Phase I study of brentuximab vedotin (SGN-35) in Japanese children with relapsed or refractory CD30-positive Hodgkin’s lymphoma or systemic anaplastic large cell lymphoma

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Introduction

Data on the treatment of pediatric patients with brentuximab vedotin are limited. The aims of this study were to assess the safety and tolerability of brentuximab vedotin in Japanese children with relapsed or refractory Hodgkin’s lymphoma (HL) or systemic anaplastic large-cell lymphoma (sALCL).
In Japan, a phase I/II study (TB-BC010088 study) involving patients with recurrent or refractory CD30-positive HL or sALCL was initiated in October 2011. Based on the results of the TB-BC010088, SG035–0003, and SG035–0004 studies, brentuximab vedotin was also approved for the treatment of patients with recurrent or refractory CD30-positive HL or ALCL in 2014 in Japan. We report here the safety and tolerability of brentuximab vedotin in Japanese children with relapsed or refractory CD30 positive HL or sALCL.

Methods

Pediatric patients, aged 2–17 years, with relapsed or refractory HL or sALCL were recruited. Brentuximab vedotin were administered at 1.8 mg/kg via intravenous infusion once every 3 weeks. Primary endpoints were dose-limiting toxicities and safety.

Results

Between September 2016, and March 2018, six patients (median age: 11.5, range 5–14 years), four with relapsed or refractory HL and two with relapsed or refractory sALCL were enrolled. Dose limiting toxicities were not observed in any of the six patients. Although three of six patients (50%) had at least one grade ≥3 adverse event, no patient had a serious adverse event. The pharmacokinetic profile of brentuximab vedotin in pediatric patients was comparable to that reported in adults. The proportion of patients who achieved overall response was 60% (95% confidence interval 14.7–94.7).

Conclusion

Our study had two limitations, namely the small sample size and the heterogeneity of the patients. However, it also represents the first prospective trial to systematically investigate the use of brentuximab vedotin in Japanese children.
Our data suggest that brentuximab vedotin at 1.8 mg/kg might have a manageable toxicity profile for the treatment of children with recurrent or refractory HL or sALCL. Despite this, the optimal dose of BV in pediatric patients is unclear. Further research in pediatric patients with recurrent or refractory HL or sALCL

is needed.

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