Bristol Myers Squibb™

Investigational Trial of Fedratinib in Patients With Myelofibrosis

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[1]

CURRENTLY ENROLLING GLOBALLY

NCT03952039 *PHASE 3*

SCREENING PERIOD (28 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

Estimated N=192

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

Crossover to fedratinib therapy
- Before C6 for confirmed progression of splenomegaly
- After C6 response assessments

Arm 2: Best available therapy

FOLLOW-UP

- Survival
- Progression

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, GI AEs, encephalopathy events, including WE, QoL/PRO, OS

CONTACT: ClinicalTrialDisclosure@bms.com

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; **ANC**, absolute neutrophil count; **C6**, Cycle 6; **CT**, computed tomography; **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; **OS**, overall survival; **PB**, peripheral blood; **PO**, by mouth; **PRO**, patient-reported outcomes; **PV**, polycythemia vera; **QoL**, quality of life; **SVR**, spleen volume reduction; **WE**, Wernicke encephalopathy.

1. Clinicaltrials.gov. NCT03952039. Accessed April 23, 2021.