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氏名	戸谷 治仁
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学位論文の題名	<p>Phase I study of once weekly treatment with bortezomib in combination with lenalidomide and dexamethasone for relapsed or refractory multiple myeloma (再発・難治性多発性骨髄腫に対する週1回ボルテゾミブとレナリドミド、デキサメタゾン併用療法の第I相試験)</p> <p>International Journal of Hematology. Vol. 103 : P.316-321, 2016</p>
論文審査担当者	<p>主査： 稲垣 宏 副査： 高橋 智, 飯田 真介</p>

Background: Proteasome inhibitors (PIs) in combination with immunomodulatory drugs (IMiDs) have been shown to be effective against relapsed/refractory multiple myeloma (RRMM). To determine the optimal dosing schedule of once weekly bortezomib (BTZ) combined with lenalidomide (LEN) and dexamethasone (DEX), especially in the outpatient setting, we conducted a phase I dose escalation study. **Methods:** A 21-day cycle of BTZ 1.3 mg/m² on days 1 and 8, LEN 10 mg/day (cohort 1) or 15 mg/day (cohort 2) on days 1–14, and DEX 20 mg/day on days 1, 2, 8, and 9 was administered. **Results:** Three patients were enrolled in each cohort. No dose-limiting toxicity was observed in either cohort. Although hematological toxicities estimated as >grade 3 were common, non-hematological toxicities of grade 3 or higher were rare. Two cases of newly diagnosed peripheral neuropathy (PN) were observed, while no grade 3/4 PN was observed. Two patients achieved partial response and two achieved stable disease. **Conclusions:** The recommended doses of BTZ and LEN were determined to be 1.3 mg/m² and 15 mg, respectively. Combination therapy of once weekly BTZ with LEN and DEX was well tolerated and shows promise as a regimen for patients with RRMM previously treated with both PIs and IMiDs.