Naxitamab Added to Induction for Newly Diagnosed High-Risk Neuroblastoma

Status: RECRUITING

Eligibility Criteria

Age: 12 months to 21 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Diagnosis: Subjects must have a diagnosis of neuroblastoma or ganglioneuroblastoma (nodular or intermixed) verified by histology or demonstration of clumps of tumor cells in bone marrow with elevated urinary catecholamine metabolites. Subjects with the following disease stages at diagnosis are eligible, if they meet the other specified criteria: 2. Subjects with newly diagnosed neuroblastoma with INRGSS Stage M disease with either of the following features: 1. MYCN amplification (\> 4-fold increase in MYCN signals as compared to reference signals), regardless of additional biologic features; OR 2. 365 days to ≥ 547 days of age without MYCN amplification, but unfavorable biologic features such as unfavorable histology (INPC) or diploid tumor (DNA index=1) or the presence of any segmental chromosome aberration (SCA) (somatic copy number loss at 1p, 3p, 4p, or 11q or somatic copy number gain at 1q, 2p, or 17q); OR 3. Age \> 547 days of age regardless of biologic features Subjects with newly diagnosed neuroblastoma with INRGSS Stage MS disease with either of the following: 1. MYCN amplification (\> 4-fold increase in MYCN signals as compared to reference signals); OR 2. 365 days to ≥ 547 days (18 months) of age without MYCN amplification, but unfavorable biologic features such as unfavorable histology (INPC) or diploid tumor (DNA index=1) or SCA as above Subjects with newly diagnosed neuroblastoma INRGSS Stage L2 disease with either of the following: 1. MYCN amplification (\> 4-fold increase in MYCN signals as compared to reference signals); OR 2. 18 months to \<5 years of age without MYCN amplification, but with unfavorable histology (INPC); OR 3. ≥5 years of age without MYCN amplification, but with undifferentiated or poorly differentiated INPC Subjects with newly diagnosed neuroblastoma INRGSS Stage L1 disease that is incompletely resected with MYCN amplification. Subjects \> 547 days of age initially diagnosed with INRGSS Stage L1, L2 or MS disease who progressed to Stage M without prior chemotherapy may enroll within 4 weeks of progression to Stage M. Subjects ≥ 365 days of age initially diagnosed with MYCN amplified INRGSS Stage L1 disease who progress to Stage M without systemic therapy may enroll within 4 weeks of progression to Stage M. 3. Subjects must be age ≤ 21 years at initial diagnosis. 4. Subjects must be \>12 months of age at enrollment. 5. Adequate cardiac function defined as: 1. Shortening fraction of ≥ 27% by echocardiogram, or 2. Ejection fraction of ≥ 50% by radionuclide evaluation or echocardiogram. 6. Adequate liver function must be demonstrated, defined as: 1. Total bilirubin ≤ 1.5 x upper limit of normal (ULN) for age AND 2. ALT (SGPT) \< 5 x upper limit of normal (ULN) for age 7. Subjects must have adequate renal function defined as an estimated Glomerular Filtration rate (eGFR) as calculated from the Bedside Schwartz equation (in units of mL/min/1.73 m2) or via radioisotope GFR of ≥ 70. The Bedside Schwartz equation is: \[(0.413) X (Height in cm)\] / SCr 8. A negative serum pregnancy test is required for female participants of childbearing potential (≥13 years of age or after onset of menses) 9. Both male and female post-pubertal study subjects must be willing to use a highly effective contraceptive method (i.e., achieves a failure rate of \<1% per year when used consistently and correctly) from the time of informed consent until 6 months after study treatment discontinuation. Such methods include: combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal, transdermal), progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable, implantable), intrauterine device (IUD), intrauterine hormone-releasing system (IUS), bilateral tubal occlusion, vasectomized partner, sexual abstinence. 10. Informed Consent: All subjects and/or legal guardians must sign informed written consent. Assent, when appropriate, will be obtained according to institutional guidelines.

Exclusion Criteria:

1. Subjects who are less than 1 year of age 2. Subjects who are 12-18 months of age with INRGSS Stage M and all stage L2 subjects with favorable biologic features (i.e., nonamplified MYCN, favorable pathology, and DNA index \> 1) are not eligible. 3. Subjects who have had prior systemic therapy except for localized emergency radiation to sites of life-threatening or function-threatening disease and/or no more than 1 cycle of chemotherapy. 4. Treatment with immunosuppressive treatment (topical, inhaled and short-term emergency steroids excluded) within 4 weeks prior to enrollment 5. Inadequate pulmonary function defined as evidence of dyspnea at rest, exercise intolerance, and/or chronic oxygen requirement. In addition, room air pulse oximetry \< 94% and/or abnormal pulmonary function tests if these assessments are clinically indicated. 6. Pregnant or breastfeeding (NOTE: breast milk cannot be stored for future use while the mother is being treated on study.) 7. Subjects receiving any investigational drug concurrently. 8. Subjects with any other medical condition, including but not limited to malabsorption syndromes, mental illness or substance abuse, deemed by the Investigator to be likely to interfere with the interpretation of the results or which would interfere with a subject's ability to sign or the legal guardian's ability to sign the informed consent, and subject's ability to cooperate and participate in the study 9. Subjects with a significant intercurrent illness (any ongoing serious medical problem unrelated to cancer or its treatment) that is not covered by the detailed exclusion criteria and that is expected to interfere with the action of investigational medicinal products (IMPs) or to significantly increase the severity of the toxicities experienced from trial treatment.

Conditions & Interventions

Interventions:
DRUG: Naxitamab
Conditions:
High-risk Neuroblastoma
Keywords:
naxitimab, induction

More Information

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