

Meeting Abstract: 2009 ASCO Annual Meeting I

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Dose-escalation trial of milatuzumab (humanized anti-CD74 monoclonal antibody) in multiple myeloma

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Abstract

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Background: CD74 (HLA-DR-associated invariant chain) is highly expressed in multiple myeloma (MM), rapidly internalized, and a promising target for immunotherapy.

Methods: A multicenter dose-escalation study was initiated in patients (pts) with relapsed/refractory MM who had failed at least 2 standard therapies. Pts received milatuzumab IV twice-weekly for 4 wks, with doses escalated by a 3+3 cohort design. Pts were evaluated over 12 wks, with

Dose-escalation trial of milatuzumab (humanized anti-CD74

treatment-related Grade 3–4 events considered dose-limiting toxicity (DLT). Responses were classified by EBMT criteria, with PK and immunogenicity evaluated by serum milatuzumab levels and human anti-milatuzumab antibody (HAHA) titers, respectively. **Results:** Twenty-one pts (12M/9F, median age 63) have now received 1.5 (n=8), 4.0 (n=9) or 8.0 mg/kg (n=4) doses twice weekly. They had MM for 0.9–16.8 years (median 5.4), predominantly IgG subtype,

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were heavily pretreated (4 median prior treatments), and were Durie-Salmon stage II (n=13) or III (n=8). After increasing premedications and slowing administration, infusions were well tolerated (Grade 1–2). There was 1 DLT (infusion reaction) and 3 SAEs (bact. meningitis, confusion/hypercalcemia, fever post demerol) at 1.5 mg/kg, 1 DLT (unexplained anemia) and 2 SAEs (cord compression, epistaxis/thrombocytopenia), at 4.0 mg/kg, but no DLTs or SAEs at 8.0 mg/kg. There has been no pattern of other AEs nor effects on routine laboratories, including serum chemistries, CBC, serum immunoglobulins, B- or T-cells, and no cases of HAHA. At current doses, milatuzumab is rapidly cleared from serum, with little accumulation and low trough levels across infusions. There have been no objective responses so far, but 4 pts have had stable disease by EBMT criteria for at least 3 months post-treatment, occurring with a possible trend towards higher milatuzumab serum levels than pts with earlier disease progression.

Conclusions: Milatuzumab doses up to 8.0 mg/kg may be given safely twice-weekly for 4 weeks. In spite of rapid clearance, several patients have had disease stabilization at 4.0 and 8.0 mg/kg doses, which is encouraging. Accrual of the next cohort receiving 16.0 mg/kg is ongoing.

Author Disclosure			
Employment or Leadership	Consultant or Advisory Role	Stock Ownership	Honoraria
Immunomedics		Immunomedics	

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targeting death receptor 5 or DR5), administered weekly to patients with advanced solid tumors or lymphomas

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