Bristol Myers Squibb™

Investigational Trials of Fedratinib in Patients with Myelofibrosis

FREEDOM TRIAL

OF FEDRATINIB IN MYELOFIBROSIS

Efficacy and Safety of Fedratinib in Patients with Primary Myelofibrosis, Post–Polycythemia Vera Myelofibrosis, or Post–Essential Thrombocythemia Myelofibrosis and Previously Treated with Ruxolitinib[1,2]

CURRENTLY ENROLLING ACROSS THE US AND CANADA

NCT03755518 *PHASE 3b*

KEY ELIGIBILITY

- Primary MF, post-PV MF, or post-ET MF, DIPSS intermediate or high
- Splenomegaly ≥ 450 cm^3 (CT or MRI) or palpable spleen ≥ 5 cm below LCM
- Previously treated with ruxolitinib
- Platelets ≥ 50,000/μL
- ANC ≥ 1 x 10^9/L
- PB myeloblasts ≤ 5%
- Normal baseline thiamine

TREATMENT

Fedratinib 400 mg/d po in 28-day cycles

Estimated enrollment N = 110

Treatment until lack of efficacy, intolerance, progression of disease, or consent withdrawal

FOLLOW-UP

Follow-up for 12 months after end of treatment

PRIMARY ENDPOINT

Spleen volume response rate at end of C6

SELECT SECONDARY ENDPOINTS

Evaluate safety, assess and implement risk mitigation for GI AEs and potential WE, myelofibrosis symptom assessment, spleen response rate by palpation, durability of spleen and symptom response

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FREEDOM 2 TRIAL

OF FEDRATINIB IN MYELOFIBROSIS

Efficacy and Safety of Fedratinib vs Best Available Therapy in Patients with Primary Myelofibrosis, Post–Polycythemia Vera Myelofibrosis, or Post–Essential Thrombocythemia Myelofibrosis and Previously Treated with Ruxolitinib[3,4]

CURRENTLY ENROLLING GLOBALLY

NCT03952039 *PHASE 3*

SCREENING PERIOD (up to 35 days)

KEY ELIGIBILITY

- Primary MF, post-PV MF, or post-ET MF, DIPSS ≥ Int-2
- Splenomegaly ≥ 450 cm^3 (CT or MRI) and palpable spleen ≥ 5 cm below LCM
- Previously treated with ruxolitinib
- Platelets ≥ 50 x 10^9/L
- ANC ≥ 1 x 10^9/L
- PB myeloblasts < 5%
- Normal baseline thiamine

TREATMENT

2:1 RANDOMIZATION

Arm 1: Fedratinib 400 mg/d po in 28-day cycles

Crossover to Fedratinib Therapy
- Before C6 for confirmed progression of splenomegaly[a]
- After C6 response assessments

Arm 2: Best available therapy

Estimated N = 192

Treatment until lack of efficacy or intolerance

[a]Enlargement of spleen volume of ≥ 25% compared with baseline scan value.

FOLLOW-UP

- Survival
- Subsequent therapies
- New malignancy
- Progression of MF to AML

PRIMARY ENDPOINT

Spleen volume response rate at end of C6

SELECT SECONDARY ENDPOINTS

Myelofibrosis symptom assessment at end of C6, proportion of subjects with ≥ 25% SVR at end of C6, evaluate safety, durability of spleen and symptom response, assess and implement risk mitigation for GI AEs and potential WE, QoL/PRO, OS

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The safety and efficacy of fedratinib and/or its uses are under investigation and have not been established. There is no guarantee that fedratinib will receive health authority approval or become commercially available in any country for the uses being investigated.

AE, adverse event; **AML**, acute myeloid leukemia; **ANC**, absolute neutrophil count; **C6**, Cycle 6; **DIPSS**, Dynamic International Prognostic Scoring System; **ET**, essential thrombocythemia; **GI**, gastrointestinal; **Int-2**, intermediate-2; **LCM**, left costal margin; **MF**, myelofibrosis; **MRI**, magnetic resonance imaging; **PB**, peripheral blood; **po**, by mouth; **PRO**, patient-reported outcome; **PV**, polycythemia vera; **QoL**, quality of life; **SC**, subcutaneous; **SVR**, spleen volume reduction; **US**, United States; **WE**, Wernicke encephalopathy.

1. Clinicaltrials.gov. NCT03755518. Accessed March 18, 2021. **2.** Bristol-Myers Squibb Company. Data on file (protocol number FEDR-MF-001). **3.** Clinicaltrials.gov. NCT03952039. Accessed March 18, 2021. **4.** Bristol-Myers Squibb Company. Data on file (protocol number FEDR-MF-002).