Single Arm Romiplostim to Prevent CIT

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Age: Patients must be >1 year old at the time of study consent.
- Diagnosis: Patients with a new diagnosis of Ewing sarcoma treated with interval-compressed chemotherapy as per AEWS0031, AEWS1221, or AEWS1031.
- Informed Consent: All patients and/or their parents or legally authorized representatives must sign a written informed consent. Assent, when appropriate, will be obtained according to institutional guidelines.

Exclusion Criteria:

- Marrow disease: Patients with metastatic Ewing sarcoma to the bone marrow are not eligible. Marrow staging is not required for this study but should be performed if clinically indicated.
- Concomitant therapy, cancer directed: Patients receiving whole lung radiation, >50% of pelvic irradiation, other substantial bone marrow radiation (i.e. ≥ 50% of vertebral marrow space), or patients undergoing pneumonectomy as a component of local control before cycle 14, are not eligible. These therapies are not an exclusion if instituted during or after cycle 14.
- Concomitant therapy, non-cancer directed:
    - Patients requiring hematopoietic stem cell rescue are not eligible.
    - Previous use of romiplostim, eltrombopag or any other platelet-producing agent is not allowed.
    - Previous therapy for immune thrombocytopenia and related conditions, including rituximab, mycophenolic acid, protracted systemic steroids, and/or IVIG, is prohibited.
    - Treatment with erythropoietin-stimulating agents is prohibited.
    - Patients receiving another investigational drug are not eligible.
    - Patients who are receiving prophylactic dosing of heparin (i.e. enoxaparin) or oral anticoagulants (i.e. rivaroxaban) for thrombosis prevention may be considered for enrollment but will be excluded from secondary aim 'a' analysis (efficacy measured as the median platelet count and transfusion dependency) given shift in transfusion thresholds.
- Concurrent Illnesses: Patients with a history of or current diagnosis of bone marrow failure, hematologic malignancy, pro-thrombotic condition, or platelet disorder (including immune or heparin induced thrombocytopenia) are not eligible.
- Patients who in the opinion of the investigator may not be able to comply with the study (including safety monitoring requirements of the study) are not eligible.

Conditions & Interventions

Interventions:
DRUG: Romiplostim (AMG-531)
Conditions:
Ewings Sarcoma, Chemotherapy Induced Thrombocytopenia
Keywords:
romiplostim, ewing sarcoma, chemotherapy induced thrombocytopenia, CIT, NPLATE

More Information

Description:
The goal of this clinical trial is to to assess the efficacy of romiplostim as a supportive care measure in patients with a new diagnosis of Ewing sarcoma receiving interval-compressed chemotherapy. The main questions it aims to answer are: 1. To demonstrate the efficacy of romiplostim in patients with newly diagnosed Ewing sarcoma, measured specifically as the rate of CIT, defined as a failure to achieve platelet recovery (≥ 75,000/μL post nadir, without transfusion, or a platelet count sufficient to resume chemotherapy per provider and institutional standard) within 7 days of planned chemotherapy cycle start, measured during the continuation phase (cycle 7 to end of cycle 13 or 16, per AEWS0031/AEWS1221, or AEWS1031 respectively) of interval-compressed chemotherapy (every 2 week vincristine/cyclophosphamide +/- doxorubicin and ifosfamide/etoposide chemotherapy) as compared to published institutional historical control rate. 2. To determine the safety of incorporation of romiplostim supportive care when given concurrently with Ewing sarcoma therapy. 3. To determine the feasibility of incorporation of romiplostim supportive care into upfront Ewing sarcoma regimens.

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