Venetoclax in Children With Relapsed Acute Myeloid Leukemia (AML)

Status: RECRUITING

Eligibility Criteria

Age: 29 days to 21 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria * Participants must have enrolled on APAL2020SC, NCT Number: NCT04726241 prior to enrollment on ITCC-101/APAL2020D. (This is only applicable for participants in USA/Canada/Australia/New Zealand sites/Blood Cancer United territory). * Participants must be ≥ 29 days of age and ≤ 21 years of age at enrollment. * Participants must have one of the following: 1. Children, adolescents, and young adults with AML without demonstrated FLT3/internal tandem duplication (ITD) mutation. Ideally, the status of the mutation needs to be proven in the current relapse. Nevertheless, patients with previous FLT3/ITD negative test from prior lines can be included based on local results in order to not delay the start of treatment. 2. And participants must have AML which is either: * Untreated second relapse, in participants who are sufficiently fit to undergo another round of intensive chemotherapy, or * Untreated first relapse, in participants who cannot tolerate additional anthracycline containing chemotherapy per investigator discretion. * Participants must have a performance status corresponding to Eastern Cooperative Oncology Group (ECOG) scores of 0, 1 or 2 (≥ 50% Lansky or Karnofsky score). * Participants must have fully recovered from the acute toxic effects of all prior anti-cancer therapy and must meet the following minimum duration from prior anti-cancer directed therapy prior to start of protocol treatment: 1. Cytotoxic chemotherapy: Must not have received cytotoxic chemotherapy within 14 days prior to start of protocol treatment, except for corticosteroids, low dose cytarabine or hydroxyurea that can be given up to 24 hours prior to start of protocol treatment. 2. Intrathecal cytotoxic therapy: No wash-out time is required for participants having received any combination of intrathecal cytarabine, methotrexate, and/or hydrocortisone. 3. Antibodies: ≥ 21 days must have elapsed from infusion of last dose of an antibody-drug conjugate before start of protocol treatment. For unmodified antibodies or T cell engaging antibodies, 2 half-lives must have elapsed before start of protocol treatment. Any toxicity related to prior antibody therapy must be recovered to Grade ≤ 1. 4. Interleukins, Interferons and Cytokines (other than Hematopoietic Growth Factors): ≥ 21 days after the completion of interleukins, interferon or cytokines (other than Hematopoietic Growth Factors) before start of protocol treatment. 5. Hematopoietic growth factors: ≥ 14 days after the last dose of a long-acting growth factor (e.g., pegfilgrastim) or ≥7 days for short-acting growth factor before start of protocol treatment. 6. Radiation therapy (RT) (before start of protocol treatment): * ≥ 14 days have elapsed for local palliative RT (small port); * ≥ 84 days must have elapsed if prior craniospinal RT or if ≥ 50% radiation of pelvis; * ≥ 42 days must have elapsed if other substantial bone marrow (BM) radiation. 7. Stem Cell Infusions (before start of protocol treatment): * ≥ 84 days since allogeneic (non-autologous) bone marrow or stem cell transplant (with or without total body irradiation \[TBI\]) or boost infusion (any stem cell product; not including donor lymphocyte infusion \[DLI\]); * No evidence of active graft versus host disease (GVHD). 8. Participants who are receiving cyclosporine, tacrolimus or other agents to treat or prevent either graft-versus-host disease post bone marrow transplant or organ rejection post-transplant are not eligible for this trial. Participants must be off medications to treat or prevent either graft-versus-host disease post bone marrow transplant or organ rejection post-transplant for at least 14 days prior to enrollment. 9. Cellular Therapy: ≥ 42 days after the completion of donor lymphocyte infusion (DLI) or any type of cellular therapy (e.g., modified T cells, natural killer \[NK\] cells, dendritic cells, etc.) before start of protocol treatment. 10. Participants with prior exposure to venetoclax are eligible in this trial. * Adequate organ function: 1. Adequate Renal Function defined as: * Creatinine clearance or radioisotope glomerular filtration rate (GFR) ≥ 60ml/min/1.73 m\^2, or * Normal serum creatinine based on age/sex 2. Adequate Liver Function defined as: * Direct bilirubin \< 1.5 x upper limit of normal (ULN), and * Alkaline phosphatase ≤ 2.5 x ULN, and * Serum glutamic pyruvic transaminase (SGPT) alanine aminotransferase (ALT) ≤ 2.5 x ULN. If higher transaminases outside these ranges (up to 5x ULN) are due to a radiographically identifiable leukemia infiltrate, the participant will remain eligible. Transaminase elevation up to 5x ULN is also allowed in case of steatosis on echography. 3. Cardiac performance: Minimum cardiac function defined as: * No history of congestive heart failure in need of medical treatment * No pre-treatment diminished left ventricular function on echocardiography (shortening fraction \[SF\] \< 25% or ejection fraction \[EF\] \< 40%) * No signs of congestive heart failure at presentation of relapse. * Participant, parent or guardian must sign and date informed consent and pediatric assent (when required), prior to the initiation of screening or study specific procedures, according to local law and legislation. Exclusion Criteria * Participants who in the opinion of the investigator may not be able to comply with the study requirements of the study, are not eligible. * Participants with Down syndrome. * Participants with Acute promyelocytic leukemia (APL) or Juvenile myelomonocytic leukemia (JMML). * Participants with isolated CNS3 disease or symptomatic CNS3 disease. * Participants with malabsorption syndrome or any other condition that precludes enteral administration of venetoclax. * Participants who are currently receiving an investigational drug other than those specified for this study. * Participants with Fanconi anemia, Kostmann syndrome, Shwachman syndrome or any other known congenital bone marrow failure syndrome. * Participants with known prior allergy to any of the medications used in protocol therapy. * Participants with documented active, uncontrolled infection at the time of study entry. * Known hepatitis C virus (HCV), hepatitis B virus (HBV) (known positive hepatitis B virus (HBV) surface antigen (HBsAg) results), or human immunodeficiency virus (HIV) infection. * Concomitant Medications * Participants who have received strong and moderate CYP3A inducers such as rifampin, carbamazepine, phenytoin, and St. John's wort within 7 days of the start of study treatment. * Participants who have consumed grapefruit, grapefruit products, Seville oranges (including marmalade containing Seville oranges) or starfruit within 3 days of the start of study treatment. * Participants who have hypersensitivity to the active substance or to any of the excipients listed in summary of product characteristics (SPC). * Pregnancy or Breast-Feeding: * Participants who are pregnant or breast-feeding. * Participants of reproductive potential may not participate unless they have agreed to use a highly effective contraceptive method per Clinical Trial Facilitation Group (CTFG) guidelines for the duration of study therapy and at least 30 days after last dose of venetoclax, or 7 months after gemtuzumab ozogamicin treatment, or for 6 months after the completion of all study therapy, whichever is longer. * Male participants must use a condom during intercourse and agree not to father a child or donate sperm during therapy and for the duration of study therapy and at least 30 days after last dose of venetoclax or 4 months after last dose of gemtuzumab ozogamicin, 6 months from the last dose of cytarabine, or 90-days after last exposure to any other chemotherapy, whichever is longer. Additional criteria to receive a gemtuzumab ozogamicin infusion: Gemtuzumab ozogamicin should not be given: * to participants with history of veno-occlusive disease (VOD)/Sinusoidal obstruction syndrome (SOS) grade 3 or 4 * to participants with CD33 negative leukemic blasts (determined at local lab) Note that these participants are eligible for the study but will not be treated with gemtuzumab ozogamicin.

Conditions & Interventions

Interventions:

DRUG: Fludarabine, DRUG: Cytarabine, DRUG: Gemtuzumab Ozogamicin, DRUG: Azacitidine, DRUG: Venetoclax

Conditions:

Acute Myeloid Leukemia

Keywords:

Venetoclax, Gemtuzumab Ozogamicin, Fludarabine, Cytarabine, Relapsed refractory, Azacitidine

More Information

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Number:

System ID: NCT05183035

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