|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **AML** | **MDS** | **ALL** | **Myelofibrosis/Other** |
| **Newly Diagnosed****Intensive Chemo** | **NCI-10434-** 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%

**ARO-021**-**SUSPENDED**- Phase III Randomized Study of Crenolanib versus Midostaurin Administered Following Inducation Chemotherapy and Consolidation Therapy in Newly Diagnosed Subjects with FLT3 Mutated Acute Myeloid Leukemia * Investigational agent: Crenolanib (FLT3 inhibitor)
* Administered inpatient after 7+3 induction (day 8)
* Randomized- 7+3 + Midostaurin vs. 7+3 + Crenolanib
* Patient population: FLT3 mut AML, 18-60 years old
* ECOG PS 0-3

**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

**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).
 | **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
* 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.  |
| **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**

**SL03-OHD-104:** An Open-Label Phase 1a/1b Dose Escalation and Expansion Cohort Study of SL-172154 (SIRPα-Fc-CD40L) in Combination With Azacitidine or With Azacitidine and Venetoclax for the Treatment of Subjects With Higher Risk Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) Disease Population:* ECOG PS 0, 1, 2
* Investigational agent: SL-172154 administered with Azacitidine. SL-172154 given IV weekly days 1, 8, 15, 22 of 28 day cycles in monotherapy. SL-172154 given IV weekly in combination arms on Days 2, 9, 16, and 23 of 28 day cycles. Azacitidine in combination arms given on days 1-7 of 28 day cycles.
* **Current cohort: Part D for previously untreated HR-MDS. Randomization to Aza monotherapy vs Aza/SL (1mg) or Aza/SL (3mg).**

**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 MalignanciesDisease 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. **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** **ZN-d5-004C: LIMITED SLOT AVAILABILITY (CLOSED)** A Phase 1/2 Dose Escalation Study of the BCL-2 Inhibitor ZN-d5 and the Wee1 Inhibitor ZN-c3 in Subjects with Acute Myeloid Leukemia Disease Population:* >/= 18 years old
* ECOG PS </= 2, eGFR >/= 60 mL/min, LVEF > 40%
* Monotherapy (with ZN-c3 only) and Expansion (A) cohorts (ZN-c3 and ZN-d5): R/R AML to 1+ lines of therapy but not venetoclax or experimental BCL-2 inhibitor
* Expansion cohort (B): R/R AML to venetoclax monotherapy or in combination with HMA or LDAC.
* Investigational Agents: ZN-c3 monotherapy cohort- PO daily x 28 day cycles. Dose escalation/expansion cohorts: ZN-c3 + ZN-d5 with ZN-d5 first four days of cycle 1 in ramp up schedule. Weekly visits

**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 malignanciesDisease 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
 | **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 malignanciesDisease 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-** 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**
 |  |
| **Translational** | **T23-03**: A comparator study of a Tasso device to traditional venous blood sampling methods for complete blood count (CBC) with 5-part differential in patients with leukemia, lymphoma, and/or other blood cell disorders*Disease Population*:* >/= 18 years of age
* Requiring a CBC blood test as part of the patient’s standard of care
* Have abnormal laboratory results of either leukopenia, leukocytosis or neutropenia.
* Normal skin integrity and healthy skin appearance around the capillary collection site
 | **UPCOMING****LCCC 2324:** Assessing Changes in Acute Myeloid Leukemia Patients Treated with Hypomethylating Agents*Disease Population*:* >/= 18 years of age
* Histological confirmation of newly diagnosed AML with no prior treatment for AML with exception of standard cytoreductive therapies including hydroxyurea (Hydrea) and leukapheresis
* Subject will receive standard of care aza/ven therapy.
 |  |  |  |
| **Pending** | **NEW DIAGNOSIS MDS AND CMML/REFRACTORY MDS/CMML, RELAPSED OR REFRACTORY AML****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
 |  **NEW DIAGNOSIS MDS AND CMML/REFRACTORY MDS/CMML, RELAPSED OR REFRACTORY AML****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
 |  | **NEW DIAGNOSIS MDS AND CMML/REFRACTORY MDS/CMML, RELAPSED OR REFRACTORY AML****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
 |  |
| **Future** | **HQP1351CG301**- Olverembatinib in patients with Chronic Phase CML (Polaris 2)**OSU-23199**- To determine safety and efficacy of SNDX-5613 and Gilteritinib**AC220-168**- Phase 3 double blind randomized placebo controlled trial of Quizartinib administered in combination Induction/Consolidation in adults with newly diagnosed FLT3-ITD negative AML**iDATA** |  |  |  |  |
|  | **Study Coordinator Contact Information:**Allison McKinney- 919-445-4896; pager 216-2945Jess Mentzer: 919-445-4962Claire Kowalczyk: 919-962-7337Miya KittIsabella GalanosCory GreenwoodRoseMary Beitia |  |  |