Revolade Tablets Specified Drug-use Survey

Last Update: Jan 14, 2025
Revolade Tablets Specified Drug-use Survey (Pediatric Aplastic Anemia Naive to Treatment With Anti-thymocyte Immunoglobulin, CETB115G1401)
ClinicalTrials.gov Identifier:
NCT06287268
Novartis Reference Number:CETB115G1401
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This is a multicenter, single-arm, non-interventional study (NIS) to confirm the safety and efficacy of eltrombopag in Anti-Thymocyte Globulin (ATG) treatment naive pediatric patients with aplastic anemia (AA). The objective of this survey is to confirm the safety and efficacy of eltrombopag in ATG treatment naive pediatric patients with AA. Eltrombopag should be administered according to the dosage and administration specified in the latest version of the package insert. The observation period is 1 year (364 days) from the start of treatment with this product, regardless of whether treatment with eltrombopag is continued or not. However, if hematopoietic stem cell transplantation is performed within 1 year after the start of treatment with eltrombopag, the observation period shall be until the date of hematopoietic stem cell transplantation.

Condition
Aplastic Anemia
Overall Status
Recruiting
Number of Participants
10
Start Date
Jul 17, 2024
Completion Date
Mar 28, 2029
Gender
All
Age(s)
6 Years - 17 Years (Child)

Interventions

Other

eltrombopag

This is an observational study. There is no treatment allocation. After confirming that patients are fulfilling the eligibility criteria, patients will be registered in this survey.

Eligibility Criteria

Inclusion Criteria:

* Patients whose legally acceptable representative has given written consent for cooperation in this survey prior to enrollment in this survey
* Patients aged ≥ 6 years and \< 18 years at the start of treatment with eltrombopag
* Pediatric patients with AA who receive eltrombopag for the first time in combination with ATG after the approval of additional dosage and administration for "ATG-naïve pediatric patients with AA"

Exclusion Criteria:

* Patients who have received ATG without concomitant use of eltrombopag
* Patients with congenital AA
* Patients with suspected or confirmed diagnosis of myelodysplastic syndrome (MDS) at the start of treatment with eltrombopag
* Patients who have received any drug products containing the same ingredient as eltrombopag (including investigational products)

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