A Phase Ib, Open-Label, Randomized Study to Assess Safety and Preliminary Efficacy of Tafasitamab (MOR208) or Tafasitamab + Lenalidomide in Addition to R-CHOP in Patients with Newly Diagnosed Diffuse Large B-cell Lymphoma (DLBCL): Preliminary Data

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Background

- R-CHOP (rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, prednisolone) is the standard of care for newly diagnosed diffuse large B-cell lymphoma (DLBCL) with a complete response (CR) rate of 70%.
- However, there is an unmet need for more effective frontline treatment options for high-risk patients.
- Approximately 20% of DLBCL patients present with a B-cell lymphoma cutaneous syndrome (BCLS), which are associated with poor response to front-line based regimens.
- CD19 is widely expressed in B-cell malignancies and functions as a positive regulator of B-cell receptor signaling.
- Tafasitamab is approved by the FDA in combination with lenalidomide for adult patients with relapsed or refractory CD19+ B-cell malignancies.

Methods

- The study consists of two phases
  - Recruitment of 66 patients took place across 34 sites in the US and Europe from Dec 2019 to Aug 2020
  - Enrollment is now complete and the study is ongoing. Here we report preliminary study data as of the 23 Sept 2020

Endpoints

- Key secondary endpoints: ORR and PET-negative complete response (CR) rate at the end of treatment, as assessed by an independent radiology review board.
- Other secondary endpoints include long-term safety and efficacy, pharmacokinetics and immunogenicity.

Results

- In the data cut-off, one patient in arm A had discontinued treatment due to AEs whilst there were no discontinuations in arm B.
- Baseline characteristics were balanced between the treatment arms.
- In arm A, three patients (9.1%) had febrile neutropenia compared with four patients (12.1%) in arm B. One patient (3.0%) in arm B was grade ≥3.
- The most frequent treatment-related AEs were hematologic (Table 3).

Conclusions

- These early data from our ongoing study are encouraging and warrant further investigation.

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