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NCI 9855: A Phase 2 Study of CDX-011 (Glembatumumab vedotin) for Metastatic Uveal Melanoma



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THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center
Making Cancer History[®]



Disclosures

Amgen – advisory board

Bristol Myers-Squibb – clinical trial support

Castle Biosciences – advisory board (cutaneous melanoma)

Deciphera – clinical trial support

Genentech – advisory board

Glaxo SmithKline – clinical trial support

Immunocore – data safety monitoring committee

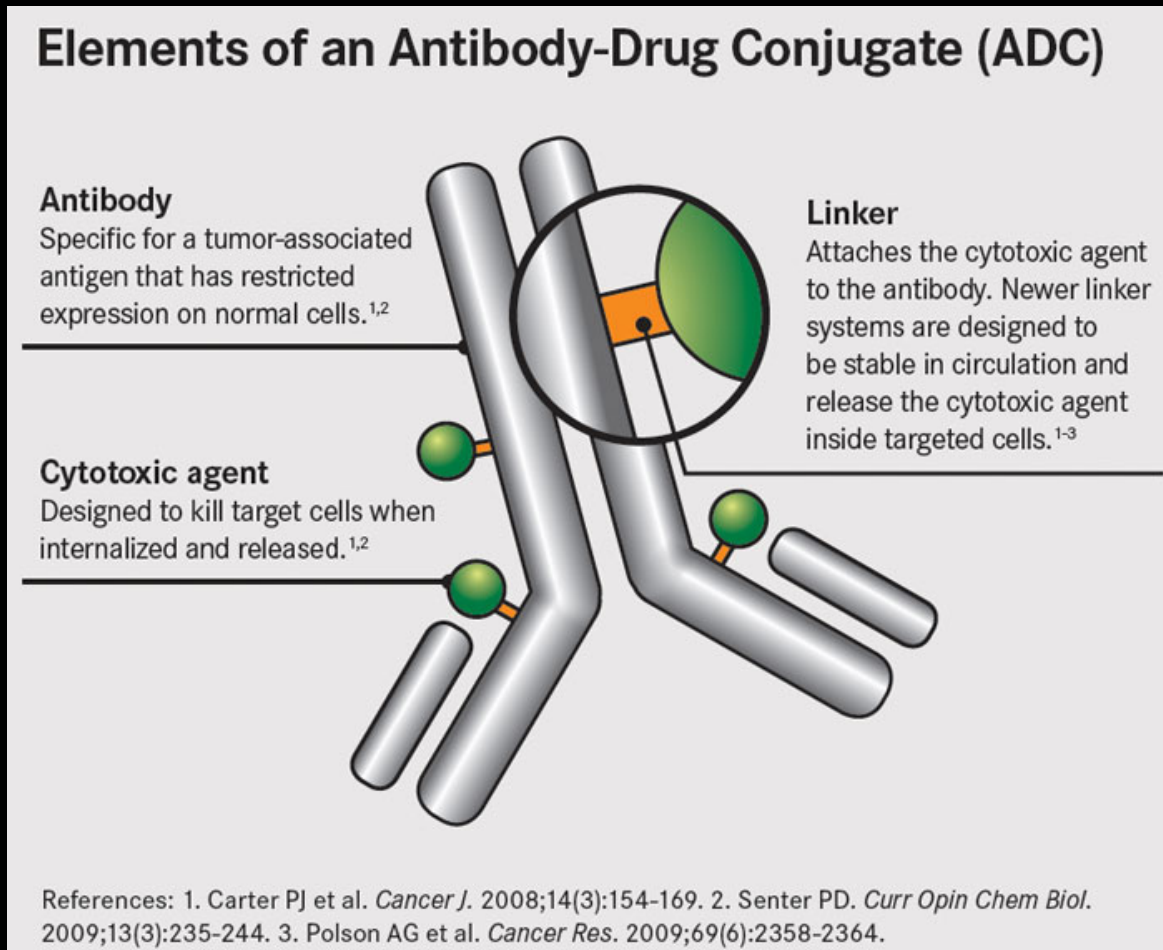
Novartis – clinical trial support

Reata – clinical trial support, data safety monitoring board

Background – antibody drug conjugates

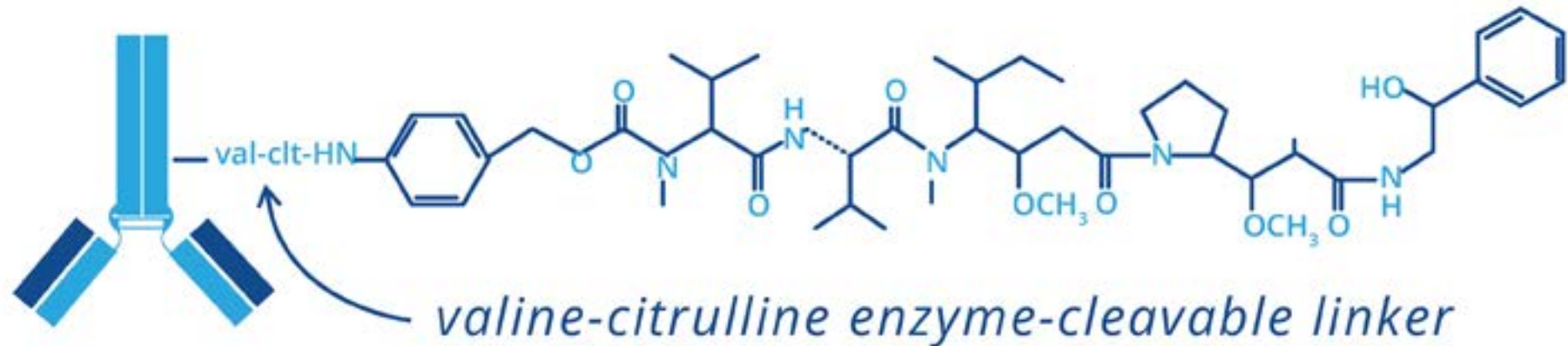
3 main components:

1. Antibody directed against a specific target
2. Cytotoxic agent
3. Protease-cleavable linker that covalently attaches the cytotoxin to the antibody



CDX-011: glembatumumab vedotin

1. IgG2 directed against GPNMB, a transmembrane protein involved in metastasis and invasion. 86% GPNMB expression in uveal melanoma ^(Williams M., *Mel Res* 2010)
2. Microtubule inhibitor MMAE (mono-methylauristatin E)
3. Valine-citrulline peptide linker covalently binds MMAE to anti-GPNMB

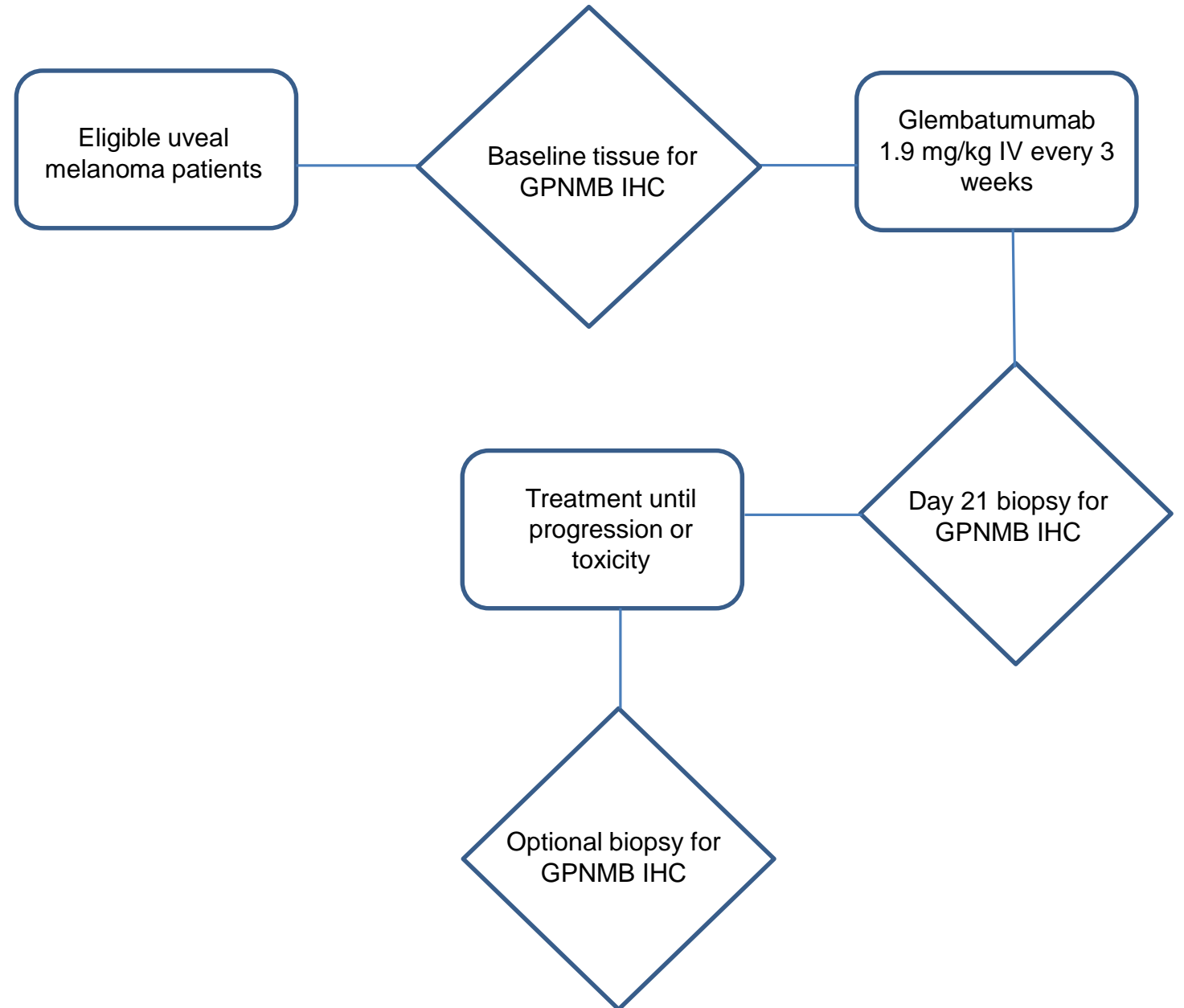


CR011: fully-human IgG₂ targeting GPNMB

MMAE: dolastatin-like tubulin inhibitor

Study Schema

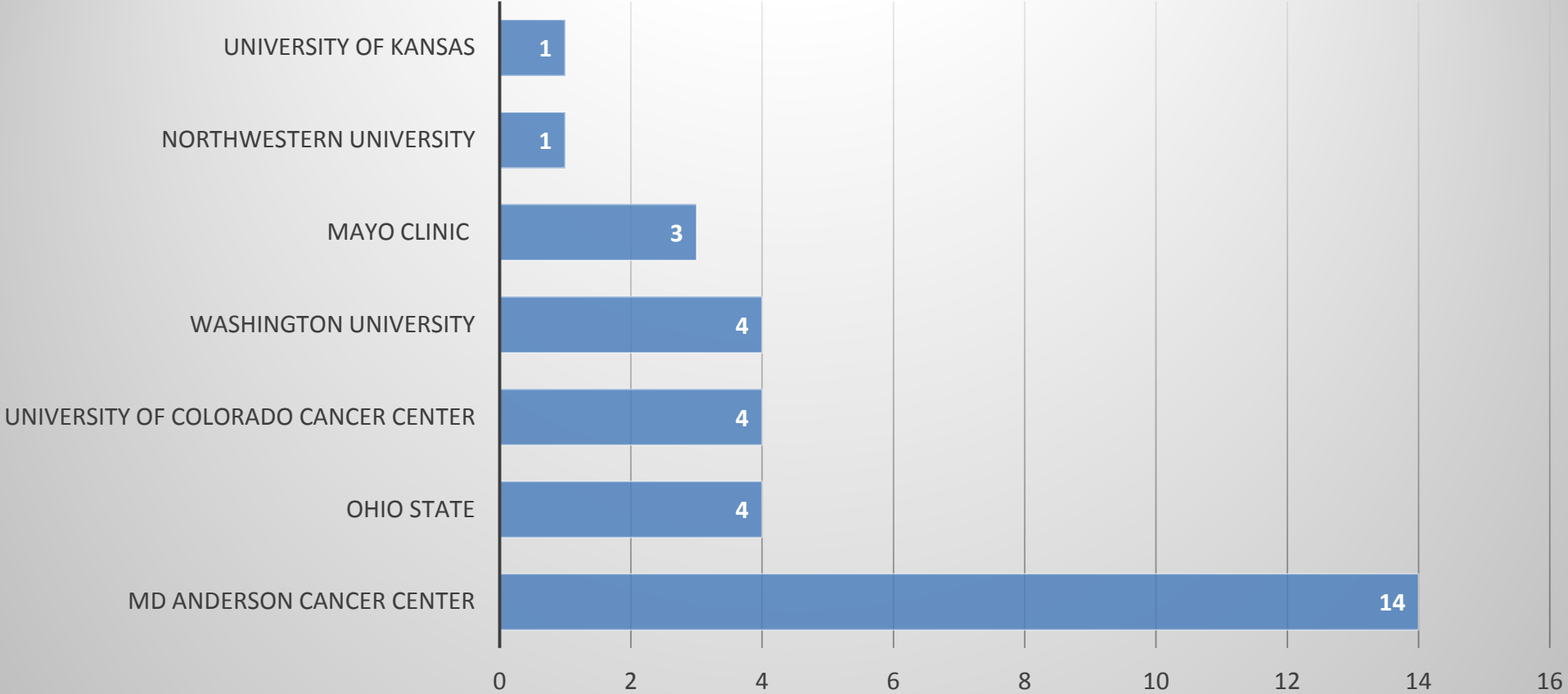
- **Single-arm, open-label Phase 2 study**
- **Simon two-stage minimax design**
 - **18 patients in first stage**
 - **14 patients in second stage**
 - **Up to 34 patients total**



STUDY ENDPOINTS

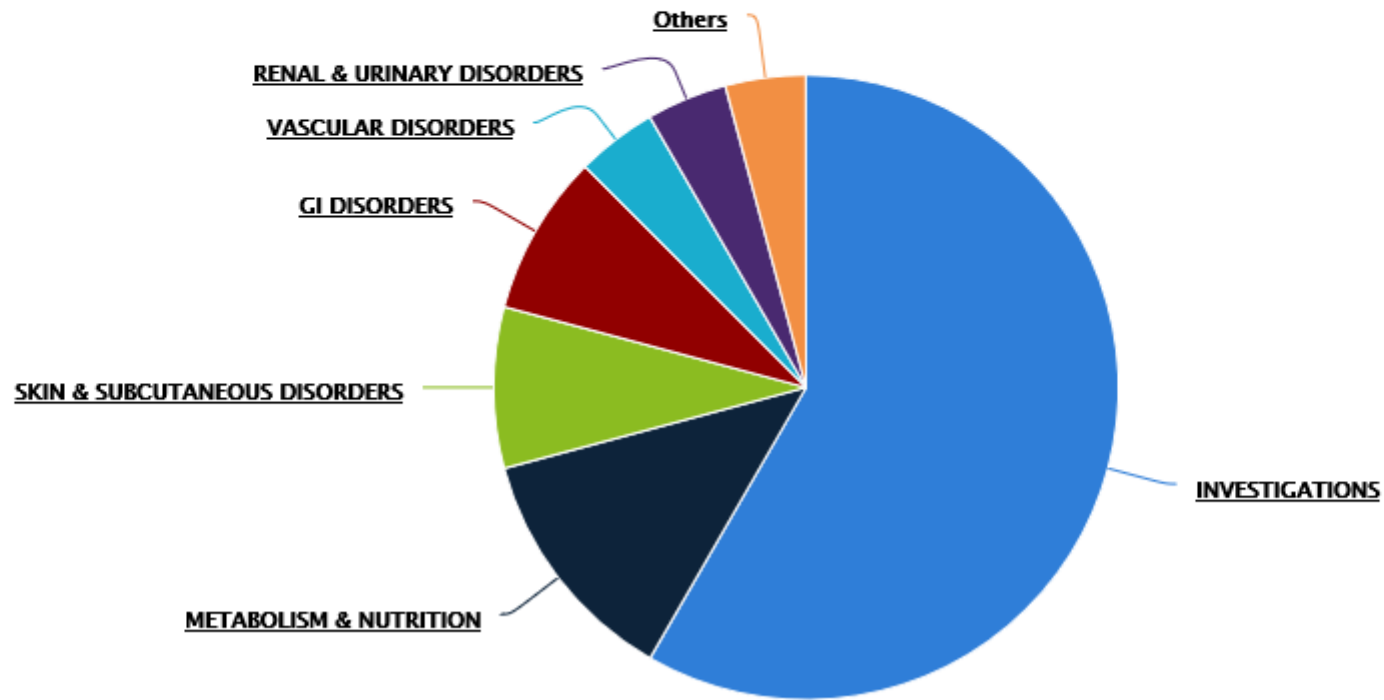
- *Primary = Overall Response Rate using RECIST 1.1*
- *Secondary = Progression-free survival, Overall survival, GPNMB expression via IHC*
- *Exploratory = Immunophenotyping of tumors, rash as a biomarker*

Enrollment to date



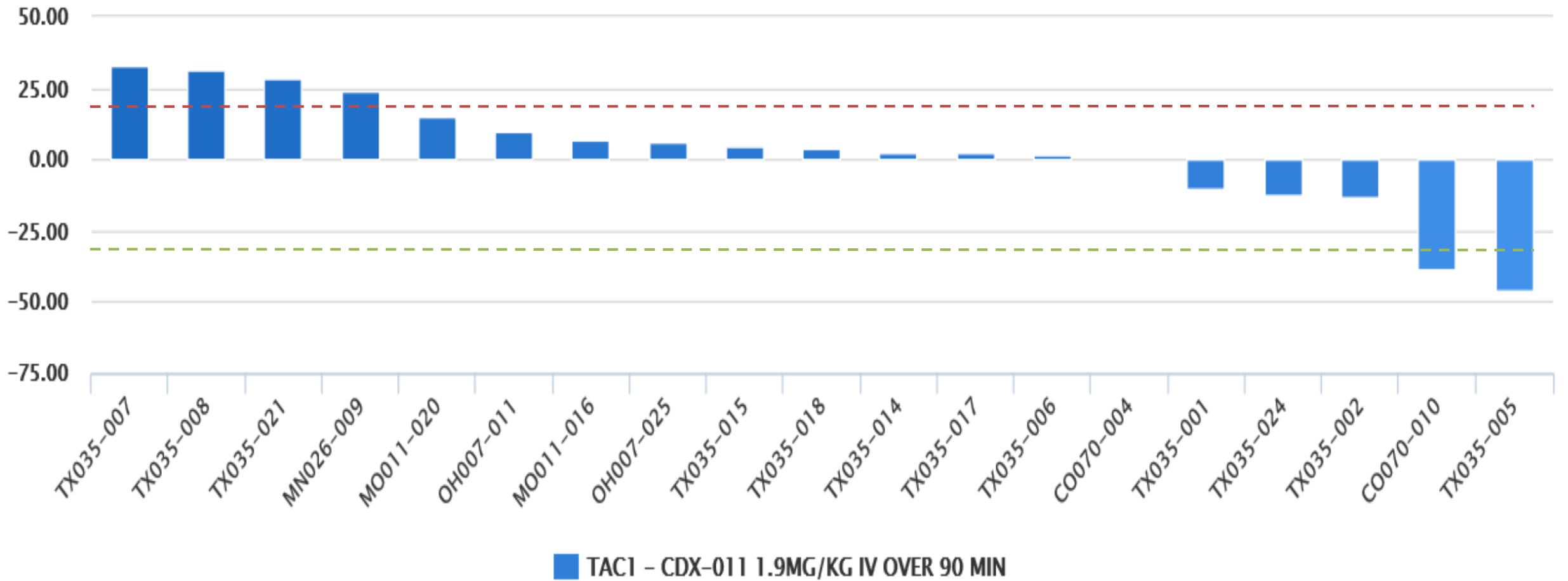
Related AEs By Class View (NCI Standard Reports)

 UPDATE RESULTS



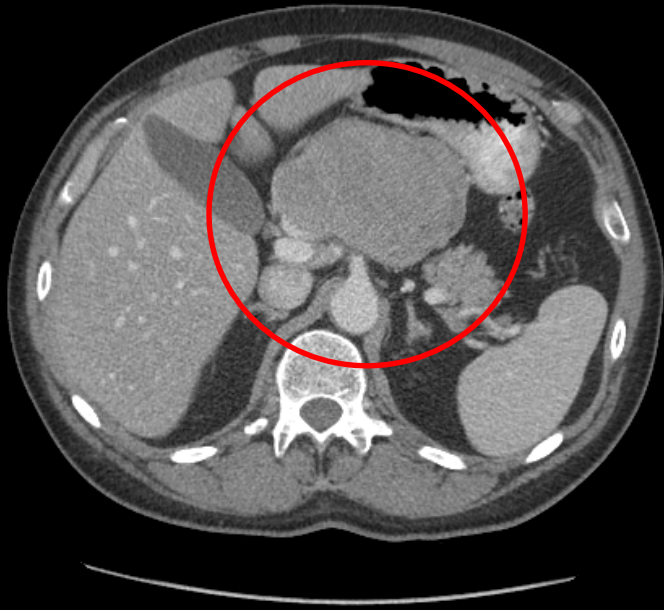
Waterfall Plot by Initial Treatment Assignment Code

Protocol: 9855

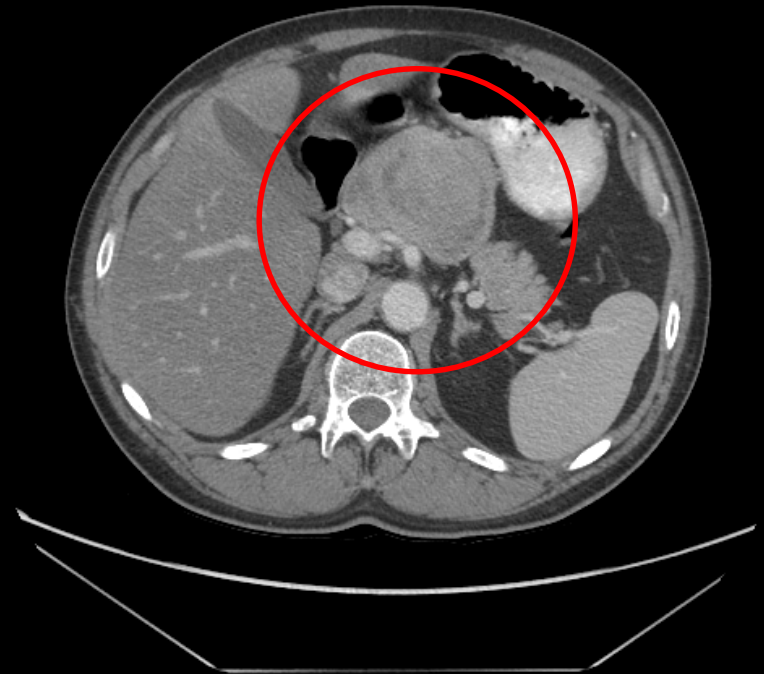


TX035-002

Jan 2016



Oct 2016



Complete response:	0
Partial response:	11% (2)
Stable disease:	68% (13)
Disease Progression:	21% (4)
Overall response rate:	11% (2)
Disease control rate:	79% (15)

Summary

- **Glembatumumab vedotin 1.9 mg/kg has been well-tolerated to date in metastatic uveal melanoma**
- **Gr 3/4 toxicities have been mainly myelosuppression**
- **First stage enrollment met trigger for continuation**
- **Second stage enrollment near complete**
- **Full study results expected in 2nd Quarter 2017**

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Protocol