**RESULTS**

- A total of 140 patients (pixantrone/comparator; n = 70/70) were randomised into the EXTEND study, of whom 126 had aggressive B-cell histology as determined by on-site pathology.
- The numbers of patients determined to have aggressive B-cell NHL (concordance rate of 76% between site and central review), the panel diagnoses in pixantrone/comparator groups were DLBCL in 83.0%/87.2%, transformed indolent lymphoma in 14.0%/10.6%, and follicular lymphoma grade III in 4.0%/2.1%.

For these post-hoc subgroup analyses, patients with the following were retrospectively identified:

- Diffuse large B-cell lymphoma (DLBCL)
- Follicular lymphoma grade III
- Transformed indolent lymphoma (confirmation that current disease was high-grade DLBCL or FG3-like in patients with a history of indolent disease).

Decisions regarding pathology were reached through consensus of two (three in case of disagreement) independent pathologists.

**SAFETY**

- Full safety and tolerability data have been previously published (Pettengell R. et al. Lancet Oncol 2012).
- Uncomplicated neutropenia was more common in the pixantrone vs comparator arm (all grades, 50.0% vs 23.9%; grade 3/4, 41.2% vs 19.4%).
- Non-cumulative neutropenia generally < 3 days
- Grade 4 approximately 10%/cycle with no increase in late cycles
- Routine G-CSF not required.
- Other grade 3/4 haematological AEs with total incidence > 10% (pixantrone vs comparator):
  - Leukopenia: 23.5% vs 7.5%
  - Thrombocytopenia: 11.8% vs 10.4%.
- Non-haematological AEs (pixantrone vs comparator):
  - All-grade diarrhoea: 4.4% vs 17.9%
  - All-grade cough: 22.1% vs 4.5%.

**DISCUSSION**

- Pixantrone is conditionally approved by the European Medicines Agency for the treatment of multiply relapsed or refractory (3rd or 4th line) aggressive B-cell NHL. The benefit of pixantrone has not been established in patients used as 5th-line or greater chemotherapy.
- In this unplanned analysis, single agent pixantrone appears to be more efficacious than physicians’ choice of monotherapy in the 3rd or 4th line setting whether or not previously exposed to rituximab.
- When patients with aggressive B-cell NHL were identified by central review, the resulting HR for PFS was lower when than disease was determined by site (0.52 versus 0.85). This suggests that the superior efficacy of pixantrone in the patients with prior rituximab was not due to inclusion of more patients with indolent disease based on site pathology.
- In all subgroups, there was a positive trend towards improved OS in patients treated with pixantrone.
- The concordance between on-site histology and retrospective central review was 76%. This was consistent with rates of concordance reported in the literature, which range from 58% to 84% (Jones SE et al. Cancer 1977;39:1071-1076).

**REFERENCES**


**CONFLICTS OF INTEREST**

This study was funded by CTI.
RP has acted as a consultant for CTI and received honoraria for speaker engagements. PT is an employee of CTI Life Sciences and owns stock in CTI.
PC, LW, JS and HM are employees of CTI and own stock in CTI.

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