibody	Patients with high-risk multiple myeloma (defined as: 1) plasma cell leukemia; 2) R-ISS Stage III10; or 3) high-risk CA as defined by IMWG consensus) who have completed pre-transplant induction treatment anti-myeloma drug combination (minimum 2 drugs). Following pre-transplant induction regimen, patients must have residual disease.	Open to accrual
Lee	Veronica De Santiago	UCI 21-116: An Open-Label, Multicenter, Non-Randomized Phase II Study of PF-06863135 Monotherapy in Participants with Multiple Myeloma Who are Refractory to at Least One Proteasome Inhibitor, One Immunodulatory Drug and One Anti-CD38 Antibody	BCMA X CD3 BITE	Patients with prior diagnosis of MM and measureable disease based on IMWG criteria as defined by at least 1 of the following: a) serum M-protein≥0.5g/dL by SPEP; b) urinary M-protein excretion≥200mg/24 hours by UPEP; c) serum immunoglobulin FLC ≥10 mg/dL (≥100 mg/L) AND abnormal serum immunoglobulin kappa to lambda FLC ratio (<0.26 or >1.65). Refractory to at least one IMiD, at least one PI, at least one anti-CD38 antibody. Patients may have received prior BCMA-directed ADC or BCMA-directed CAR T-cell therapy.	Open to accrual
Follicular Lymphoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
O'Brien	Emiri Matsuda	UCI 20-126: A Phase 1, Multicenter, Open-Label Study of CB-010, a CRISPR-Edited Allogeneic Anti-CD19 CAR-T Cell Therapy in Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (ANTLER)	anti-CD19 chimeric antigen receptor	Have histologically confirmed aggressive lymphoma including DLBCL, HGBL, PMBCL, tFL, FL, MZL, MCL. No response to second or more lines of therapy.	Open to accrual
Brem	Veronica De Santiago	UCI 17-47: A Phase Ib/II Open-Label, Dose Escalation and Expansion Study of Orally Administered VRx-3996 and Valganciclovir in Subjects with Epstein-Barr Virus-Associated Lymphoid Malignancies	a selective HDAC Class I inhibitor	HIV Excluded, R/R pathologically confirmed EBV+ lymphoid malignancy or lymphoproliferative disease (LPD) regardless of histologic subtype including: 1. EBV+ post-transplant LPD 2. EBV-associated LPD associated with acquired immunodeficiency Absence of available therapy with reasonable likelihood of cure or significant clinical benefit	Open to accrual
Brem	Veronica De Santiago	UCI 20-148: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial to Evaluate the Efficacy and Safety of Tafasitamab plus Lenalidomide in Addition to Rituximab versus Lenalidomide in Addition to Rituximab in Patients with Relapsed/Refractory Follicular Lymphoma Grade 1-3A or R/R Marginal Zone Lymphoma	Fc-enhanced, humanized mAb against the pan B-cell antigen CD19	Patients ≥18 years of age with histologically confirmed Grade 1, 2, or 3a FL or histologically confirmed nodal MZL, splenic MZL, or extranodal MZL of the MALT (CD19+ and CD20+ by flow cytometry or immunohistochemistry) as assessed locally. Patients must have been previously treated with at least 1 prior systemic anti-CD20 immunotherapy or chemo-immunotherapy, followed by documented relapsed, refractory, or PD after treatment.	Open to accrual

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Marginal Zone Lymphoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
O'Brien	Emiri Matsuda	UCI 20-126: A Phase 1, Multicenter, Open-Label Study of CB-010, a CRISPR-Edited Allogeneic Anti-CD19 CAR-T Cell Therapy in Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (ANTLER)	anti-CD19 chimeric antigen receptor	Have histologically confirmed aggressive lymphoma including DLBCL, HGBL, PMBCL, tFL, FL, MZL, MCL. No response to second or more lines of therapy.	Open to accrual
Brem	Veronica De Santiago	UCI 17-47: A Phase Ib/II Open-Label, Dose Escalation and Expansion Study of Orally Administered VRx-3996 and Valganciclovir in Subjects with Epstein-Barr Virus-Associated Lymphoid Malignancies	a selective HDAC Class I inhibitor	HIV Excluded, R/R pathologically confirmed EBV+ lymphoid malignancy or lymphoproliferative disease (LPD) regardless of histologic subtype including: 1. EBV+ post-transplant LPD 2. EBV-associated LPD associated with acquired immunodeficiency Absence of available therapy with reasonable likelihood of cure or significant clinical benefit	Open to accrual
Brem	Veronica De Santiago	UCI 20-148: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial to Evaluate the Efficacy and Safety of Tafasitamab plus Lenalidomide in Addition to Rituximab versus Lenalidomide in Addition to Rituximab in Patients with Relapsed/Refractory Follicular Lymphoma Grade 1-3A or R/R Marginal Zone Lymphoma	Fc-enhanced, humanized mAb against the pan B-cell antigen CD19	Patients ≥18 years of age with histologically confirmed Grade 1, 2, or 3a FL or histologically confirmed nodal MZL, splenic MZL, or extranodal MZL of the MALT (CD19+ and CD20+ by flow cytometry or immunohistochemistry) as assessed locally. Patients must have been previously treated with at least 1 prior systemic anti-CD20 immunotherapy or chemo-immunotherapy, followed by documented relapsed, refractory, or PD after treatment.	Open to accrual
Mantle Cell Lymphoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Pinter-Brown	Kristen Mueller	UCI 19-58: Phase III Open-label Study on Zanubrutinib plus Rituximab versus Bendamustine plus Rituximab in Patients with Previously Untreated Mantle Cell Lymphoma Who Are Ineligible for Stem Cell Transplantation	BTK Inhibitor with CD20 monoclonal antibody	No prior systemic therapy. WHO 2016 diagnosis of MCL. >70 years of age, >65 with comobodities. Measurable disease = 1 nodal lesion > 1.5cm, 1 extranodal lesion > 1cm	Open to accrual
O'Brien	Emiri Matsuda	UCI 20-126: A Phase 1, Multicenter, Open-Label Study of CB-010, a CRISPR-Edited Allogeneic Anti-CD19 CAR-T Cell Therapy in Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (ANTLER)	anti-CD19 chimeric antigen receptor	Have histologically confirmed aggressive lymphoma including DLBCL, HGBL, PMBCL, tFL, FL, MZL, MCL. No response to second or more lines of therapy.	Open to accrual
Brem	Blake Johnson	ECOG-EA4151: A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma In Minimal Residual Disease-Negative Fir	anti-CD20 with HSCT	Must have tissue from original diagnositc biopsy available for submission.	Open to accrual
Brem	Veronica De Santiago	UCI 17-47: A Phase Ib/II Open-Label, Dose Escalation and Expansion Study of Orally Administered VRx-3996 and Valganciclovir in Subjects with Epstein-Barr Virus-Associated Lymphoid Malignancies	a selective HDAC Class I inhibitor	HIV Excluded, R/R pathologically confirmed EBV+ lymphoid malignancy or lymphoproliferative disease (LPD) regardless of histologic subtype including: 1. EBV+ post-transplant LPD 2. EBV-associated LPD associated with acquired immunodeficiency Absence of available therapy with reasonable likelihood of cure or significant clinical benefit	Open to accrual
Brem	Veronica De Santiago	UCI 20-149: A Phase I/II Open-Label Study to Evaluate the Safety and Efficacy of Loncastuximab Tesirine and Ibrutinib in Patients with Advanced Diffuse Large B-Cell Lymphoma or Mantle Cell Lymphoma	Anti-CD19 anitbody	Patients ≥18 years of age with relapsed or refractory DLBCL or MCL who have received at least one proir line of therapy. Patients who have received previous CD19-directed therapy must have a biopsy which shows CD19 expression after completion of the CD19-directed therapy. Patients with previous therapy w/ibrutinib, other BTK inhibitors, and loncastuximab tesirine are exclused.	Suspended
Brem	Veronica De Santiago	EA4181: A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR A) in Patients </= 70 years old with Untreated Mantle Cell Lymphoma	Alkylating agent + CD20 monoclonal antibody with BTK inhibitor	Patients 18-70 years of age with previously untreated MCL, with cyclin D1 (BCL1) expression and/or t(11;14). Patients being treated with gastric reducing agent proton pump inhibitors must be switched to alternative drug. HIV-infected patients with undetectable viral load within 6 months of start date are eligible. Patients with HBV or HCV must have undetectable viral load. Not eligible if patient requires a strong cytochrome P450 (CYP) 3A inhibitor.	Open to accrual

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Malignant Hematology

Diffuse Large B-Cell Lymphoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
O'Brien	Elizabeth Chin	UCI 15-18: An Open-Label, Multi-Center Phase 1 Study to Investigate the Safety and Tolerability of REGN1979, an Anti-CD20 x Anti-CD3 Bispecific Monoclonal Antibody, in Patients with CD20+ B-Cell Malignancies Previously Treated with CD20-Directed Antibody	anti-CD20 x anti-CD3 bispecific antibody	Have documented CD20+ B-cell malignancy, with active disease not responsive to prior therapy, for whom no standard of care options exists, and for whom treatment with an anti-CD20 antibody may be appropriate Patients with NHL must have had prior treatment with an anti-CD20 antibody therapy Measurable disease. Must have failed CAR-T therapy.	Open to accrual
Brem	Veronica De Santiago	UCI 17-47: A Phase Ib/II Open-Label, Dose Escalation and Expansion Study of Orally Administered VRx-3996 and Valganciclovir in Subjects with Epstein-Barr Virus-Associated Lymphoid Malignancies	a selective HDAC Class I inhibitor	HIV Excluded, R/R pathologically confirmed EBV+ lymphoid malignancy or lymphoproliferative disease (LPD) regardless of histologic subtype including: 1. EBV+ post-transplant LPD 2. EBV-associated LPD associated with acquired immunodeficiency including HIV-positive meeting certain criteria Absence of available therapy with reasonable likelihood of cure or significant clinical benefit	Open to accrual
Brem	Veronica De Santiago	UCI 20-31: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Comparing the Efficacy and Safety of Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) Alone Versus in Combination with Acalabrutinib in Subjects 65 Years or under with Previously Untreated Non-Germinal Center Diffuse Large B-Cell Lymphoma	anti-CD20 + 2nd generation BTK inhibitor	Newly diagnosed non-germinal center diffuse large B-cell lymphoma. >65 years of age.	Open to accrual
Brem	Veronica De Santiago	UCI 20-149: A Phase I/II Open-Label Study to Evaluate the Safety and Efficacy of Loncastuximab Tesirine and Ibrutinib in Patients with Advanced Diffuse Large B-Cell Lymphoma or Mantle Cell Lymphoma	Anti-CD19 anitbody	Patients ≥18 years of age with relapsed or refractory DLBCL or MCL who have received at least one proir line of therapy. Patients who have received previous CD19-directed therapy must have a biopsy which shows CD19 expression after completion of the CD19-directed therapy. Patients with previous therapy w/ibrutinib, other BTK inhibitors, and loncastuximab tesirine are exclused.	Suspended
O'Brien	Kristen Mueller	UCI 20-198: A Phase I, Dose Escalation, Safety and Tolerability Study of NX-2127, a Bruton's Tyrosine Kinase Degrader, in Adults with Relapsed/Refractory B-cell Malignancies	BTK degrader + iMiD	Patients ≥18 years of age who have received at least 2 prior lines of therapy. Patients in Phase 1a(dose escalation) must have histologically confirmed R/R CLL, SLL, WM, MCL, and MZL, FL (grade 1 – 3b), and DLBCL with MYC and BCL2 and/or BCL6 rearrangements and high-grade B-cell lymphoma NOS. Patients in Phase1b(dose expansion) must have histologically documented R/R B-cell malignancy.	Open to accrual
Brem	Kristen Mueller	SWOG-S1918: A Phase II/III Randomized Study of R-miniCHOP with or without Oral Azacitidine (CC-486) in Participants Age 75 Years or Older with Newly Diagnosed Diffuse Large B-Cell Lymphoma, Grade IIB, Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-Cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements	Oral hypomethylating agent	Patients age ≥ 75 with newly diagnosed DLBCL (Ann Arbor Stage IIX (bulky), III or IV). Patients with HIV, HBV, HCV are eligible given undetectable viral load within 28 days prior to registration.	Open to accrual
Brem	Veronica De Santiago	A051301 : PhIII Ibrutinib During & Following Auto SCT vs Placebo in Pts w/ R/R DLBCL of Activated B-Cell Sub	BTK inhibitor	Diagnosis of WHO diffuse large B-cell lymphoma, non-GCB by central review confirmation. No more than 3 prior regimens for large cell component. Monoclonal antibody alone or involved field/involved site radiotherapy do not count as lines of therapy. Must be eligible to proceed with high-dose chemotherapy and autologous stem cell transplantation. Prior use of ibrutinib is allowed unless patient has had disease progression while receiving ibrutinib.	Open to accrual

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Diffuse Large B-Cell Lymphoma cont.					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Brem	Veronica De Santiago	UCI 21-60: A Randomized, Open-Label, Phase III Trial of Epcoritamab vs Investigator's Choice Chemotherapy in Relapsed/Refractory Diffuse Large B-Cell Lymphoma	IgG1-bispecific antibody targeting CD3+ T-cells and CD20+ B-cells	Patients must have one of the confirmed histologies below with CD20-positivity: 1. DLBCL, NOS (per WHO 2016 classification), including de novo or histologically transformed from FL 2. "double-hit" or "triple-hit" DLBCL, including de novo or histologically transformed from FL 3. FL Grade 3B Relapsed/refractory previously treated with at least 1 line of systemic antineoplastic therapy. Failed previous HDT-ASCT or ineligible for HDT-ASCT at screening. Primary CNS tumor or CNS involvement is excluded. Any prior therapy with a bispecific antibody targeting CD3 and CD20 is excluded.	Pending activation
Hodgkin's Lymphoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Brem	Veronica De Santiago	UCI 17-47: A Phase Ib/II Open-Label, Dose Escalation and Expansion Study of Orally Administered VRx-3996 and Valganciclovir in Subjects with Epstein-Barr Virus-Associated Lymphoid Malignancies	A selective HDAC Class I inhibitor	HIV Excluded, R/R pathologically confirmed EBV+ lymphoid malignancy or lymphoproliferative disease (LPD) regardless of histologic subtype including: 1. EBV+ post-transplant LPD 2. EBV-associated LPD associated with acquired immunodeficiency including HIV-positive meeting certain criteria Absence of available therapy with reasonable likelihood of cure or significant clinical benefit	Open to accrual
Brem	Veronica De Santiago	S1826: A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >/= 12 years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma	PD1-inhibitor vs. ADC CD30 antibody	Newly diagnosed Advanced Stage Classical Hodgkins Lymphoma Stage III/IV	Open to Accrual
Waldenstrom's Macroglobulinemia and other NHL subtypes					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Brem	Veronica De Santiago	UCI 17-47: A Phase Ib/II Open-Label, Dose Escalation and Expansion Study of Orally Administered VRx-3996 and Valganciclovir in Subjects with Epstein-Barr Virus-Associated Lymphoid Malignancies	A selective HDAC Class I inhibitor	HIV Excluded, R/R pathologically confirmed EBV+ lymphoid malignancy or lymphoproliferative disease (LPD) regardless of histologic subtype including: 1. EBV+ post-transplant LPD 2. EBV-associated LPD associated with acquired immunodeficiency Absence of available therapy with reasonable likelihood of cure or significant clinical benefit	Open to accrual
Brem	Veronica De Santiago	UCI 21-04: An Open-Label, Phase II Trial of Nanatinostat in Combination with Valganciclovir in Subjects with Epstein-Barr Virus-Positive (EBV+) Relapsed/Refractory Lymphomas ("NAVAL-1")	A selective HDAC Class I inhibitor	Histologically confirmed by 2016 WHO classification EBV+ lymphoma per local lab by EBER-ISH. Patients with no available standard therapies. For ENKTL: Relapsed/refractory disease following 1 or more prior systemic therapies, and must have failed an asparaginase containing regimen. For non-ENKTL patients: Relapsed/refractory disease following 2 or more prior therapies. Patients with HIV are eligible. Presence or history of CNS involvement by lymphoma are excluded.	Open to accrual
Pinter-Brown	Kristen Mueller	UCI 20-196: Phl/II AB-101 Monotherapy & AB-101 + Rituximab in Pts w/ Relapse/Refrac NHL of B-Cell Origin	ADCC, anti-CD20 monoclonal antibody	Must have progressed or demonstrated intolerance to at least 2 lines of FDA-approved therapies, one of which included anti-CD20 monoclonal antibody therapy. Must have confirmed diagnosis of relapsed or refractory indolent or aggressive NHL of B-cell origin. Cannot have history of another life-threatening malignancy within the prior 2 years. Cannot have active HIV, hepatitis B or hepatitis C infection.	Pending activation
Cutaneous T-Cell Lymphoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**

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Malignant Hematology

Pinter-Brown	Kristen Mueller	UCI 21-51: Open-Label, Phase II Study to Assess the Safety of Mogamulizumab Given Every 4 Weeks Following Induction in Participants with Relapsed/Refractory Cutaneous T-Cell Lymphoma (CTCL)	Anti-CCR4 monoclonal antibody	Histologically confirmed diagnosis of MF or SS. Patients must have failed at least 1 prior course of systemic therapy. Participants previously treated with anti-CD4 antibody or alemtuzumab are eligible, provided their CD4+ cell counts are ≥ 200/mm3. Patients with current evidence of LCT, CNS metastasis, HIV, or herpes are excluded.	Pending activation
Pinter-Brown	Blake Johnson	UCI 21-99: An Open-Label, Multi-Center, Non-Randomized Phase I Dose-Escalation Study to Investigate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of ONO-4685 Given as Monotherapy in Patients with Relapsed or Refractory T-Cell Lymphoma	CD3-bispecific antibody targeting PD-1	Histologically or cytologically confirmed diagnosis of one of the following subtypes of T-cell lymphoma: AITL, PTCL-NOS, nodal PTCL with TFH, FTCL, MF, or SS. Must have received at least 2 prior systemic therapies. Patients eligible for CD30-directed therapy (e.g., brentuximab vedotin [BV]) will have BV as one of their systemic therapies. Patients with CNS involvement or ATLL are excluded.	Pending activation
Peripheral T-Cell Lymphoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Pinter-Brown	Blake Johnson	UCI 21-99: An Open-Label, Multi-Center, Non-Randomized Phase I Dose-Escalation Study to Investigate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of ONO-4685 Given as Monotherapy in Patients with Relapsed or Refractory T-Cell Lymphoma	CD3-bispecific antibody targeting PD-1	Histologically or cytologically confirmed diagnosis of one of the following subtypes of T-cell lymphoma: AITL, PTCL-NOS, nodal PTCL with TFH, FTCL, MF, or SS. Must have received at least 2 prior systemic therapies. Patients eligible for CD30-directed therapy (e.g., brentuximab vedotin [BV]) will have BV as one of their systemic therapies. Patients with CNS involvement or ATLL are excluded.	Pending activation
Supportive Care					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**

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Malignant Hematology

Correlative					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Fleischman		UCI 14-03: Role of Inflammation in the Pathogenesis of Myeloproliferative Neoplasm			Open to accrual
Fruman		UCI 15-65: Effect of candidate blood cancer therapies on normal human lymphocytes			Pending activation
Nam		NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study		• Actively undergoing cancer treatment (chemotherapy, targeted therapy, immunotherapy, and/or radiation therapy) or follow-up care treatment that requires regular visits to UCI Health - Orange or Newport • Must be currently testing for SARS-CoV-2 or has had first positive test < 14 days	Open to accrual
Fortier		UCI 19-27 Influence of Acculturation and Social Support on Health-Related Quality of Life in Acute Lymphoblastic Leukemia Survivors			Open to accrual
Lee	Veronica De Santiago	UCI 20-166: Screening to Improve Survival in AL Amyloidosis		Patients 60 years of age and older diagnosed with λ LC MGUS or λ LC SMM with dFLC greater than 23 mg/L and κ::λ free LC ratio below normal.	Open to accrual
Ciurea	Elizabeth Chin	UCI 20-186: Assessment of Chimerism and Relapse Post Bone marrow/Hematopoietic Cell Transplant (HCT) Using AlloHeme Test (ACROBAT)		Patients 18 years of age and older diagnosed with AML, ALL, or MDS who will undergo an Allo-HCT from an HLA matched related or unrelated donor or haploidentical donor. Must not have history of prior All-HCT.	Open to accrual
O'Brien	Billy Sanchez	UCI 21-16: Multicenter Evaluation of SARS-CoV-2 Vaccines in Patients with CLL/SLL		Patients aged >18 years diagnosed with CLL/SLL	Open to accrual
Other					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Pakbaz	Kristen Mueller	UCI 20-127: A Phase III Randomized Placebo controlled Double-Blind Study of Romiplostim for the Treatment of Chemotherapy-Induced Thrombocytopenia in Patients Receiving Oxaliplatin-based Chemotherapy for Treatment of Gastrointestinal, Pancreatic, or Colorectal Cancer	Thrombopoietin receptor agonist	Patients ≥18 years of age diagnosed with gastrointestinal, pancreatic, or colerectal adenocarcinoma, receiving an oxaliplatin-based chemotherapy regimen, containing 5 FU or capecitabine plus oxaliplatin. Must have at least 3 remaining planned cycles of chemo at enrollment. Must have plt count < 75 x 109/L on day 1. Must be 14 days removed from the start of the chemotherapy cycle immediately prior to study day 1.	Open to accrual
Pakbaz	Kristen Mueller	UCI 20-128: A Phase III Randomized Placebo-Controlled Double-Blind Study of Romiplostim for the Treatment of Chemotherapy-Induced Thrombocytopenia in Patients Receiving Chemotherapy for Treatment of Non-small Cell Lung Cancer (NSCLC), Ovarian Cancer, or Breast Cancer	Thrombopoietin receptor agonist	Patients ≥18 years of age diagnosed with stage NSCLC, breast cancer, or ovarian cancer. Patients must be receiving a carboplatinum based combination chemotherapy. Must have at least 3 remaining planned cycles of chemo at enrollment. Must have plt count < 75 x 109/L on day 1. Must be 21 or 28 days removed from the start of the chemotherapy cycle immediately prior to study day 1, depending on chemotherapy regimen.	Open to accrual

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