# Clinical Trials Data EGFR - Document 145

# Genetically Modified T-cell Immunotherapy in Treating Patients With Relapsed/Refractory Acute Myeloid Leukemia and Persistent/Recurrent Blastic Plasmacytoid Dendritic Cell Neoplasm

## Clinical Trial: https://clinicaltrials.gov/study/NCT02159495

"eligibilityCriteria": "Inclusion Criteria:\n\n\* ARM 1 - AML: Research patients enrolled are those patients with relapsed or refractory CD123+ AML de novo, or secondary OR participants who are at high risk for disease recurrence NOTE: CD123+ biphenotypic acute leukemia or CD123+ acute lymphoblastic leukemia (ALL) may also be considered but only after discussion with the study principal investigator (PI)\n\n \* Relapsed AML is defined as patients that had a first complete remission (CR) before developing recurrent disease (increased bone marrow blasts)\n \* Refractory AML is defined as patients that have not achieved a first CR after 2 cycles of induction chemotherapy; for patients with AML evolving from myelodysplastic syndrome, they should have completed at least one cycle of induction chemotherapy\n\* ARM 2 - BPDCN: Research participants with a diagnosis of BPDCN, according to World Health Organization (WHO) classification by hematopathology, who underwent at least 1 line of systemic therapy for BPDCN and who have persistent or recurrent disease in at least one of the following are eligible: peripheral blood, bone marrow, lymph nodes, spleen, cutaneous lesions or other sites OR participant who are at high risk for disease recurrence\n\* FOR BOTH STUDY ARMS: Research participants must have bone marrow and/or peripheral blood samples available for confirmation of diagnosis of AML or BPDCN; CD123 positivity must be confirmed by either flow cytometry or immunohistochemistry within 90 days of study entry; cytogenetics, flow cytometry, and molecular studies (such as FMS-like tyrosine kinase-3 \\[FLT-3\\] status) will be obtained as per standard practice; however, for research participants who are at a high risk of recurrence, they must have historical bone marrow and/or peripheral blood samples available for confirmation of diagnosis of AML or BPDCN; CD123 positivity must be confirmed by either flow cytometry or immunohistochemistry prior to start of lymphodepletion\n\* Karnofsky performance status score \\>= 70\n\* A life expectancy \\>= 16 weeks at time of enrollment\n\* Pediatric research participants must weigh \\> 50 kg\n\* Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control or abstinence) prior to study entry and for six months following duration of study participation; should a woman become pregnant or suspect that she is pregnant while participating on the trial, she should inform her treating physician immediately\n\* Calculated creatinine clearance (absolute value) of \\>= 50 mL/minute or creatinine \\< 2.0 mg/dl or \\< 2 times upper limit of normal for the research participant's age group\n\* Serum bilirubin =\\< 3.0 mg/dL\n\* Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) =\\< 5 times the institutional upper limits of normal\n\* Ejection fraction measured by echocardiogram (ECHO) or multi gated acquisition scan (MUGA) \\>= 50%\n\* ONLY research participants experiencing hypoxia with oxygen saturation less than 92% are required to have diffusion capacity of carbon monoxide (DLCO) or forced expiratory volume in one second (FEV1) \\> 45% predicted\n\* Research participants' last dose of prior chemotherapy or radiation must be \\>= 2 weeks before leukapheresis\n\n \\\* Note: the above criterion is not applicable if the research participant's donor is undergoing leukapheresis\n\* If a research participant has undergone prior allogeneic stem cell transplant, he/she must be off all immunosuppressants for graft versus host disease (GVHD) for at least 2 weeks before undergoing leukapheresis\n\n \\\* Note: the above criterion is not applicable if the research participant's donor is undergoing leukapheresis\n\* Negative serum or urine pregnancy test\n\* All research participants must have the ability to understand and willingness to sign a written informed consent or age appropriate assent for pediatric patients\n\n \\\* Note: For research participants who do not speak English, a short form consent may be used with a City of Hope (COH) certified interpreter/translator to proceed with screening and leukapheresis, while the request for a translated full consent is processed; however, the research participant is allowed to proceed with lymphodepletion and T cell infusion only after the translated full consent form is signed\n\* ELIGIBILITY TO PROCEED WITH PERIPHERAL BLOOD MONONUCLEAR CELL (PMBC) COLLECTION:\n\n \\\* If research participant is undergoing leukapheresis:\n \* He/she has acceptable venous access as assessed by Donor Apheresis Center or if venous access was not acceptable, a Hickman Catheter or temporary line was placed prior to scheduled leukapheresis\n \* He/she has undergone prior alloSCT, they must be at least 2 weeks from having received the last dose of immunosuppressant medications to undergo PBMC collection for T cell manufacturing\n \* His/her last dose of prior chemotherapy, immunotherapy or radiation is at least 2 weeks out from PBMC collection\n\* ELIGIBILITY TO UNDERGO LYMPHODEPLETION Note: evaluations should be performed no more than 7 days prior to lymphodepletion\n\n \* Research participant with central nervous system (CNS) leukemic involvement that is refractory to intrathecal chemotherapy and/or cranio-spinal radiation but effectively treated to completion remission (\\< 5 white blood cell\\[WBC\\]/mm\\^3 and no blast in cerebrospinal fluid \\[CSF\\]) is eligible to proceed with lymphodepletion\n \* Research participants must have a donor or stem cells source identified for allogeneic transplantation, either related (7/8 or 8/8 allele matched or haploidentical), unrelated 7/8 or 8/8 allele match) donor, or cord blood stem cell source (at lease 4/6 matched)\n \* Research participants with a response less than a CR or complete response with incomplete hematopoietic recovery (CRi) or detectable minimal residual disease (MRD) positive disease\n \* Research participant has a released cryopreserved T cell product for CAR T cell infusion on approximately day 0\n \* Research participant must be at least 2 weeks out from having received the last dose of investigational agent\n \* Karnofsky performance status (KPS) \\>= 70\n \* Documented measurable or evaluable disease\n \* Non hematological toxicity related to prior therapy must either have returned to =\\< grade 2, baseline, or deemed irreversible\n \* Research participants of reproductive potential must agree to use and utilize and adequate method of contraception throughout treatment and for at least 8 weeks after T cell infusion\n \* If a research participant has undergone prior allogeneic stem cell transplant, he/she must be off all immunosuppressants for GVHD for at least 7 days before beginning lymphodepletion\n \* Pulmonary: not requiring supplemental oxygen or mechanical ventilation, oxygen saturation 90% or higher on room air\n \* Cardiovascular: not requiring pressor support, no symptomatic cardiac arrhythmias, no acute coronary syndrome, or uncontrolled hypertension\n \* Renal Function: calculated creatinine clearance (absolute value) of \\>= 50 mL/minute or creatinine \\< 2.0 mg/dl or \\< 2 times upper limit of normal for the research participant's age group\n \* Liver Function: adequate liver function defined as total bilirubin =\\< 3.0 mg/dl\n \* ALT and AST =\\< 5 times the institutional upper limits of normal\n \* Neurological: research participant without clinically significant encephalopathy/new focal deficits\n \* Infectious diseases: no clinical evidence of uncontrolled active infectious process\n\* ELIGIBILITY CRITERIA AT TIME OF INFUSION OF GENETICALLY MODIFIED T CELLS\n\n \* Research participants has undergone lymphodepletion\n \* Pulmonary: not requiring supplemental oxygen or mechanical ventilation, oxygen saturation 90% or higher on room air\n \* Cardiovascular: not requiring pressor support, no symptomatic cardiac arrhythmias, no acute coronary syndrome, or uncontrolled hypertension\n \* Renal Function: calculated creatinine clearance (absolute value) of \\>= 50 mL/minute or creatinine \\< 2.0 mg/dl or \\< 2 times upper limit of normal for the research participant's age group\n \* Liver Function: adequate liver function defined as total bilirubin =\\< 3.0 mg/dl\n \* ALT and AST =\\< 5 times the institutional upper limits of normal\n \* Neurological: research participant without clinically significant encephalopathy/new focal deficits\n \* Infectious diseases: no clinical evidence of uncontrolled active infectious process\n \* Research participant must be off all anti-leukemic drugs, with the exception of the lymphodepleting regimens, at least 7 days prior to CAR T cell infusion\n\* ELIGIBILITY CRITERIA TO UNDERGO OPTIONAL T CELL ABLATION\n\n \* Research participant has \\>= 1% CAR T cells in the peripheral blood\n \* Pulmonary: not requiring supplemental oxygen or mechanical ventilation, oxygen saturation 90% or higher on room air\n \* Cardiovascular: not requiring pressor support, no symptomatic cardiac arrhythmias, no acute coronary syndrome, or uncontrolled hypertension\n \* Renal Function: serum creatinine did NOT increase by more than 2.5 fold from baseline (at time of screening)\n \* Liver Function: adequate liver function defined as total bilirubin =\\< 3.0 mg/dl\n \* AST =\\< 5 x ULN, ALT =\\< 5 x ULN\n \* Neurological: research participant without clinically significant encephalopathy/new focal deficits\n \* Infectious diseases: no clinical evidence of uncontrolled active infectious process\n\* ALLOGENEIC DONOR CRITERIA FOR APHERESIS DONATION:\n\n \* Related donor selection will be conducted in accordance with City of Hope's Department of Hematology \\& Hematopoietic Cell Transplantation criteria and, in the case of unrelated donor from a transplant center, will comply with the National Marrow Donor Program's (NMDP) donor selection standards; when a potentially eligible recipient of an unrelated donor product from an NMDP Center is identified, the recipient will complete an NMDP search transfer request to allow City of Hope (COH) NMDP staff to contact the NMDP Coordinating Center, who in turn, will contact the donor's prior Donor Center; the search will follow the NMDP Policy for subsequent donation requests; any form deemed appropriate and necessary by the NMDP, including the Subsequent Donation Request Form, Therapeutic T Cell Collection Prescription and Therapeutic Stem Cell Collection Prescription, will be submitted as required\n \* In the case of a related donor: The identified donor must be the original donor whose stem cells were used for the research participant's allogeneic stem cell transplantation (alloSCT)\n \* For both related and unrelated donors: The donor's hepatitis B surface antigen must be negative and the hepatitis C antibody must be nonreactive; in the case of a positive hepatitis C antibody result, the hepatitis C virus (HCV) viral polymerase chain reaction (PCR) will have to be performed and the results should be negative\n\nExclusion Criteria:\n\n\* Research participants with uncontrolled intercurrent illness including, but not limited to ongoing or active or poorly controlled infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, poorly controlled pulmonary disease or psychiatric illness/social situations that would limit compliance with study requirements; such social situations include but are not limited to lack of reliable means of transportation for follow up, inability to make time for required clinic visits due to work or family needs, or lack of reliable ways of communication with the study team in the event that the participant is seriously ill\n\* Research participants who have tested human immunodeficiency virus (HIV) positive, or have active hepatitis B or C infection based on testing performed within 4 weeks of enrollment\n\* Research participants with presence of other active malignancy. However, research participants with history of prior malignancy treated with curative intent and in complete remission are eligible\n\* Pregnant and lactating women are excluded from this study\n\nStudy-Specific Exclusion\n\n\* Failure of research participant to understand the basic elements of the protocol and/or the risks/benefits of participating in this phase I study\n\* History of allergic reactions attributed to compounds of similar chemical or biological composition to cetuximab\n\* Dependence on corticosteroids:\n\n \* If the participant is undergoing leukapheresis: physiological replacement doses of steroids are allowed - prednisone no more than 7.5 mg, hydrocortisone less than 12 mg/m\\^2/day\n\n \* However, all participants must be able to reduce steroid requirement to no more than physiological replacement doses prior to start of lymphodepletion\n\* Active autoimmune disease requiring systemic immunosuppressive therapy\n\* Research participants will be excluded, who in the opinion of the investigator, may not be able to comply with the safety monitoring requirements of the study",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "12 Years",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
The clinical trial details provided specify eligibility criteria focused on:  
  
1. Two study arms for specific conditions:   
 - ARM 1: Acute Myeloid Leukemia (AML) or CD123+ acute lymphoblastic leukemia (ALL) after discussion with the principal investigator.  
 - ARM 2: Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN).  
  
2. Key inclusion requirements such as:  
 - Presence of CD123+ marker confirmed by flow cytometry or immunohistochemistry.  
 - Classification details of relapsed, refractory, or high-risk disease states.  
 - Overall performance status, organ function, and other health-related criteria like bone marrow samples for confirmation, past treatments, etc.  
  
3. General health exclusions and specific conditions related to blood, cardiac, liver functions, and others.  
  
Notably, there is no mention of eligibility dependent on EGFR gene mutation status. EGFR gene mutations are most commonly associated with certain cancers like non-small cell lung cancer and aren't mentioned as a criterion for this trial which targets blood malignancies associated with CD123 positivity.  
  
Therefore, a patient with an EGFR gene mutation would not fall under the eligibility based solely on that characteristic. Eligibility would depend on meeting the criteria for the specific hematological conditions outlined (e.g., relapsed/refractory CD123+ AML or BPDCN) and associated health status requirements, rather than the presence of an EGFR gene mutation.