A Study to Investigate the Efficacy, Safety, and Pharmacokinetics of Oral Rilzabrutinib Compared With Placebo in Participants 18 Years of Age and Older With Warm Autoimmune Hemolytic Anemia

NCT07086976

Status	RECRUITING
Phase	Phase 3
Sponsor	Sanofi
Enrollment	90 participants

Key Eligibility Criteria

Inclusion (4)

- Male and female participants with a documented (confirmed) diagnosis of primary wAIHA for at least 3 months.
- Participants who have previously failed to maintain a sustained response after treatment with CS (CS-resistance \[defined as failure to obtain hemoglobin response within 3 weeks on at least 1 mg/kg or 60 mg prednisone or equivalent per day\], CS-dependent wAIHA \[defined as need to continue on prednisone or equivalent at a dose of \>10 mg/day to maintain a response\]), or are intolerant or ineligible to CS (defined as with contraindications, pre-existing medical conditions or CS-related complications that may render CS intolerant or ineligible per the best clinical judgement of the investigators).
- Participants with Eastern Cooperative Oncology Group (ECOG) performance status Grade 2 or lower.
- Contraceptive use by men and women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.

Exclusion (12)

- Participants with clinically significant medical history or ongoing chronic illness that would jeopardize the safety of the participant or compromise the quality of the data derived from his or her participation in the study as determined by the Investigator.
- Participants with medical history of lymphoma, leukemia, or any malignancy within the past 5 years except for basal cell or squamous epithelial carcinomas of the skin that have been resected with no evidence of metastatic disease for the past 3 years.
- Participants with symptomatic herpes zoster within 3 months prior to screening.
- Participants with secondary wAIHA from any cause including drugs, Evans Syndrome, lymphoproliferative disorders (low count monoclonal B-cell lymphocytosis is allowed), infectious or autoimmune disease, or active hematologic malignancies. Participants with positive antinuclear antibodies but without a definitive diagnosis of an autoimmune disease are allowed.
- Participants with history of myelodysplastic syndrome.

... and 7 more (see full listing online)

Locations (91 total)

Mayo Clinic in Arizona - Phoenix- Site Number : 8400032, Phoenix, Arizona, United States
Noble Clinical Research- Site Number : 8400003, Tucson, Arizona, United States
City of Hope National Medical Center- Site Number : 8400023, Duarte, California, United States
... and 88 more locations