	AML	MDS	ALL	Myelofibrosis/Other
Newly Diagnosed Intensive Chemo	**NCI-10434-SUSPENDED** Randomized Phase 2 Study of CPX-351 + Pomalidomide versus CPX-351 in Newly Diagnosed AML with MDS-Related Changes ○ Investigational agent: Pomalidomide- IMiD ○ Administered inpatient after CPX induction (day 21) ○ Patient population: AML-MRC, t-AML, 18-75 years ○ ECOG PS 0-2, EF >=50% **NCI-10596-LIMITED SLOTS** Phase Ib Study of Menin Inhibitor SNDX-5613 in combination with daunorubicin and cytarabine in newly diagnosed patients with AML and NPM1 mutated/FLT3 wildtype of MLL/KMT2A rearranged disease. • Investigational agent: SNDX-5613 (menin inhibitor) • Administered orally q12hrs daily • Patient population: New AML with NPM1/FLT3 wildtype or MLL/KMT2A • 18-75 yrs with ECOG PS 0-2, (0-1 for patient 65+)	**None available**	**EA9181-** A Phase III Randomized Trial of Steroids + Tyrosine Kinase Inhibitor (TKI) Induction with Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-positive Acute Lymphoblastic Leukemia (ALL) in Adults Disease population: • >/= 18- </= 75 with newly diagnosed BCR-ABL1 positive disease • ECOG PS 0-3 • Investigator discretion of TKI- Ponatinib or Dasatinib in Arm A pos registration. Then randomization to Arm B: Hyper CVAD, Steroids, TKI or Arm C: Blinatumomab and TKI	None available
Newly Diagnosed Non-intensive chemo	**BAML 16-001-S17**- A Phase 1b Dose Escalation and Expansion Study of SNDX5613, azacitidine (Aza) and venetoclax (Ven) in newly diagnosed, untreated Acute Myeloid Leukemia (AML) Patients ≥ 60 years with NPM1 mutated/FLT3-ITD and FLT3-TKD wild type AML or Mixed Lineage Leukemia (MLL) Gene Rearrangement: Limited Slot Availability • Investigational agent: SNDX5613- Menin inhibitor • Oral agent given with Aza/Ven • Phase 1 • Patient population: Newly Dx AML, >60 years, not intensive chemo candidate, must have NPM1 or MLL rearrangement • ECOG 0-2	**AK117-205**- Randomized double blind placebo controlled Phase 2 study of AK117/Placebo in combination with Azacitidine in patients with newly diagnosed HR MDS. • Investigational agent: AK117-205 (novel humanized IgG4 mAb- binds with CD47) vs placebo given every 2 weeks. Azacitidine given days 1-7 of each 28 day cycle. • Patient population: new diagnosis HR MDS (per WHO classification < 20% marrow blasts; IPSS-R >/= 3.5) • ECOG PS 0-2, 18 years +	**None available**	**NCI-10538:** A Randomized Phase II trial of Venetoclax in combination with ASTX727, an All-oral therapy for Chronic Myelomonocytic Leukemia and other MDS/MPN with excess blasts. Disease population: • New Diagnosis of MDS/MPN with >/= 5% marrow blasts • >/= 18 years; ECOG </= 2 • Adequate organ function Investigational Agent: • Venetoclax Days 1-14; ASTX727 Days 3-7 in C1- Days 1-5 in C2+ for 28 day cycles

	AML	MDS	ALL	Myelofibrosis/Other
	BAML-16-001-S12(Beat AML by LLS)- A randomized Phase 2 Trial of 28 day (Arm A) versus 14 day (Arm B) Schedule of Venetoclax + Azacitidine in newly diagnosed acute myeloid leukemia patients >/= 60 • Randomized to Arm A or Arm B- Venetoclax 28 days vs 14 days. • Patient population: Previously untreated AML (>/= 60 years) • ECOG PS 0, 1, 2 • Adequate organ function • CrCL > 40 mL/min by any equation • Must enroll via M1 master protocol first to obtain study samples: blood, aspirate, skin punch. **HCRN AML 20-472**: Phase II Study of Tagraxofusp in Newly Diagnosed Secondary AML after Previous Exposure to Hypomethylating Agents (TAGALONG Study) Disease population: • Newly diagnosed AML and CD123 positivity • Documented diagnosis of prior MDS, CMML, MDS/MPN overlap with 2+ cycles of HMA. • >/= 18 years old • Ecog PS 0-2 • Investigational agent: Tagraxofusp given inpatient during cycle 1. Cycle 1 and 2 are 21 days- Tagraxofusp given at 12 mcg/kg IV over 15 minutes for 5 consecutive days (5 days over 10 days max if toxicity resolution needed). Subject in CR after cycle 2 continue Tagraxofusp up to 12 cycles (28 days each). Subjects without CR after cycle 2 will have Azacitidine added Days 1-7 of 28 day cycles (up to 4 cycles).	**FP2CLI004- FARON:** Phase I/II Open-label study to assess safety, tolerability and preliminary efficacy of the CLEVER-1 antibody Bexmarilimab in combination with standard of care therapy in patients with Myelodysplastic Syndrome or Chronic Myelomonocytic Leukemia or Acute Myeloid Leukemia. Disease population: • >/= 18 years old with life expectancy > 12 weeks • New Diagnosis of MDS or CMML (10-19% blasts) with indication for azacytidine treatment; MDS or CMML with failure to achieve a response with HMA (must be 4 cycles); R/R AML (at least 1 prior therapy) • WBC count < 20 x 10*9/L; CrCl >/= 30 mL/min by Cockcroft gault • Adequate organ function; ECOG 0-1 only Investigational agent: • Bexmarilimab (Anti CLEVER-1) given with Azacitidine. • Azacitidine Days 1-7, Bexmarilimab Days 1, 8, 15, 22 of 28 day cycles x 3 cycles then given on Days 1 and 15 beginning with Cycle 4. • Potential for later treatment arm: Triplet with Aza/Vene/Bexmab in 1L newly diagnosed unfit AML		• Or ASTX727 monotherapy Days 1-5 of each 28 day cycle **A22-301-CLOSED:** A Single-arm multicenter study to assess the Efficacy, Safety, and Tolerability of Ropeginterferon alfa-2b-njft (P1101) in Adult Patients with Essential Thromocytopenia **A22-203- CLOSED**: Phase IIIb randomized, open label parallel group study to assess efficacy, safety, and tolerability of two dosing regimens of Ropeginterferon Alfa-2b-njft (P1101) in Adult patients with Polycythemia Vera. **FP2CLI004- FARON:** Phase I/II Open-label study to assess safety, tolerability and preliminary efficacy of the CLEVER-1 antibody Bexmarilimab in combination with standard of care therapy in patients with Myelodysplastic Syndrome or Chronic Myelomonocytic Leukemia or Acute Myeloid Leukemia. Disease population: • >/= 18 years old with life expectancy > 12 weeks • New Diagnosis of MDS or CMML (10-19% blasts) with indication for azacytidine treatment; MDS or CMML with failure to achieve a response with HMA (must be 4 cycles); R/R AML (at least 1 prior therapy) • WBC count < 20 x 10*9/L; CrCl >/= 30 mL/min by Cockcroft gault • Adequate organ function; ECOG 0-1 only Investigational agent: • Bexmarilimab (Anti CLEVER-1) given with Azacitidine. • Azacitidine Days 1-7, Bexmarilimab Days 1, 8, 15, 22 of 28 day cycles x 3 cycles then given on Days 1 and 15 beginning with Cycle 4. • Potential for later treatment arm: Triplet with Aza/Vene/Bexmab in 1L newly diagnosed unfit AML

	AML	MDS	ALL	Myelofibrosis/Other
Relapsed/ Refractory	**DSP-5336-101:** A Phase 1/2, Open-Label, Dose-Escalation, Dose-Expansion Study of DSP-5336 in Adult Acute Leukemia Patients with and without Mixed Lineage Leukemia (MLL) rearrangement or Nucleophosmin 1 (NPM1) Mutation • Disease population: *In Dose Escalation*: relapsed/refractory AML, ALL, or acute leukemia of ambiguous lineage. *In Dose Expansion*: Relapsed/Refractory AML with KMT2A (MLL) fusion or NPM1 mutation. • >/= 18 with ECOG </= 2 • Investigational agent: DSP-5336, menin inhibitor, given BID continuous dosing. • **Current Cohorts: Phase I- DSP monotherapy for HR MDS or R/R AML** • **OR: DSP with Aza/Vene OR DSP with Gilteritinib in AML only- Investigator choice** **LP-118-US-I01**: **LIMITED SLOTS** A Phase 1/1b Study Evaluating the Safety, Pharmacokinetics, and Preliminary Efficacy of LP-118 in Subjects with Relapsed or Refractory Hematological Malignancies Disease population: • >/= 18 years old • Group 1- Low tumor risk: R/R CLL/SLL, R/R MF, R/R MDS/MPN, R/R CMML-2, R/R MPN-BP, R.R MDS with excess blasts, R/R AML, R/R ALL • Also eligible: Group 2- Intermediate and high tumor risk: R/R NHL, Refractory MZL/WM, Refractory RT, R/R MM, R/R T-PLL • ECOG PS </= 2, LVEF >/= 40% • No CYP3A strong inhibitors. • Investigational agent: LP-118 PO once daily for 28 day cycles with ramp up in a Cycle 0- C1D1 is target dose for entire cycle. Ramp up is *inpatient.* Weekly visits in cycle 1 in outpatient setting. **GFH009X2101:** A Phase I, Open-label dose escalation and dose expansion study of Intraventous GFH009 Single Agent in Patients with R/R Hematologic Malignancies Disease population: • >/= 18 years old • R/R AML not candidates for SCT at screening • ECOG 0-2 with life expectancy > 12 weeks • Investigational agent: GFH009 (CDK9 inhibitor- with apoptosis and tumor inhibition activity) IV given once weekly in 28 day cycles. COHORT 3: AML patients receiving Venetoclax with hypomethylating agent and did not respond- pts continue Venetoclax while receiving GFH009.	**LP-118-US-I01**: **LIMITED SLOTS** A Phase 1/1b Study Evaluating the Safety, Pharmacokinetics, and Preliminary Efficacy of LP-118 in Subjects with Relapsed or Refractory Hematological Malignancies Disease population: • >/= 18 years old • Group 1- Low tumor risk: R/R CLL/SLL, R/R MF, R/R MDS/MPN, R/R CMML-2, R/R MPN-BP, R.R MDS with excess blasts, R/R AML, R/R ALL • Also eligible: Group 2- Intermediate and high tumor risk: R/R NHL, Refractory MZL/WM, Refractory RT, R/R MM, R/R T-PLL • ECOG PS </= 2, LVEF >/= 40% • No CYP3A strong inhibitors. • Investigational agent: LP-118 PO once daily for 28 day cycles with ramp up in a Cycle 0- C1D1 is target dose for entire cycle. Ramp up is *inpatient.* Weekly visits in cycle 1 in outpatient setting. **CD123 Positive- VERY LIMITED SLOTS** **AZD9829: D9470C00001-** A modular Phase I/II, Open label, Multicenter Study to Assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of AZD9829 as monotherapy or in combination in patients with CD123-Positive hematological malignancies Disease population: • 18+ yrs, CD123 expression based on flow, ECOG </= 2, adequate organ function, LVEF >/= 45% Investigational agent: • AZD9829-: ADC comprised of wild type human IgG1 antibody with specific binding to CD123- given via IV infusion q3 weeks	**A041703: -** A Phase II Study of Inotuzumab Ozogamicin Followed by Blinatumomab for Ph-Negative CD22-Positive B-Lineage Acute Lymphoblastic Leukemia in Newly Diagnosed Older Adults or Adults with Relapsed or Refractory Disease. • Investigational agent: Inotuzumab + Blinatumomab • Disease population: 18+ years with relapsed/refractory ALL • ECOG PS = 0-2 • Must have CD22 **LP-118-US-I01**:**LIMITED SLOTS** A Phase 1/1b Study Evaluating the Safety, Pharmacokinetics, and Preliminary Efficacy of LP-118 in Subjects with Relapsed or Refractory Hematological Malignancies Disease population: • >/= 18 years old • Group 1- Low tumor risk: R/R CLL/SLL, R/R MF, R/R MDS/MPN, R/R CMML-2, R/R MPN-BP, R.R MDS with excess blasts, R/R AML, R/R ALL • Also eligible:Group 2- Intermediate and high tumor risk: R/R NHL, Refractory MZL/WM, Refractory RT, R/R MM, R/R T-PLL • ECOG PS </= 2, LVEF >/= 40% • No CYP3A strong inhibitors. • Investigational agent: LP-118 PO once daily for 28 day cycles with ramp up in a Cycle 0- C1D1 is target dose for entire cycle. Ramp up is *inpatient.* Weekly visits in cycle 1 in outpatient setting.	**INCB-57643-103-** A Phase 1, Open-Label, Safety and Tolerability Study of INCB057643 in Participants With Myelofibrosis and Other Advanced Myeloid Neoplasms • Investigational agent: INCB-57643-103- BET Inhibitor with or without Jakafi • Phase I- Group A: Relapsed, refractory, or intolerant of last therapy and have received previous treatment with JAK inhibitor. Group B: Must have currently been treated with Ruxolitinib monotherapy at a stable dose for >/= 8 weeks prior to first dose of study treatment. • Disease population: Part 1:R/R Primary MF or secondary MF, R/R MDS, R/R MDS/MPN Part 2: R/R Primary MF or secondary MF. **CABL001/Asciminib-DOSE LEVEL CLOSED** A Phase II multicenter, open-label, single-arm dose escalation study of Asciminib monotherapy in 2nd line Chronic Phase-Chronic Myelogenous Leukemia. Disease population: • >/= 18 years old • CML-CP previously treated with 1 ATP-binding site TKI for at least 6 months • Intolerance and/or resistance to TKI therapy • Investigational Agent: Asciminib PO daily x 28 days- escalation from 40 mg daily to 200 mg bid planned. • **Current Cohorts: 2L**

	AML	MDS	ALL	Myelofibrosis/Other
	Current Cohorts: Group 3 Cohort 4: R/R AML with ASXL1 mutation. Group 3 Cohort 5: R/R AML with BCOP, EZH2, SF3B1, SRSF2, STAG2, U2AF1, ARSR2 **CD123 Positive- VERY LIMITED SLOTS** **AZD9829: D9470C00001-** A modular Phase I/II, Open label, Multicenter Study to Assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of AZD9829 as monotherapy or in combination in patients with CD123-Positive hematological malignancies Disease population: • 18+ yrs, CD123 expression based on flow, ECOG </= 2, adequate organ function, LVEF >/= 45% Investigational agent: • AZD9829-: ADC comprised of wild type human IgG1 antibody with specific binding to CD123- given via IV infusion q3 weeks **FP2CLI004- FARON:** Phase I/II Open-label study to assess safety, tolerability and preliminary efficacy of the CLEVER-1 antibody Bexmarilimab in combination with standard of care therapy in patients with Myelodysplastic Syndrome or Chronic Myelomonocytic Leukemia or Acute Myeloid Leukemia. Disease population: • >/= 18 years old with life expectancy > 12 weeks • New Diagnosis of MDS or CMML (10-19% blasts) with indication for azacytidine treatment; MDS or CMML with failure to achieve a response with HMA (must be 4 cycles); R/R AML (at least 1 prior therapy) • WBC count < 20 x 10*9/L; CrCl >/= 30 mL/min by Cockcroft gault • Adequate organ function; ECOG 0-1 only Investigational agent: • Bexmarilimab (Anti CLEVER-1) given with Azacitidine. • Azacitidine Days 1-7, Bexmarilimab Days 1, 8, 15, 22 of 28 day cycles x 3 cycles then given on Days 1 and 15 beginning with Cycle 4. • Potential for later treatment arm: Triplet with Aza/Vene/Bexmab in 1L newly diagnosed unfit AML **BEAT AML S21**- A Phase I, open label dose escalation and dose expansion, multicenter clinical trial to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of ZE46-0134 in adults with FLT3 mutated Relapsed or Refractory AML Disease population: • >/= 18 years old with relapsed/refractory FLT3 ITD or TKD AML patients.			

	AML	MDS	ALL	Myelofibrosis/Other
	• Must have failed Gilteritinib or did not meet criteria to be treated with Gilteritinib. • Life expectancy > 3 months, ECOG </= 2, and adequate organ function Investigational agent: • ZE46-0134 given orally daily for 28 day cycles • ZE46-1034 novel small molecule that selectively inhibits pan-FLT3 and targets clinically relevant FLT 3 mutations • Frequent site visit requirements in Cycle 1. Cycle 2 and beyond 4 required monthly visits.			
Pending	**HQP1351CG301**- Olverembatinib in patients with Chronic Phase CML (Polaris 2) **Jan 2025** **OSU-23199**- To determine safety and efficacy of SNDX-5613 and Gilteritinib **Jan 2025** **AC220-168**- Quizartinib monotherapy vs salvage chemo in R/R AML pts after first line treatment **Jan 2025** **MYELOMATCH**- **FEB 2025**			
Future	**iDATA**			

	AML	MDS	ALL	Myelofibrosis/Other

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