P308 - Interimanalyse der prospektiven nicht-interventionellen Phase IV Studie PaVe (CINC424BDE12): Krankheitssymptome und Lebensqualität von Patienten mit Polycythämia vera unter Ruxolitinib-Therapie / **Interim results of the phase IV PaVe trial (CINC424BDE12), a prospective, non-interventional study of symptoms and quality of life in polycythaemia vera patients receiving ruxolitinib therapy**

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The oral JAK1/JAK2 inhibitor ruxolitinib was approved for the treatment of adult patients with polycythaemia vera (PV) who are resistant or intolerant to hydroxyurea. Data demonstrating the effect of ruxolitinib on the quality of life of PV patients outside of clinical trials are limited. The prospective, non-interventional phase IV study PaVe was therefore initiated to determine disease related symptoms and quality of life before and during ruxolitinib treatment in patients followed in the community setting. A cohort of 303 patients was monitored using the Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF). This validated self-assessment form allows patients to report symptom severity and quality of life in 19 areas (Scherber R., Blood 2011). Patients scored the symptoms on a scale from 1 to 10, where 1 is the “absent” and 10 is the “worst imaginable” symptom severity. Based on 10 individual symptom scores the total symptom score (TSS) was calculated (Emanuel RM, JCO 2012). Here, interim data is reported for those 303 patients (105 JAK-Inhibitor naive; 198 JAK-Inhibitor pretreated) for whom baseline data are available, at least one treatment of ruxolitinib is documented and the inclusion criteria for the documentation are fulfilled. Compared to baseline, JAK-inhibitor naive patients reported a statistically highly significant decrease in TSS during ruxolitinib treatment at 1 month, which was maintained at 12 months and decreased even more at month 24 (baseline mean TSS: 31.0, decrease 1 month: -6.0, 12 month: -8.8, respectively; $p< 0,05$ each). JAK-inhibitor pretreated patients already had a decreased TSS compared to JAK-naive patients and remained stable over the course of 24 months (baseline mean TSS: 26.2, month 24: 25.1). JAK-inhibitor naive patients also experienced statistically significant improvements ($p< 0,05$ each) in the individual symptoms of fatigue, abdominal discomfort, itching and weight loss with decreases (±SD) of -1.7 (± 2.6), -1.4 (± 1.9), -2.1 (± 2.8) and -1.6 (± 3.0) at month 12 and compared to baseline, respectively. Analyses including the correlation of clinical status with symptom self-assessment will be presented. Our data show that significant symptom improvement and an increase in overall quality of life may be achieved with ruxolitinib treatment in PV patients in daily clinical practice. Moreover, in the large majority of JAK-inhibitor naive patients, this improvement is seen within the first month of treatment.