Testing the Addition of 131I-MIBG or Lorlatinib to Intensive Therapy in People With High-Risk Neuroblastoma (NBL)

Status: RECRUITING

Eligibility Criteria

Age: 365 days to 30 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Patients must be enrolled on ANBL00B1 (NCT00904241) or APEC14B1 (NCT02402244) prior to enrollment on ANBL1531 (NCT03126916) * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Patient must be \>= 365 days and =\< 30 years of age at diagnosis * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Patients must have a diagnosis of neuroblastoma or ganglioneuroblastoma (nodular) verified by tumor pathology analysis or demonstration of clumps of tumor cells in bone marrow with elevated urinary catecholamine metabolites; the following disease groups are eligible: * Patients with International Neuroblastoma Risk Group (INRG) stage M disease are eligible if found to have either of the following features: * MYCN amplification (\> 4-fold increase in MYCN signals as compared to reference signals), regardless of additional biologic features; OR * Age \> 547 days regardless of biologic features * Patients with INRG stage MS disease with MYCN amplification * Patients with INRG stage L2 disease with MYCN amplification * Patients \> 547 days of age initially diagnosed with INRG stage L1, L2 or MS disease who progressed to stage M without prior chemotherapy may enroll within 4 weeks of progression to stage M * Patients \>= 365 days of age initially diagnosed with MYCN amplified INRG stage L1 disease who progress to stage M without systemic therapy may enroll within 4 weeks of progression to stage M * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Patients initially recognized to have high-risk disease must have had no prior systemic therapy (other than topotecan/cyclophosphamide initiated on an emergent basis and within allowed timing); patients observed or treated with a single cycle of chemotherapy per a low or intermediate risk neuroblastoma regimen (e.g., as per ANBL0531, ANBL1232 or similar) for what initially appeared to be non-high risk disease but subsequently found to meet the criteria will also be eligible; patients who receive localized emergency radiation to sites of life-threatening or function-threatening disease prior to or immediately after establishment of the definitive diagnosis will be eligible * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Creatinine clearance or radioisotope glomerular filtration rate (GFR) \>= 70 mL/min/1.73 m\^2 or a serum creatinine based on age/sex as follows: * 1 to \< 2 years: male = 0.6; female = 0.6 * 2 to \< 6 years: male = 0.8; female = 0.8 * 6 to \< 10 years: male = 1; female = 1 * 10 to \< 13 years: male = 1.2; female = 1.2 * 13 to \< 16 years: male = 1.5; female = 1.4 * \>= 16 years: male = 1.7; female = 1.4 * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Total bilirubin =\< 1.5 x upper limit of normal (ULN) for age, and * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Serum glutamate pyruvate transaminase (SGPT) (alanine aminotransferase \[ALT\]) \< 10 x ULN; for the purposes of this study, ULN for SGPT (ALT) is 45 * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Shortening fraction of \>= 27% by echocardiogram, or ejection fraction of \> 50% by echocardiogram or radionuclide angiogram * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: No known contraindication to peripheral blood stem cell (PBSC) collection; examples of contraindications might be a weight or size less than the collecting institution finds feasible, or a physical condition that would limit the ability of the child to undergo apheresis catheter placement (if necessary) and/or the apheresis procedure * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): See ANBL2131 (NCT06172296) protocol for eligible high-risk neuroblastoma diagnoses * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): In addition, all patients transferring from ANBL2131 (NCT06172296) to ANBL1531 (NCT03126916) Arm E must have tumors with an ALK aberration * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Given the lack of data with lorlatinib in infant populations, patients transferring from ANBL2131 (NCT06172296) to ANBL1531 (NCT03126916) must be \> 1 year of age at time of transfer to ANBL1531 (NCT03126916). Patients \< 1 year of age found to have a qualifying ALK alteration as part of ANBL2131 (NCT06172296) may continue to participate in ANBL2131 (NCT06172296) * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Patients initially recognized to have high-risk disease must have received no more than one cycle of topotecan/cyclophosphamide either after enrollment to ANBL2131 (NCT06172296) or started emergently prior to enrollment to ANBL2131 (NCT06172296) * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Patients may have received up to one cycle of intermediate risk chemotherapy prior to initial enrollment to ANBL2131 (NCT06172296) * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Patients may have received localized emergency radiation to sites of life-threatening or function-threatening disease prior to or immediately after establishment of the definitive diagnosis * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): In order to facilitate patient transfer and ensure timely distribution of lorlatinib, there are no blood count requirements to meet at time of transfer from ANBL2131 (NCT06172296) to ANBL1531 ((NCT03126916) Arm E. Note the blood count criteria that must be met prior to start of Induction cycle 2 on Arm E. Lorlatinib therapy should start no sooner than day 1 of Induction cycle 2 * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): No known irreversible grade 2 or greater atrioventricular (AV) block * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Due the potential psychiatric risks from lorlatinib, patients should not have a personal history of a serious psychiatric disorder requiring pharmacologic intervention or severe enough to be considered life-threatening * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): No known contraindication to PBSC collection. Examples of contraindications might be a weight or size less than the collecting institution deems feasible, or a physical condition that would limit the ability of the child to undergo apheresis catheter placement (if necessary) and/or the apheresis procedure

---

Exclusion Criteria:

* FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Patients with INRG stage L2 tumors without amplification of MYCN regardless of tumor histology (may meet criteria for high risk classification but are not eligible for this trial) * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Patients with bone marrow failure syndromes * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Patients for whom targeted radiopharmaceutical therapy would be contraindicated due to underlying medical disorders * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Female patients who are pregnant since fetal toxicities and teratogenic effects have been noted for several of the study drugs; a

pregnancy test is required for female patients of childbearing potential * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Lactating females who plan to breastfeed their infants * FOR PATIENTS ENROLLING TO ANBL1531 (NCT03126916) WITHOUT PRIOR ANBL2131 (NCT06172296) ENROLLMENT: Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Patients who have previously received treatment with lorlatinib or other ALK inhibitor * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Patients who have undergone treatment arm randomization callback or started induction cycle 2 on ANBL2131 (NCT06172296) * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Patients who have an INRG Stage L2 tumor without amplification of MYCN regardless of tumor histology (may meet criteria for high risk classification but are not eligible for this trial) * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Patients with bone marrow failure syndromes * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Female patients who are pregnant since fetal toxicities and teratogenic effects have been noted for several of the study drugs. A pregnancy test is required for female patients of childbearing potential * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Lactating females who plan to breastfeed their infants * PATIENTS WITH TUMORS HARBORING ALK ALTERATIONS TRANSFERRING TO ANBL1531 (NCT03126916) ARM E FROM ANBL2131 (NCT06172296) (EFFECTIVE WITH AMENDMENT 13C): Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation

Conditions & Interventions

Interventions:
PROCEDURE: Autologous Hematopoietic Stem Cell Transplantation, PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Aspiration and Biopsy, DRUG: Busulfan, DRUG: Carboplatin, DRUG: Cisplatin, PROCEDURE: Computed Tomography, DRUG: Cyclophosphamide, DRUG: Dexrazoxane Hydrochloride, BIOLOGICAL: Dinutuximab, DRUG: Doxorubicin Hydrochloride, PROCEDURE: Echocardiography Test, DRUG: Etoposide Phosphate, RADIATION: External Beam Radiation Therapy, RADIATION: Iobenguane I-123, RADIATION: Iobenguane I-131, DRUG: Isotretinoin, DRUG: Lorlatinib, PROCEDURE: Magnetic Resonance Imaging, DRUG: Melphalan Hydrochloride, PROCEDURE: Multigated Acquisition Scan, PROCEDURE: Positron Emission Tomography, BIOLOGICAL: Sargramostim, PROCEDURE: Therapeutic Conventional Surgery, DRUG: Thiotepa, DRUG: Topotecan Hydrochloride, DRUG: Vincristine Sulfate
Conditions:
Ganglioneuroblastoma, Ganglioneuroblastoma, Nodular, Neuroblastoma

More Information

Contact(s): Gwaltney, Lindsey - lbgwaltney@vcu.edu
Principal Investigator: Gowda, Madhu, S
Phase: PHASE3
IRB
Number: HM20015351
System ID: NCT03126916

Thank you for choosing StudyFinder. Please visit http://studyfinder.cctr.vcu.edu to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.