A phase I study of the anti-kappa monoclonal antibody, MDX-1097, in previously treated multiple myeloma patients.

**Sub-category:**
Multiple Myeloma

**Category:**
Lymphoma and Plasma Cell Disorders

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**Abstract:**

**Background:** Previous in vitro studies have described an anti-kappa light chain chimeric antibody, MDX-1097, that specifically recognizes a cell surface antigen designated kappa myeloma antigen (KMA) expressed on multiple myeloma (MM) cell lines and malignant plasma cells isolated from MM and Waldenstrom's macroglobulinemia patients. MDX-1097 mediated anti-tumour activity in vitro via antibody dependent cellular cytotoxicity (ADCC) and antibody dependent cellular phagocytosis (ADCP). In addition, MDX-1097 had a favorable pre-clinical toxicological profile in human tissue cross-reactivity and non human primate studies. Based on these promising pre-clinical data a Phase I single ascending dose study was conducted to determine the safety, tolerability and MTD of MDX-1097.

**Methods:** Patients with kappa type MM who had received at least one prior line of standard treatment, achieved at least a minimal response and had stable measurable disease were eligible. Twelve patients completed the study, each receiving a single dose of MDX-1097 on day 1 (n = 3 for dose levels: 0.3, 1.0, 3.0 or 10 mg/kg) and followed until day 45 post-infusion.

**Results:** No serious adverse events and no dose limiting toxicities were reported. Importantly, no soluble antigen related sink was observed over the dose range studied and the terminal elimination half- life of the antibody ranged from 237 hours at 0.3 mg/kg to 124 hours at 10 mg/kg. No patients developed antibody responses to MDX-1097 by day 45. A transient increase in serum kappa light chain levels was seen immediately following the infusion of MDX-1097 in all patients. This was considered to be due to binding of MDX-1097 to serum kappa light chains resulting in transient impairment of renal clearance. No responses based on the established protocol parameters were observed. However, a single patient with bone pain and multi-focal areas of disease as demonstrated on PET scanning had resolution of her bone pain and normalization of her PET scan following treatment.

**Conclusions:** Based on the favorable safety data and pharmacokinetic profile seen in this Phase I study, a Phase II multi-dose efficacy study of MDX-1097 at a dose of 10 mg/kg will commence soon.

**Abstract Disclosures**

**Faculty & Discussant Disclosures**

**Annual Meeting Planning Committee Disclosures**

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**Associated Presentation(s):**

1. A phase I study of the anti-kappa monoclonal antibody, MDX-1097, in previously treated multiple myeloma patients.

**Meeting:** 2010 ASCO Annual Meeting

**Presenter:** Andrew Spencer

**Session:** Lymphoma and Plasma Cell Disorders (General Poster Session)

**Other Abstracts in this Sub-Category:**
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Meeting: 2010 ASCO Annual Meeting  Abstract No: TPS307  First Author: N. C. Munshi
Category: Lymphoma and Plasma Cell Disorders - Multiple Myeloma

2. PANORAMA 2: A phase II study of panobinostat (LBH589) in combination with bortezomib (BTZ) and dexamethasone (DEX) in patients with relapsed and BTZ-refractory multiple myeloma (MM).

Meeting: 2010 ASCO Annual Meeting  Abstract No: TPS308  First Author: M. Alsina
Category: Lymphoma and Plasma Cell Disorders - Multiple Myeloma

3. Results of an ongoing open-label, phase II study of carfilzomib in patients with relapsed and/or refractory multiple myeloma (R/R MM).

Meeting: 2010 ASCO Annual Meeting  Abstract No: 8000  First Author: R. Vij
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1. A phase I study of the anti-kappa monoclonal antibody, MDX-1097, in previously treated multiple myeloma patients.

Meeting: 2010 ASCO Annual Meeting  Abstract No: 8143  First Author: A. Spencer
Category: Lymphoma and Plasma Cell Disorders - Multiple Myeloma

2. Phase Ib study of oral panobinostat (LBH589) plus lenalidomide (LEN) plus dexamethasone (DEX) in patients (Pts) with relapsed (Rel) or Rel and refractory (Ref) multiple myeloma (MM).

Meeting: 2010 ASCO Annual Meeting  Abstract No: 8030^  First Author: M. Mateos
Category: Lymphoma and Plasma Cell Disorders - Multiple Myeloma

3. Response of newly diagnosed myeloma with 1q21 amplification to bortezomib-based PAD induction therapy.

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Meeting: 2010 ASCO Annual Meeting
Presenter: Andrew Spencer
Session: Lymphoma and Plasma Cell Disorders (General Poster Session)

2. Panobinostat plus lenalidomide and dexamethasone phase I trial in multiple myeloma (MM).

Meeting: 2009 ASCO Annual Meeting
Presenter: Andrew Spencer
Session: Lymphoma and Plasma Cell Disorders (Poster Discussion Session)


Meeting: 2006 Prostate Cancer Symposium
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