NOW ENROLLING: Oral Decitabine and Cedazuridine (ASTX727) Phase 3 Clinical Study - AML Expansion

Phase 3 Crossover Study of Oral Decitabine and Cedazuridine (ASTX727) Versus IV Decitabine in Subjects with Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukemia (CMML), or Acute Myeloid Leukemia (AML)

Key Eligibility Criteria*:
MDS, CMML, or AML patients eligible for treatment with IV decitabine

Cycle 1: ASTX727 tablet
Cycle 2: IV Decitabine
Cycle ≥3†: ASTX727 tablet

Cycle 1: IV Decitabine
Cycle 2: ASTX727 tablet
Cycle ≥3†: ASTX727 tablet

Treatment, ASTX727 or decitabine, is given daily x5 every 28-day cycle

MDS and CMML ENROLLMENT COMPLETE

Except as stated, all compounds presented here are investigational, efficacy and safety have not been established. There is no guarantee that these agents will become commercially available. Oral decitabine and cedazuridine (ASTX727) is approved in the U.S. for the treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. See full Prescribing Information.

For more information: www.clinicaltrials.gov identifier: NCT03306264 or email: information-request@astx.com

*For a full list of eligibility requirements go to clinicaltrials.gov
†Continued dosing with ASTX727 until disease progression, unacceptable toxicity, subject discontinues treatment, or subject withdraws from study
Oral Decitabine and Cedazuridine (ASTX727) Low Dose (LD) Phase 1-2 Clinical Study

NOW ENROLLING:
ASTX727 LD Phase 1-2 Clinical Study in Lower-Risk MDS

Phase 1-2 Study of Oral Decitabine and Cedazuridine (ASTX727) Low Dose (ASTX727 LD) Extended Schedule in Subjects with Lower Risk (IPSS Low or Intermediate-1) Myelodysplastic Syndromes (MDS)

Part A
Decitabine + Cedazuridine
Daily x5 - Off x2 - Daily x5
(28-Day Cycle)

Part B
Decitabine + Cedazuridine
Daily x5 or Daily x7
(28-Day Cycle)

Assess for:
Safety
PK & PD (LINE-1, HbF)
Hematologic Response

Best Regimen from Phase 1
ASTX727 Standard Dose
Daily x3 (28-Day Cycle)

Assess for:
Hematologic Response
Safety
PD & PK

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Oral decitabine and cedazuridine (ASTX727) is approved in the U.S. for the treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. See full Prescribing Information.

For more information: www.clinicaltrials.gov identifier: NCT03502668 or email: information-request@astx.com

IPSS - International Prognostic Scoring System; Int-1 - intermediate-1; PK - pharmacokinetic; PD - pharmacodynamics; LINE-1 - long interspersed nucleotide element-1; HbF - fetal hemoglobin
NOW ENROLLING:
Tolinapant (ASTX660) Phase 1-2 Study
in Solid Tumors and Lymphomas

Phase 1-2 Study of the Safety, Pharmacokinetics, and Preliminary Activity of Tolinapant (ASTX660) in Subjects with Advanced Solid Tumors and Lymphomas

Key Eligibility Criteria*:  
- Relapsed/Refractory T-Cell Lymphoma  
- Evidence of progressive disease  
- Treatment with at least two prior systemic therapies  
- ECOG 0-2

Primary Endpoint: Response Rate

CTCL†  
PTCL†

This compound is investigational, and efficacy and safety have not been established. There is no guarantee that this agent will become commercially available.

For more information: www.clinicaltrials.gov identifier: NCT02503423 or email: information-request@astx.com

*For a full list of eligibility requirements go to clinicaltrials.gov  
†6 Cohorts in study - enrollment completed in: HNSCC, DLBCL, Cervical Carcinoma, & other tumor types  
ECOG - Eastern Cooperative Oncology Group; HNSCC - head and neck squamous cell carcinoma; DLBCL - diffuse large B-cell lymphoma; PTCL - peripheral T-cell lymphoma; CTCL - cutaneous T-cell lymphoma
Phase 1-2 Study of the Safety, Pharmacokinetics, and Activity of ASTX029 in Subjects with Advanced Solid Tumors

Now Enrolling:
ASTX029 Phase 1-2 Study in Solid Tumors

Primary Endpoint:
Preliminary Efficacy

Tumors characterized by gene aberrations in the MAPK signal pathway

Phase 1 – Dose Escalation (Part A) & Expansion (Part B)
- Regimen 1 (Continuous)
  Study drug orally QD on days 1-21 of each 21-day cycle
- Regimen 2 (Intermittent)
  Study drug orally QD on days 1-14 of each 21-day cycle

Phase 2

This compound is investigational, and efficacy and safety have not been established. There is no guarantee that this agent will become commercially available.

For more information: www.clinicaltrials.gov identifier: NCT03520075 or email: information-request@astx.com

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Phase 1-2 Study of the Safety, Pharmacokinetics, and Preliminary Activity of ASTX295 in Subjects with Wild-Type TP53 Advanced Solid Tumors

This compound is investigational, and efficacy and safety have not been established. There is no guarantee that this agent will become commercially available.

For more information: www.clinicaltrials.gov identifier: NCT03975387 or email information-request@astx.com

NOW ENROLLING:
ASTX295 Phase 1-2 Study in Solid Tumors

Primary Endpoints:
Overall Response Rate & Disease Control Rate

Phase 1 Part A - Dose Escalation
Continuous oral drug once daily (QD) dosing for 28 days of each 28 day cycle

Phase 1 Part B - Dose Expansion
MTD and/or RDE
Dose expansion at the RDE

RP2D and Regimen
Phase 2

QD - once daily; MTD - maximum tolerated dose; RDE - recommended dose for expansion; RP2D - recommended Phase 2 dose
NOW ENROLLING:
Tolinapant (ASTX660) Phase 1 Study in r/r AML

Phase 1 Study of the Safety, Tolerability, Pharmacokinetics, and Antileukemic Activity
of Tolinapant (ASTX660) as a Single Agent and in Combination with Oral Decitabine and
Cedazuridine (ASTX727) in Subjects with Relapsed/Refractory (r/r) Acute Myeloid Leukemia (AML)

Phase 1 - Part 1
Combination Dose Escalation
Tolinapant (ASTX660) +
Oral Decitabine/Cedazuridine (ASTX727)

1:1 Randomization

Arm A: Tolinapant (ASTX660) +
Oral Decitabine/Cedazuridine (ASTX727)

Arm B: Tolinapant (ASTX660) RDE +
Oral Decitabine/Cedazuridine (ASTX727)

Phase 1 - Part 2
Single Agent vs.
Combination Dose Escalation

Phase 1 - Part 3
Dose Expansion

But as stated, all compounds presented here are investigational; efficacy and safety have not been established. There is no guarantee that these agents will become commercially available.

Oral decitabine and cedazuridine (ASTX727) is approved in the U.S. for the treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. See full Prescribing Information.

For more information: www.clinicaltrials.gov identifier: NCT04155580 or email information-request@astx.com

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Oral ASTX030 (Azacitidine and Cedazuridine) Phase 1-3 Clinical Study

NOW ENROLLING:
Oral ASTX030 (Azacitidine and Cedazuridine in Combination)

Phase 1-3 Study of Oral ASTX030 (Azacitidine and Cedazuridine given in Combination) Versus Subcutaneous Azacitidine in Subjects with Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukemia (CMML), or Acute Myeloid Leukemia (AML)

Phase 1
Primary Objective: Identify ASTX030 dose that achieves target mean azacitidine AUC within 90-110% of SC azacitidine

Part A (dose escalation)
Cycle 1: single doses of oral azacitidine (day -3), SC azacitidine (day 1), oral cedazuridine (day 22); and oral cedazuridine + azacitidine (days 2-7)
Cycle ≥2: oral ASTX030 (cedazuridine + azacitidine, days 1-7)

Part B (dose expansion)
Oral cedazuridine + azacitidine at RDE as separate tablets

Phase 2 & 3
Primary Objectives:
Phase 2: Confirm final selected dose of ASTX030
Phase 3: Establish azacitidine AUC equivalence with SC azacitidine at final selected dose of ASTX030

Sequence A
Cycle 1: oral ASTX030
Cycle 2: SC azacitidine
Cycles ≥3: oral ASTX030

Sequence B
Cycle 1: SC azacitidine
Cycle 2: oral ASTX030
Cycles ≥3: oral ASTX030

This compound is investigational, and efficacy and safety have not been established.
There is no guarantee that this agent will become commercially available.

For more information: www.clinicaltrials.gov identifier: NCT04256317 or email: information-request@astx.com

AUC – area under the curve; RDE – recommended dose for expansion; RP2D – recommended Phase 2 dose; SC - subcutaneous
NOW ENROLLING:
Oral TAS1440 with ATRA in r/r AML

Phase 1 Study of Safety, Pharmacokinetics, and Preliminary Activity of TAS1440, as a Single Agent and in Combination with All-Trans Retinoic Acid (ATRA) in Subjects with Relapsed or Refractory (r/r) Acute Myeloid Leukemia (AML)

Cycle 1, Part 1
Monotherapy Dose Escalation

TAS1440 Single agent administered once daily (QD) on specific days during each 28-day cycle

Cycle 2, Part 2
Combination Dose Escalation

TAS1440 administered QD on specific days during each 28-day cycle in combination with ATRA

This compound is investigational, and efficacy and safety have not been established. There is no guarantee that this agent will become commercially available.

For more information: www.clinicaltrials.gov identifier: NCT04282668 or email information-request@astx.com

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Phase 1 Study of Safety, Pharmacokinetics, and Preliminary Activity of TAS1553 in Subjects with Relapsed or Refractory (r/r) Acute Myeloid Leukemia (AML) and Other Myeloid Neoplasms

NOW ENROLLING:
TAS1553 Phase 1 Clinical Study in r/r AML

Part 1
Dose Escalation

- Accelerated Titration
- Study drug orally QD on Days 1-7 and 15-21 of each 28-day cycle

Part 2
Dose Expansion

- Cohort 1: R/R AML
- Cohort 2: MDS/MPN
- Primary Endpoints: Safety and Tolerability, Response Rate

This compound is investigational, and efficacy and safety have not been established. There is no guarantee that this agent will become commercially available.

For more information: www.clinicaltrials.gov identifer: NCT04637009 or email information-request@astx.com

Taiho Pharmaceutical Co., Ltd. investigational agent being developed in collaboration with Astex Pharmaceuticals, Inc.
Oral Decitabine/Cedazuridine (ASTX727) + Venetoclax Phase 1 Clinical Study

COMING SOON:
Oral Decitabine/Cedazuridine (ASTX727) + Venetoclax

Single-Arm, Open-Label Pharmacokinetic, Safety, and Efficacy Study of ASTX727 in Combination with Venetoclax in Adult Patients with Acute Myeloid Leukemia

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For more information email: information-request@astx.com