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Adverse events (AEs) and the return of myelofibrosis (MF)-related symptoms after interruption or discontinuation of ruxolitinib (RUX) therapy.

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Abstract

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Background: RUX is a JAK1/JAK2 inhibitor that demonstrated significant clinical benefit in patients (pts) with MF in COMFORT-I (NCT00952289), a phase 3, randomized (1:1), double-blind, placebo (PBO)-controlled study (N=309). **Methods:** Pts assessed MF-related symptoms daily using the modified Myelofibrosis Symptom Assessment Form v2.0; Total Symptom Score (TSS) was calculated from individual scores for abdominal discomfort, pain under left ribs, early satiety, night sweats, itching, and bone/muscle pain. Therapy was interrupted if platelet or absolute neutrophil count fell below 50,000/ μ L or 500/ μ L, respectively. AEs were evaluated during treatment interruption or discontinuation. The protocol suggested an optional tapering strategy and possible addition of steroids if RUX therapy was discontinued for reasons other than thrombocytopenia. **Results:** In RUX-treated patients with treatment interruption, TSS gradually returned to baseline levels over approximately 1 week. The most common AE leading to treatment interruption or discontinuation in each group was thrombocytopenia (n=11, RUX) and abdominal pain (n=4, PBO). Of these, only 1 RUX pt discontinued for thrombocytopenia. A summary of new onset/worsening AE data after treatment interruption or discontinuation is presented (Table). Of 58 pts who discontinued study treatment, 23 (n=10, RUX; n=13, PBO) experienced a total of 43 SAEs (19, RUX; 24, PBO) that showed no specific pattern or difference between treatment groups. Four of 21 RUX-treated pts had dose tapering following study drug discontinuation. **Conclusions:** Apart from the expected return of MF-related symptoms, there was no pattern of AEs to suggest that RUX interruption or discontinuation is associated with a specific withdrawal syndrome.

	RUX (N=155)	PBO (N=151)
Treatment interruption, n	49	54
Mean duration, days	16	9
Grade \geq 3 AEs, n	8	7
SAEs, n	3	3
	Gastrointestinal hemorrhage; fatigue and neutropenic fever; urosepsis	Anemia; pulmonary edema; hepatic encephalopathy and acute gout
Treatment discontinuation, n	21	37
Grade \geq 3 AEs, n	12	17
SAEs, n	10	13

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