11541 **Poster Session**

Patient reported outcomes and tolerability in patients receiving ripretinib versus sunitinib after imatinib treatment in INTRIGUE: A phase 3 open-label study.

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Background: Ripretinib (R) is a switch-control tyrosine kinase inhibitor (TKI) indicated for the treatment of patients (pts) with advanced gastrointestinal stromal tumor (GIST) after prior treatment with ≥3 TKIs. In the INTRIGUE study (NCT03673501) there was no significant difference in median PFS (primary endpoint) between R and sunitinib (S). We present exploratory analyses of tolerability data and selected pt reported outcomes (PROs). **Methods:** Pts were randomized 1:1 to R 150 mg QD or S 50 mg QD 4 weeks on/2 weeks off.Dose modification was allowed for toxicity management. The event of interest was severe or life-threatening (grade ≥3) treatment-related adverse event prior to progression (sTRAE). Days with at least one sTRAE were summed for all treated pts and for pts with ≥1 sTRAE event. PROs were assessed using questions from EORTC QLQ-C30 and Dermatology Life Quality Index (DLQI) at cycle 1 (C1) day 1 (D1), D15, and D29; D1 and D29 of all other cycles; as well as at end of treatment. Differences in PRO scores between baseline and later assessments were calculated across visits. Long-term data will be presented. **Results:** Pts receiving R (n = 223) versus (vs) S (n = 221) experienced fewer sTRAEs (24% vs 51%, respectively). For all treated pts, the mean time with sTRAEs was 11 days for R and 42 days for S (ratio 0.27, P<0.0001). For pts with ≥1 sTRAE, the mean number of days with a sTRAE was 48 days for R vs 81 days for S (ratio 0.59, p = 0.037). Completion of PRO assessments across the two treatment arms was similar (baseline: R [n = 199], S [n = 199]; C1 D29: R [n = 167], S [n = 177]). Significant differences in self-reported functioning and symptoms were observed by C1 D29. For PROs relating to commonly reported sTRAEs, except constipation, pts in the R arm reported better outcomes than pts in the S arm. Pts in the R arm reported significantly (p<0.05) less decline compared to baseline in pt-reported role function as well as less increase, or improvement, in symptoms of fatigue, appetite loss, diarrhea, nausea/vomiting, and pain vs pts in the S arm. Moderate or severe effect of skin toxicity on pt life, as measured by DLQI in the R arm (n = 165) and in the S arm (n = 175), was observed in 6.6% of pts in the R arm vs 14.8% of pts in the S arm (p = 0.015). **Conclusions:** In the INTRIGUE study the total number of days with sTRAEs was fewer for pts receiving R vs S. Pts in the R arm also reported significantly less decline in pt-reported role function and less increase in symptoms related to commonly reported sTRAEs, except constipation, vs pts in the S arm. Medical writing provided by Costello Medical. Clinical trial information: NCT03673501. Research Sponsor: Deciphera Pharmaceuticals, LLC.