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

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Multiple Myeloma

Category:
Lymphoma and Plasma Cell Disorders

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2010 ASCO Annual Meeting

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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)

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

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

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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)

3. Prostate cancer quality of care: The American College of Surgeons Special Study.

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