# Abstract: P1044

## Title: THE IMPACT OF NEW OR WORSENING ANEMIA ON CLINICAL OUTCOMES IN 2233 PATIENTS WITH MYELOFIBROSIS TREATED WITH RUXOLITINIB: RESULTS FROM THE EXPANDED-ACCESS JUMP STUDY

#### **Abstract Type: Poster Presentation**

#### **Topic: Myeloproliferative neoplasms - Clinical**

#### **Background:**

Transient dose-dependent anemia is a known consequence of ruxolitinib (RUX) treatment and can influence decisions regarding initiation, dosing, and discontinuation of therapy. Whether new/worsening anemia after RUX initiation affects efficacy is unknown. A recent analysis of pooled COMFORT-I/II data indicated that new/worsening anemia did not impact spleen volume response or symptom control (Al-Ali et al., Abstract MPN-571, Presented at SOHO 2023).

### Aims:

To validate the results from the post hoc COMFORT analysis using data from JUMP, the largest trial of RUX in patients (pts) with myelofibrosis (MF) to date.

#### Methods:

JUMP was a large (N=2233), single-arm, phase 3b, expanded-access trial of RUX treatment for pts with MF in a setting similar to routine clinical practice. The study evaluated safety and efficacy of RUX in pts aged  $\geq$ 18 years with diagnosed primary or secondary intermediate (Int)-1, Int-2, or high-risk MF (International Prognostic Scoring System criteria) with baseline (BL) platelets  $\geq$ 50×109/L. Pts received RUX twice daily at a starting dose of 5–20 mg based on BL platelet count. In this post hoc analysis, pts were stratified at BL based on anemia due to MF (hemoglobin [Hb] <100 g/L) and transfusion status among pts with anemia (transfusion-requiring anemia [TRA; received  $\geq$ 2 units of red blood cells over 8 weeks before first RUX dose] or non-transfusion-requiring anemia [NTRA]). Outcomes were stratified by presence/absence of new/worsening anemia following RUX initiation (Hb decrease  $\geq$ 15 g/L or new transfusion requirement at Wk 4, 8, or 12). Outcomes evaluated were spleen length response (SLR;  $\geq$ 50% reduction at Wk 24 or 48 from BL),  $\geq$ 6.5-point increase in Functional Assessment of Cancer Therapy–Lymphoma total score (FACT-Lym TS response) from BL at Wk 24 and 48, and overall survival (OS) per Kaplan-Meier method.

### **Results:**

2233 pts were included (BL status: nonanemic, n=1386 [62.1%]; NTRA, n=521 [23.3]; TRA, n=326 [14.6]). Median (range) age of all pts was 67.0 (18–89) years, and 54.5% were men. BL characteristics were comparable between pts with vs without new/worsening anemia. Rates of SLR at Wk 24 among pts with vs without new/worsening anemia were 31.5% vs 31.2% (nonanemic; P=0.93), 24.4% vs 27.9% (NTRA; P=0.49), and 25.0% vs 29.8% (TRA; P=0.48; **Figure**). FACT-Lym TS response at Wk 24 for pts with vs without new/ worsening anemia was 34.5% vs 34.0% (nonanemic; P=0.86), 32.7% vs 29.6% (NTRA; P=0.52), and 41.7% vs 32.1% (TRA; P=0.13). Similar trends were observed at Wk 48 among pts with vs without new/worsening anemia for both SLR (35.6% vs 26.1%; P=0.02 [nonanemic], 29.6% vs 27.2%; P=0.71 [NTRA], and 19.0% vs 33.3%; P=0.10 [TRA]) and FACT-Lym (30.4% vs 23.3%; P=0.02 [nonanemic], 26.4% vs 27.6%; P=0.84 [NTRA], and 34.2% vs 33.3%; P=0.91 [TRA]). For nonanemic pts at BL, time to median OS was not reached in either cohort; however, better OS was seen in those without vs with new/worsening anemia (hazard ratio: 0.56, [95% CI: 0.36–0.88]; P=0.01). For pts with BL anemia (NTRA and TRA), no OS difference was observed in those with or without new/worsening anemia (P=0.24).

#### Summary/Conclusion:

Analysis of 2233 pts in JUMP indicates that onset of new/worsening anemia following RUX initiation did not diminish clinical benefit of treatment. RUX was associated with improvements in spleen size and symptom burden irrespective of BL anemia and transfusion status. These data are consistent with a recent analysis of pooled COMFORT-I/II data (n=277). Taken together, these results support real-world use of RUX in pts with MF, regardless of BL anemia or development of treatment-related anemia.



Figure: JUMP Outcomes Stratified by Baseline Anemia and Transfusion Status and New or Worsening Anemia

FACT-Lym, Functional Assessment of Cancer Therapy-Lymphoma; NTRA, non-transfusion-requiring anemia; TRA, transfusion-requiring anemia.

Keywords: Janus Kinase inhibitor, Ruxolitinib, Myelofibrosis, Anemia