A Study to Evaluate BMS-986470 in Healthy Volunteers and Participants With Sickle Cell Disease

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria \- Cohort A. i) Healthy male and female (who are not of childbearing potential) participants, as determined by the investigator based on medical history and other determinations. Females not of childbearing potential must have been amenorrhoeic for at least 12 months without an alternative medical cause and have follicle-stimulating hormone (FSH) levels of at least 40 IU/L or have undergone a hysterectomy, bilateral oophorectomy, or bilateral salpingectomy. ii) Body mass index (BMI) of 18.0 to 32.0 kg/m\^2, inclusive. BMI = weight (kg)/ (height \[m\])\^2 as measured at screening. iii) No evidence of organ dysfunction or any clinically significant deviation from normal in physical examination, vital signs, ECG, or clinical laboratory assessments beyond what is consistent with the target population. \- Cohort B. i) Participants with a documented diagnosis of Sickle Cell Disease (SCD) with genotype HbSS, HbSβ0-thal, or HbSβ+-thal. ii) Participants with ≥ 4 vaso-occlusive crises (VOCs) within the previous 12 months or ≥ 2 VOCs within the previous 6 months. iii) Participant has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. iv) Must have the following laboratory values:. A. Hemoglobin ≥ 5.5 and ≤ 12 g/dL (males) or ≥ 5.5 and ≤ 10.6 g/dL (females). B. Absolute neutrophil count ≥ 1500/µL. C. Platelet count ≥ 100 × 10\^3/µL. D. Absolute reticulocyte count \> 100 × 10\^3/µL or \> 50 × 10\^3/µL if taking hydroxyurea. Exclusion Criteria \- Cohort A. i) Any significant medical condition or any condition that confounds the ability to interpret data from the study. ii) Participant has any condition, including the presence of laboratory abnormalities, that places the participant at unacceptable risk if the participant was to participate in the study. iii) Any major surgery or planned surgery (except GI surgery) within 12 weeks of the first study intervention administration. \- Cohort B. i) Participants with any condition, including significant acute or chronic medical illness, active or uncontrolled infection, or the presence of laboratory abnormalities, that places participants at unacceptable risk if participating in this study. ii) Participants with more than 6 severe VOCs defined as VOCs requiring ≥ 24 hours of hospital admission within 12 months prior to the first dose of study intervention or any VOC requiring ≥ 24 hours of hospital admission within 30 days prior to the first dose of study intervention. iii) Participants with any episode of acute chest syndrome within the last 6 months prior to the first dose of study intervention. iv) Creatinine clearance (CrCl) \< 60 mL/min/1.72m2 using Chronic Kidney Disease Epidemiology (CKD-EPI) equation * Cohort A and B. i) Participant is receiving regularly scheduled RBC or platelet transfusions or has received a RBC transfusion within 28 days and a platelet transfusion within 14 days prior to starting treatment with BMS-986470. * Other protocol-defined Inclusion/Exclusion criteria apply.

Conditions & Interventions

Interventions:

DRUG: BMS-986470, DRUG: Placebo

Conditions:

Anemia, Sickle Cell, Healthy Volunteers

More Information

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Principal Investigator:

Phase: PHASE1

IRB

Number:

System ID: NCT06481306