INPHOG
Indian Pediatric Hematology Oncology Group

ICCI
Indian Childhood Cancer Initiative

Ongoing and Upcoming Clinical Trials for Childhood Cancer in India with Access to Newer, Expensive Therapies

OCT 2025

Contents

Leukemia – Inotuzumab

Title

A multicentre Phase III randomised controlled trial to test the efficacy of targeted agents during induction and a response-adapted consolidation in adolescent and young adult patients with denovo ALL

CTRINumber CTRI/2025/03/082015

Principal Investigator

Hasmukh Jain

Study Design

Randomized, Parallel Group, Multiple Arm Trial

Phase

Phase 3

Cancer

Acute Lymphoblastic Leukaemia

Age

15 to 39 years

Intervention

Bortezomibplus Inotuzumab plus SOC Vs Bortezomib plus SOC Vs Inotuzumab plus SOC

InclusionCriteria

Age From	15.00 Year(s)
Age To	39.00 Year(s)
Gender	Both
Details	1. Patients aged 15 to 39 years old with newly diagnosed acute lymphoblastic leukemia as per the World Health Organization definition will be included in the study. 2. Treatment-naive patients will be included, except for those who have received up to 7 days of steroids or hydroxyurea or 1 dose of L-asparaginase. 3. Both B-lineage and T-lineage acute lymphoblastic leukemia, including T lymphoblastic lymphoma, will be considered for the study. 4. Eastern Cooperative Oncology Group performance status of 3 or lower. 5. Patients will be considered irrespective of the involvement of the central nervous system, testis, or other extramedullary sites. 6. Written informed consent or assent.

Exclusion Criteria

1. Burkitt's leukemia, early T cell precursor acute lymphoblastic leukemia and lymphoid blast crisis in a case of myeloproliferative neoplasm
2. Contraindication to anthracyclines or any other intensive chemotherapy, except if the abnormality is considered related to acute lymphoblastic leukemia itself

- Aspartate transaminase and or alanine transaminase greater than 5 times the upper
- limit of normal
- Total bilirubin greater than 2 point 5 times the upper limit of normal unless due to
- predominant indirect hyperbilirubinemia
  Serum creatinine greater than 2 times the upper limit of normal or creatinine clearance less than 50 millilitres per minute estimated by the Cockcroft Gault equation
  Myocardial infarction in the 6 months before enrolment or cardiomyopathy classified as New York Heart Association grade 3 or 4, left ventricular ejection fraction less than 50 per cent; ejection fraction assessment to be performed only if clinically indicated

3. Seropositive illness, human immunodeficiency virus positive or active hepatitis B
4. Pregnant or nursing woman
5. Not willing to follow up as per the protocol
6. Intolerance to treatment with a monoclonal antibody
7. History of hypersensitivity to boron compounds
8. History of malignancy within 3 years before the date of enrolment, except for squamous and basal cell carcinomas of the skin, carcinoma in situ of the cervix or malignancies that, in the opinion of the investigator, are considered cured or do not warrant treatment during the intensive phase, with minimal risk of recurrence within 3 years
9. Active or uncontrolled infections that make the patient unfit to receive therapy as per the protocol

Control

Standard of Care (SOC) with CAR T-cell therapy for the high-risk group

Sites

Amala Institute of Medical Sciences, Kochi
Cancer Institute (W.I.A), Chennai
JIPMER, Puducherry
SKIMS, Srinagar
TMC, Kolkata
TMH, Mumbai

Recruitment Status

Open to recruitment

Date of First Enrollment

1st May 2025

Estimated Duration of Trial

6 years

Primary Sponsor

TMH Mumbai

Leukemia – CAR T-Cell

Title

A multicentre Phase III randomized control trial to test the efficacy of targeted agents during induction and a response-adapted consolidation in adolescent and young adult patients with denovo ALL

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6. Intolerance to treatment with a monoclonal antibody
7. History of hypersensitivity to boron compounds
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Control

Standard of Care (SOC) with CAR T-cell therapy for the high-risk group

Sites

Amala Institute of Medical Sciences, Kochi
Cancer Institute (W.I.A), Chennai
JIPMER, Puducherry
TMC, Kolkata
TMH, Mumbai

Recruitment Status

Open to recruitment

Date of First Enrollment

1st May 2025

Estimated Duration of Trial

6 years

Primary Sponsor

TMH Mumbai

Title

Safety and Feasibility of de-centralized CAR-T cell manufacturing and treatment of relapsed and refractory B-cell acute leukemia and lymphomas

CTRINumber CTRI/2022/10/046234

Principal Investigator
Vikram Mathews

Study Design
Single Arm Study

Phase
Phase 1/ Phase 2

Cancer
Acute Lymphoblastic Leukemia

Age
2 to 65 years

Intervention
Anti-CD19 CAR-T Cells

Inclusion Criteria

Age From	2.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Subjects must have relapsed or refractory CD19-positive ALL or lymphoma, treated with at least two lines of therapy for lymphoma. The disease must have either progressed after the last regimen or presented failure to achieve partial or complete remission with the last regimen. Subjects with Philadelphia Chromosome positive acute lymphoblastic leukemia (Ph+ALL) subjects are eligible if they progressed, had stable disease or relapsed after two lines of therapy, including tyrosine kinase inhibitors (TKIs). Subjects with DLBCL must have progressed, had SD, or recurred after initial treatment regimens that include an anthracycline and an anti-CD20 monoclonal antibody. Subjects with transformed FL, MZL, or CLL/SLL must have progressed, had SD or recurred with transformed disease after initial treatment for DLBCL. Subjects who relapse â‰¥12 months after therapy should have progressed after autologous transplant or been ineligible for autologous transplant. 2. The patientâ€™s disease must be CD19 positive, either by immunohistochemistry or flow cytometry analysis on the last biopsy available. 3. Age â‰¥ 2 years. Performance status: Performance Status: Adult Subjects: ECOG â‰¥ 2; Subjects > 10 years of age: Karnofsky â‰¥ 80%; Subjects â‰¤ 10 years of age: Lansky scale â‰¥ 80%

	Normal Organ and Marrow Function (supportive care is allowed per institutional standards) 4. Total bilirubin â‰¤ 1.5 ULN o AST(SGOT) â‰¤ 3 times ULN o ALT(SGPT) â‰¤ 3 times ULN o Serum Creatinine â‰¤ 1.5mg% o Subjects must have the following hematologic function parameters: 5. ANC> 1000, Platelets > 50,000 6. 7. At least 2 weeks or 5 half-lives, whichever is shorter, must have elapsed since any prior systemic therapy at the time the subject is planned for leukapheresis, except for systemic inhibitory/stimulatory immune checkpoint therapy, which requires 5 half-lives. 8. Subjects must have the ability to understand and the willingness to sign a written informed consent document.

Exclusion Criteria

1. Autologous transplant within 6 weeks of planned CAR-T cell infusion.
2. History of allogeneic stem cell transplant.
3. Recipient of CAR-T cell therapy outside of this protocol.
4. Active central nervous system or meningeal involvement by tumour. Subjects with untreated brain metastases/CNS disease will be excluded from this clinical trial because of their poor prognosis and because they often develop progressive neurologic dysfunction that would confound the evaluation of neurologic and other adverse events. Patients with a history of CNS or meningeal involvement must be in a documented remission by CSF evaluation and contrast-enhanced MRI imaging for at least 90 days before registration.
5. History of active malignancy other than non-melanoma skin cancer, carcinoma in situ (e.g. cervix, bladder, breast).
6. Active HIV infection.
7. Subjects with uncontrolled intercurrent illness, including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, pulmonary abnormalities or psychiatric illness/social situations that would limit compliance with study requirements.
8. Pregnant or breastfeeding women are excluded from this study because CAR-T cell therapy may be associated with the potential for teratogenic or abortifacient effects. Women of childbearing potential must have a negative serum pregnancy test. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with CAR-T cells, breastfeeding should be discontinued. These potential risks may also apply to other agents used in this study. Subjects of child-bearing or child-fathering potential must be willing to practice birth control from the time of enrollment in this study and for four (4) months after receiving the preparative regimen.
9. Evidence of myelodysplasia or cytogenetic abnormality indicative of myelodysplasia on any bone marrow biopsy before initiation of therapy
10. Serologic status reflecting active hepatitis B or C infection. Patients who are positive for hepatitis B core antibody, hepatitis B surface antigen (HBsAg), or hepatitis C antibody must have a negative polymerase chain reaction (PCR) before enrollment. (PCR-positive patients will be excluded.)

Control
NA

Sites

CMC Vellore

Recruitment Status

Not yet recruiting

Date of First Enrollment

NA

Estimated Duration of Trial

5 years

Sponsors/Funding

CMC Vellore
ICMR

Title

Evaluating Efficacy and Safety of HCAR19 in pediatric, adolescents and young adults with relapsed/ refractory B-acute lymphoblastic leukemia (ESHA) - A Phase Ib/II Clinical Trial.

CTRINumber CTRI/2023/03/050689

Principal Investigator
Gaurav Narula

Study Design
Other

Phase
Phase 1/ Phase 2

Cancer
Acute Lymphoblastic Leukemia

Age
3 to 25 years

Intervention
HCAR19

Inclusion Criteria

Age From	3.00 Year(s)
Age To	25.00 Year(s)
Gender	Both
Details	a. Disease Criteria: i. Relapsed or refractory pediatric, adolescent or young adult (3-25 years at screening) with B-cell ALL. ii. Relapse for the purpose of this study is defined as 1. Presence of > 5% blasts at screening, and confirmation by FCM, AND 2. Second or subsequent bone marrow (BM) relapse, OR 3. Any BM relapse after allogeneic SCT 4. First Relapse will be considered if: 1. First Relapse has occurred very early, within 18 months of initial diagnosis 2. Is not in remission after re-induction chemotherapy as defined by FSM MRD 3. First Relapse in High-risk groups such as Ph+ and Ph-like ALL, and other known poor-prognostic cytogenetics/molecular profiles iii. Refractory B-ALL is defined as: 1. Not achieving an initial CR after 2 cycles of a standard chemotherapy regimen (primary refractory). AND 2. Such patients have received 1 or more lines of second-line or salvage chemotherapy and are still not in FCM-based MRD-defined remission. iv. CD19 expression criteria: 1. CD19 tumour expression in bone marrow (BM) or peripheral blood (PB) within 3 months of study entry.

	2. B-lineage of blast and expression of CD19 should be established. 3. There should be no other detectable clone that does not express CD19. 4. Absence of CD19-negative subclone of any type at time of study entry. b. Host Criteria: i. Age criteria: Age 3 years to less than 25 completed years at screening for enrolment in the study. ii. Fitness criteria: a. Adequate organ function. Clinically assessed, with further investigation if clinically indicated. This will include but not limited to those with severe systemic compromise of any major organ system as assessed by ejection fraction of < 50% for age as assessed by DTPA scan, anatomical and functional loss of respiratory function as assessed by radiology or respiratory rate at rest in excess of 20% above normal for age, or performance status of less than 80% (KPS & Pediatric scores), will be considered ineligible. iii. For males or females of reproductive potential, has agreed to use an effective contraception method during the study for a minimum of 6 months after study treatment.

Exclusion Criteria

a. Failure to meet any of the inclusion criteria

b. Patients who test positive on urine pregnancy testing and are pregnant or are lactating
c. Isolated extra-medullary relapse
d. Concomitant genetic syndromes associated with bone marrow failure states such as Fanconi anaemia, Kostmann syndrome, Schwachmann syndrome or any other BM failure syndromes with the exception of Down syndrome.
e. Any syndrome with genetic predisposition to cancer, e.g., Li Fraumeni syndrome
f. Any prior malignancy
g. Active or latent hepatitis B or active hepatitis C detected at screening. Any test in the preceding 8 weeks will be considered valid
h. Any uncontrolled infection at the time of screening.
i. Positive HIV test at screening.
j. Grade II to IV graft-versus-host-disease (GVHD) for post-Allo-SCT patients.
k. Receiving an investigational medicinal product within 30 days of screening.
l.. Medications or treatments that will be excluded:
â€¢ Corticosteroids within 72 hours of HCAR19 T-cell infusion, except for physiologic replacement.
â€¢ Allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to infusion
â€¢ Any ongoing GVHD therapies
â€¢ Chemotherapy stopped prior to lymphodepletion based on clearance
â€¢ CNS prophylaxis treatment
m. Active CNS disease, whether established clinically, radiologically, or by CSF studies. An exception would be CNS 2 disease i.e. CSF containing blasts, but < 5 WBCs/microliter. Such patients, with no other evidence of CNS involvement, would be eligible.

Control

NA

Sites

TMH, Mumbai

Recruitment Status

Open to recruitment

Date of First Enrollment

16th Mar 2023

Estimated Duration of Trial

3 years

Sponsors/Funding

TMH Mumbai
Immunoadoptive Cell TherapyPrivate Limited ImmunoACT

Title

A phase 2 study to determine the safety and efficacy of IMN-003A cell therapy in patients with relapsed and refractory CD19-positive B-cell malignancies

CTRINumber CTRI/2022/03/041162

Principal Investigator
Sharat Damodar

Study Design
Other

Phase
Phase 2

Cancer
Acute Lymphoblastic Leukemia

Age
3 to 45 years

Intervention
Anti-CD19 CAR Positive T-Cells

Inclusion Criteria

Age From	3.00 Year(s)
Age To	45.00 Year(s)
Gender	Both
Details	**R**elapsed / Refractory B-Acute Lymphoblastic Leukaemia 1. Age 3 years to 45 years at the time of screening 2. Beyond first relapse 3. Any relapse 6 months after hematopoietic stem cell transplant (HSCT) 4. Primary refractory disease 5. Philadelphia-positive ALL intolerant of TKI 6. Ineligible for allogeneic HSCT 7. Declines allogeneic HSCT Relapsed / Refractory B-cell Non-Hodgkin â€™s Lymphoma 1. Age 18 years or older 2. Beyond first relapse 3. Primary refractory disease 4. Post autologous HSCT 5. Previous treatment with CD20 monoclonal antibody & anthracycline 6. At least one positive lesion on CT/PET scan 7. Biopsy-proven disease

	Applicable to all patients 1. Documentation of CD19 tumour expression demonstrated in bone marrow or peripheral blood by flow cytometry within 3 months of study entry or in a lymph node by immunohistochemistry 2. Adequate bone marrow, renal, hepatic, pulmonary & cardiac function 3. ECOG performance status of 0 or 1 or Lansky (age <16 years) performance status â‰¥ 70 at screening Other inclusion criteria apply as per the clinical trial protocol.

Exclusion Criteria

Relapsed / Refractory B-Acute Lymphoblastic Leukemia

1. Presence of Grade 2 to 4 acute or extensive chronic graft-versus-host disease (GVHD) or ongoing immunosuppressants

Relapsed / Refractory B-cell Non-Hodgkinâ€™s Lymphoma

1. History of Richterâ€™s transformation of CLL
2. History of allogeneic stem cell transplantation

Applicable to all patients

1. Previous treatment with a CD19-targeted monoclonal antibody or gene therapy
2. Clinically significant active infection
3. Current CNS disease or other CNS pathology

Control

NA

Sites

Apollo Cancer Centre Chennai
CMC Vellore
PGI Chandigarh
Narayana Hrudayalaya Bangalore
PGIMER Chandigarh

Recruitment Status

Open to recruitment

Date of First Enrollment

17th Mar 2022

Estimated Duration of Trial

5 years

Sponsors/Funding

Immuneel Therapeutics Private Limited

Lymphoma – Nivolumab

Title

Efficacy and safety of substitution of bleomycin by low-dose nivolumab in ABVD (Doxorubicin plus Bleomycin plus Vinblastine plus Dacarbazine) backbone chemotherapy in newly diagnosed advanced-stage pediatric Hodgkin Lymphoma: A phase II/III, multicentric, open-label, randomized controlled trial

CTRINumber CTRI/2025/03/082456

Principal Investigator
Debasish Sahoo

Study Design
Randomized, Parallel Group, Active Controlled Trial

Phase
Phase 2/Phase 3

Cancer
Hodgkin Lymphoma

Age
1 to 18 years

Intervention
Low-dose nivolumab- Adriamycin, Vinblastine, Dacarbazine

Inclusion Criteria

Age From	1.00 Year(s)
Age To	18.00 Year(s)
Gender	Both
Details	1. Children aged less than 18 years with newly diagnosed classical Hodgkin lymphoma 2. Stage II B- IV disease 3. No prior treatment for disease (except steroids up to 7 days for superior mediastinal syndrome) 4. Informed consent given. 5. Patients in the reproductive age group and childbearing potential should agree on contraception or abstinence 6. Lansky performance score more than 20

Exclusion Criteria

1. Cardiac dysfunction
2. Retroviral infection
3. Active Hepatitis B or C infection
4. Jaundice, with bilirubin more than 2 mg/dL or AST and ALT more than 5 times of upper limit

of normal
5. Creatinine clearance less than 70 mL/ min/ 1.73 m2 (Calculated using Schwartz formula)
6. Past history of uveitis
7. Prior history or suspicion of autoimmune disorders
8. Underlying immunodeficiency disorders

Control

Adriamycin, Bleomycin, Vinblastine, Dacarbazine

Sites

AIIMS Delhi
AIIMS Bhubaneshwar
KGMU, Lucknow
RML Delhi
Safdarjung Delhi
LHMC Delhi
R&R Hospital Delhi

Recruitment Status

Not yet recruiting

Date of First Enrollment

NA

Estimated Duration of Trial

5 years

Sponsors/Funding

AIIMS Bhubaneshwar
National Cancer Grid

Title

Phase II Study of Bendamustine and fixed dose Nivolumab in Children and young adults with Relapsed or Refractory Hodgkin Lymphoma

CTRINumber CTRI/2025/06/088241

Principal Investigator

Shyam Srinivasan

Study Design

Non-randomized, Active Controlled Trial

Phase

Phase 2

Cancer

Hodgkin Lymphoma

Age

1 to 25 years

Intervention

Bendamustine, Nivolumab

Inclusion Criteria

Age From	1.00 Year(s)
Age To	25.00 Year(s)
Gender	Both
Details	1. All diagnosed cases of first or subsequent relapse and refractory Hodgkin's Lymphoma proven by histopathology 2. Written informed consent according to institutional guidelines

Exclusion Criteria

1. Participants more than 25 years of age
2. Subjects with nodular lymphocyte-predominant HL
3. HL was previously documented to be nonresponsive to nivolumab
4. Prior radiation therapy within 3 weeks, or chest radiation less than or equal to 24 weeks prior to the first cycle of therapy
5. Seropositive for hepatitis B, hepatitis C, and HIV
6. History of or active autoimmune disease
7. Subjects with active interstitial pneumonitis
8. History of allergy to study drug components
9. Patients with renal, liver or cardiac compromise as determined by the clinician

Control

Bendamustine

Sites
TMH Mumbai

Recruitment Status
Started recruiting patients – 3 enrolled

Date of First Enrollment
Not Specified

Estimated Duration of Trial
3 years

Sponsors/Funding
TMH Mumbai

Lymphoma – CAR T-Cell

Title

Safety and Feasibility of de-centralized CAR-T cell manufacturing and treatment of relapsed and refractory B-cell acute leukemias and lymphomas

CTRINumber CTRI/2022/10/046234

Principal Investigator
Vikram Mathews

Study Design
Single Arm Study

Phase
Phase 1/ Phase 2

Cancer
Non-Hodgkin Lymphoma

Age
2 to 65 years

Intervention
Anti-CD19 CAR-T Cells

Inclusion Criteria

Age From	2.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Subjects must have relapsed or refractory CD19-positive ALL or lymphoma, treated with at least two lines of therapy for lymphoma. The disease must have either progressed after the last regimen or presented failure to achieve partial or complete remission with the last regimen. Subjects with Philadelphia Chromosome positive acute lymphoblastic leukemia (Ph+ALL) subjects are eligible if they progressed, had stable disease or relapsed after two lines of therapy, including tyrosine kinase inhibitors (TKIs). Subjects with DLBCL must have progressed, had SD, or recurred after initial treatment regimens that include an anthracycline and an anti-CD20 monoclonal antibody. Subjects with transformed FL, MZL, or CLL/SLL must have progressed, had SD or recurred with transformed disease after initial treatment for DLBCL. Subjects who relapse â‰¥12 months after therapy should have progressed after autologous transplant or been ineligible for autologous transplant. 2. The patientâ€™s disease must be CD19 positive, either by immunohistochemistry or flow cytometry analysis on the last biopsy available.

	3. Age â‰¥ 2 years. Performance status: Performance Status: Adult Subjects: ECOG â‰¥ 2; Subjects > 10 years of age: Karnofsky â‰¥ 80%; Subjects â‰¤ 10 years of age: Lansky scale â‰¥ 80% Normal Organ and Marrow Function (supportive care is allowed per institutional standards) 4. Total bilirubin â‰¤ 1.5 ULN o AST(SGOT) â‰¤ 3 times ULN o ALT(SGPT) â‰¤ 3 times ULN o Serum Creatinine â‰¤ 1.5mg% o Subjects must have the following hematologic function parameters: 5. ANC> 1000, Platelets > 50,000 6. 7. At least 2 weeks or 5 half-lives, whichever is shorter, must have elapsed since any prior systemic therapy at the time the subject is planned for leukapheresis, except for systemic inhibitory/stimulatory immune checkpoint therapy, which requires 5 half-lives. 8. Subjects must have the ability to understand and the willingness to sign a written informed consent document.

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1. Autologous transplant within 6 weeks of planned CAR-T cell infusion. 2. History of allogeneic stem cell transplant.
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5. History of active malignancy other than non-melanoma skin cancer, carcinoma in situ (e.g. cervix, bladder, breast).
6. Active HIV infection.
7. Subjects with uncontrolled intercurrent illness, including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, pulmonary abnormalities or psychiatric illness/social situations that would limit compliance with study requirements.
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9. Evidence of myelodysplasia or cytogenetic abnormality indicative of myelodysplasia on any bone marrow biopsy prior to initiation of therapy
10. Serologic status reflecting active hepatitis B or C infection. Patients who are positive for hepatitis B core antibody, hepatitis B surface antigen (HBsAg), or hepatitis C antibody must have a negative polymerase chain reaction (PCR) prior to enrollment. (PCR-positive patients will be excluded.)

Control

NA

Sites

CMC Vellore

Recruitment Status

Not yet recruiting

Date of First Enrollment

NA

Estimated Duration of Trial

5 years

Sponsors/Funding

CMC Vellore
ICMR

Neuroblastoma - Naxitamab

Title

A Pivotal Phase 2 Trial of Antibody Naxitamab hu3F8 and Granulocyte Macrophage Colony Stimulating Factor GM-CSF in High-Risk Neuroblastoma Patients with Primary Refractory Disease or Incomplete Response to Salvage Treatment in Bone and or Bone Marrow

CTRINumber CTRI/2025/06/089843

Principal Investigator

Venkata Rama Mohan Gullamudi

Study Design

Single Arm Study

Phase

Phase 2

Cancer

Neuroblastoma

Age

1 to 99 years

Intervention

Naxitamab, Sargramostim (GM-CSF)

Inclusion Criteria

Age From	12.00 Month(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Documented diagnosis of NB as defined per INRC as Histopathology of tumour biopsy, or BM aspirate or biopsy indicative of NB by histology, plus high blood or urine catecholamine metabolite levels or MYCN amplification, or MIBG-avid lesion(s) 2. High-risk NB patients with either primary refractory disease or incomplete response to salvage treatment (in both cases, including SD, MR and PR) evaluable in bone and or BM as defined in section 6.7. If the disease is only present in the bone, the patient must have evaluable disease outside the radiation areas to be eligible for the trial. Please see section 7.2.1. If disease is only present in the BM, the involvement must be more than 5 percent. 3. Life expectancy greater than or equal to 6 months 4. Age greater than or equal to 12 months 5. Acceptable haematological status at screening (haematological support is allowed if administered greater than or equal to 1 week before screening procedure), defined

	as: Haemoglobin greater than or equal to 8 grams per decilitre (5.0 Millimoles per litre) White blood cell count greater than or equal to 1000 per microlitre (1.0 x109 per Litre) ANC greater than or equal to 500 per microlitre (0.5 x109 per Litre) Platelet count greater than or equal to 25,000 per microlitre (25 x 109 per Litre) 6. Acceptable liver function is defined as: ALT and AST less than or equal to 5 times ULN Bilirubin less than or equal to 1.5 x ULN 7. Acceptable kidney function is defined as: eGFR greater than 60 millilitres per minute per 1.73 square meter calculated by the 2009 revised Bedside Schwartz Equation 8. Written informed consent from legal guardians and or patient in accordance with local regulations. Children must provide assent as required by local regulations.

Exclusion Criteria

1. Any systemic anti-cancer therapy, including chemotherapy or immunotherapy, within 3 weeks of 1st dose of GM-CSF
2. Evaluable Neuroblastoma outside bone and BM defined as follows: MIBG avid tumour. Definite MIBG uptake in tumor tissues outside bone and BM MIBG nonavid tumour Definite uptake in tumor tissues outside bone and BM on FDG PET
3. Actively progressing disease at trial entry according to Park criteria
4. Existing major organ dysfunction CTCAE greater Grade 2, with the exception of hearing loss, hematological status, kidney and liver function
5. Active life-threatening infection
6. Prior treatment with naxitamab
7. Karnofsky or Lansky score less than 50 percent
. Pregnancy or a woman who is breast-feeding (women of child-bearing potential must have a negative pregnancy test at screening). A woman of child-bearing potential is excluded if she does not agree to use highly effective contraception for a period of 42 days after the last naxitamab infusion according to section 9.2.5. A sterilized or infertile woman is exempt from the requirement to use contraception after naxitamab treatment: she must have undergone surgical sterilization (hysterectomy, or bilateral ovariectomy).
9. Inability to comply with protocol requirements, including PK studies, as determined by the investigator
10. History of allergy or known hypersensitivity to GM-CSF, yeast derived products, or any component of GM-CSF or naxitamab
11. History of anaphylactic reactions CTCAE grade 4 related to prior GD2 antibody therapy
12. NB in CNS within 6 months of 1st dose of GM-CSF
13. Prior treatment with omburtamab (mu8H9) within 6 months of 1st dose of GM-CSF
14. Patients who have had allogeneic hematopoietic stem cell transplantation (allo SCT) or donor lymphocyte infusion (DLI). DLI or buffy coat infusion is defined as any kind of active allogenic lymphocyte suspension Within 6 months of 1st dose of GM-CSF or With a lymphocyte count less than 0.2 x109 per liter
15. Patients who received Hematopoietic Progenitor Cell (HPC) boost or “top-up” of allogenic stem cells (lymphocyte-depleted) within 2 months of 1st dose of GM-CSF.
16. Any clinically meaningful abnormal finding in physical examination, vital signs, ECG, haematology, clinical chemistry, or urinalysis prior to inclusion into the trial, which in the opinion of the investigator, may put the subject at risk because of his or her participation in the study.
17. Treatment with immunosuppressive agents (local steroids excluded) within a month prior

to 1st dose of GM-CSF. 18. Inadequate cardiac function is defined as either left ventricular ejection fraction of less than 50 per cent by echocardiography or other clinically relevant cardiac disorders at the discretion of the investigator.

Control

NA

Sites

TMH Mumbai

Recruitment Status

Recruiting

Date of First Enrollment

NA

Estimated Duration of Trial

4 years 11 months

Sponsors/Funding

Y mAbs Therapeutic AS
Novotech clinical research India private limited

Solid Tumour
NTRK FUSION POSITIVE

Title

A phase IV, open-label, multi-cohort study to evaluate the safety and tolerability of oral Entrectinib in Indian patients with unresectable, locally advanced or metastatic solid tumours harbouring specific oncogenic genomic alterations.

CTRINumber CTRI/2024/11/076926

Principal Investigator

Study Design

Non-randomized, Active Controlled Trial

Phase

Phase 4

Age

12 to 80 years

Intervention

Entrectinib

Inclusion Criteria

Age From	12.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	Potential patients are eligible to be included in the study only if all of the following criteria apply: 1. Age more than equal to 18 years at the time of signing the Informed Consent Form 2. Ability to comply with the study protocol, in the investigator's judgment 3. Ability to swallow Entrectinib intact without chewing, crushing, or opening the capsules 4. Patient has a positive benefit/risk profile for treatment with entrectinib by the investigator. COHORT A (ROS1-POSITIVE NSCLC) SPECIFIC INCLUSION CRITERIA: 1. Histologically- or cytologically-confirmed diagnosis of advanced or recurrent (Stage IIIB/C, not amenable to radical treatment) or metastatic (Stage IV) NSCLC that harbors a documented ROS1 gene rearrangement. 2. Documented positivity for ROS1 gene rearrangements must have been determined locally at CLIA-certified or equivalently accredited diagnostic laboratories using nucleic acid-based testing methods that rely on direct assessment of ROS1 gene rearrangements in tumour tissue. Examples of acceptable methods include NGS,

	Sanger sequencing, reverse transcriptase-polymerase chain reaction, NanoString and EdgeSeq. Fluorescence in situ hybridization is also an acceptable method, with ROS1 positivity, defined as the detection of at least 15 percent of neoplastic nuclei with ROS1 gene rearrangements among a minimum of 50 total neoplastic nuclei. Immunohistochemistry is not an acceptable method. COHORT B (NTRK FUSION POSITIVE SOLID TUMOR) SPECIFIC INCLUSION CRITERIA: 1. Patients who are 12 years of age or older will be enrolled in this cohort. Patient or legal guardian must provide signed assent and informed consent to participate in the study. 2. Documented NTRK1/2/3 gene fusion positivity, as determined by a Clinical Laboratory Improvement Amendments (CLIA) or equivalently certified next-generation sequencing (NGS) assay (tissue). Gene fusion positivity is defined as a 3â€™ NTRK1/2/3 fusion with a protein-coding gene fusion partner, which is predicted to be in-frame with an intact kinase domain.

Exclusion Criteria

Potential patients are excluded from the study if any of the following criteria apply:
1. Patients unable to provide consent
2. Patient is not eligible as per the local PI and investigator's discretion.

Control
Active Controlled Trial

Sites
Apollo Chennai
Apollo Delhi
RGCI Delhi
NSCB Kolkata
TMH Mumbai

Recruitment Status
Not yet recruiting

Date of First Enrollment
NA

Estimated Duration of Trial
1 year 2 months

Sponsors/Funding
Roche Products, Pharmaceutical Industry-Global