

# Discussion

Charles G. Drake MD/PhD

Director: Genitourinary Oncology

Co-Director: Immunotherapy

Associate Director for Clinical Research



COLUMBIA UNIVERSITY  
MEDICAL CENTER

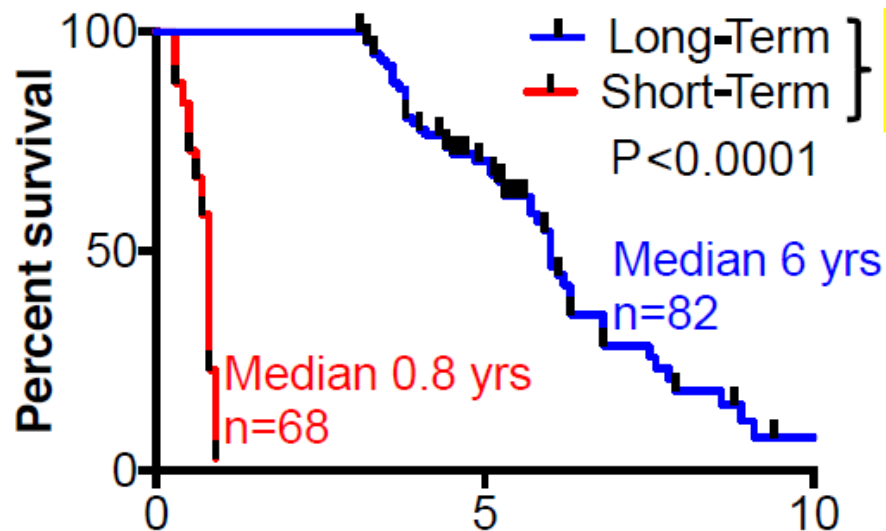
*Herbert Irving Comprehensive Cancer Center*

## Identification of unique neoantigen qualities in long-term pancreatic cancer survivors

**Vinod P. Balachandran**, Marta Łuksza, Julia N. Zhao, Vlad Makarov, John Alec Moral, Romain Remark, Daniel K. Wells, Arnold J. Levine, Douglas T. Fearon, Miriam Merad, Sacha Gnjatic, Christine A. Iacobuzio-Donahue, Jedd D. Wolchok, Ronald P. DeMatteo, Timothy A. Chan, Benjamin D. Greenbaum, Taha Merghoub, Steven D. Leach

**Surgeons Rule !**

# Overview

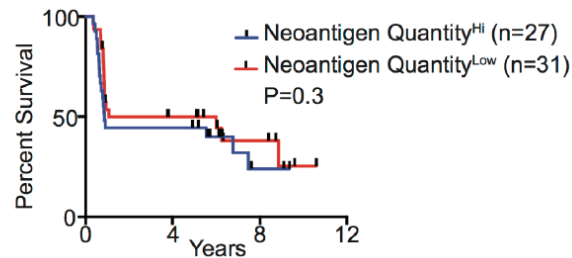
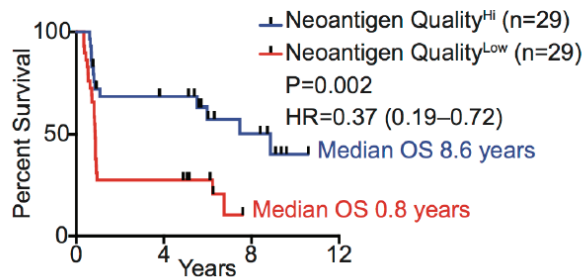


**Stage  
Matched**

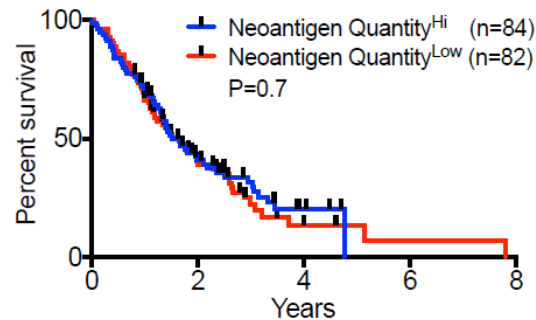
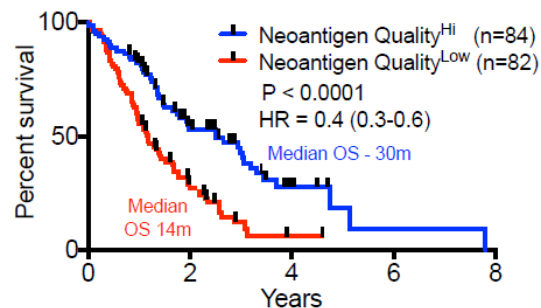
All patients had

- Surgically resected primary tumors
- No metastatic tumors
- No neoadjuvant chemotherapy

# Key Data



## International Cancer Genome Consortium



## THE LIONESS

☞ A GREAT RIVALRY existed among the beasts of the forest over which could produce the largest litter. Some shamefacedly admitted having only two, while others boasted proudly of having a dozen.

At last the committee called upon the lioness.

"And to how many cubs do you give birth?" they asked the proud lioness.

"One," she replied sternly, "but that one is a lion!"



Quality not  
quantity

# Questions

- Does 'quality over quantity' apply to other tumor types?
- Precise definition of 'quality'
- 'How much antigenicity does it take to make the immune system happy'

## Neoadjuvant nivolumab versus combination ipilimumab and nivolumab followed by adjuvant nivolumab in patients with resectable stage III and oligometastatic stage IV melanoma

- **Sangeetha M. Reddy**, RN Amaria, CN Spencer, M Tetzlaff, A Reuben, M Andrews, S Woodman, H Zhu, L Wang, S Zhang, J Blando, L Vence, H Jiang, D Gopalakrishnan, C Hudgens, K Wani, H Tawbi, A Diab, IC Glitza, SP Patel, W Hwu, M Wong, P Hwu, J Cormier, A Lucci, R Royal, JE Lee, L Simpson, E Burton, J Gershenwald, M Ross, J Allison, P Sharma, M Davies, **J Wargo**
- The University of Texas MD Anderson Cancer Center

**Surgeons Rule !**

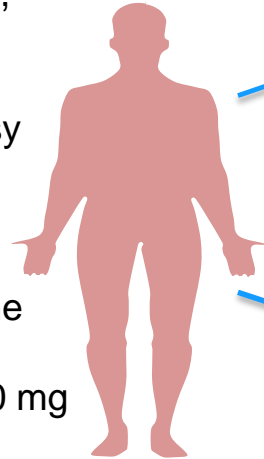
# Overview

## Inclusion Criteria

- Resectable stage IIIB/IIIC, oligometastatic stage IV melanoma
- >1 site amenable to biopsy

## Exclusion Criteria

- Brain, bone mets, LMD
- Active, known autoimmune disease
- Systemic steroid use (>10 mg prednisone daily)
- Prior anti-PD1/PD-L1, CTLA-4 treatment



Stratify by  
Stage and  
PDL1  
Status

Ipi 3mg/kg +  
Nivo 1 mg/kg  
q 3 wks x 3 doses  
(n=20)

Surgery

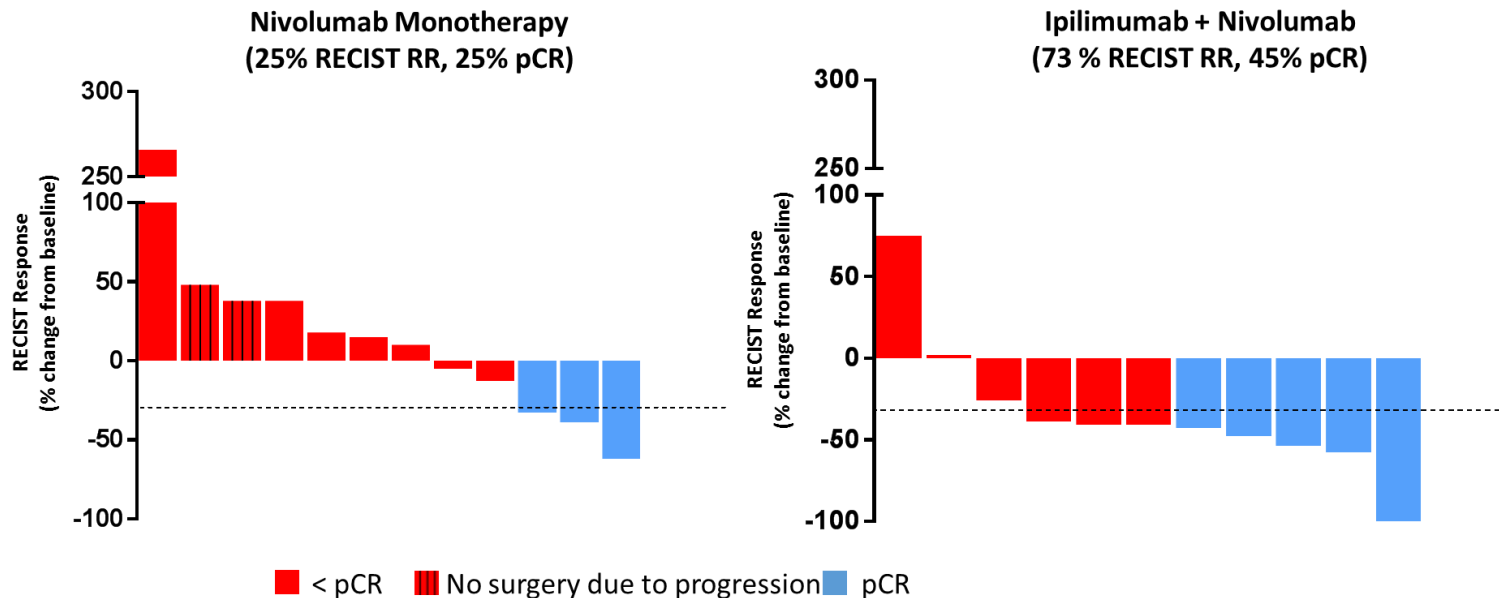
Nivo 3mg/kg  
q 2 wks x 4 doses  
(n=20)

**Primary Endpoint:**  
Path CR rate at  
surgical resection

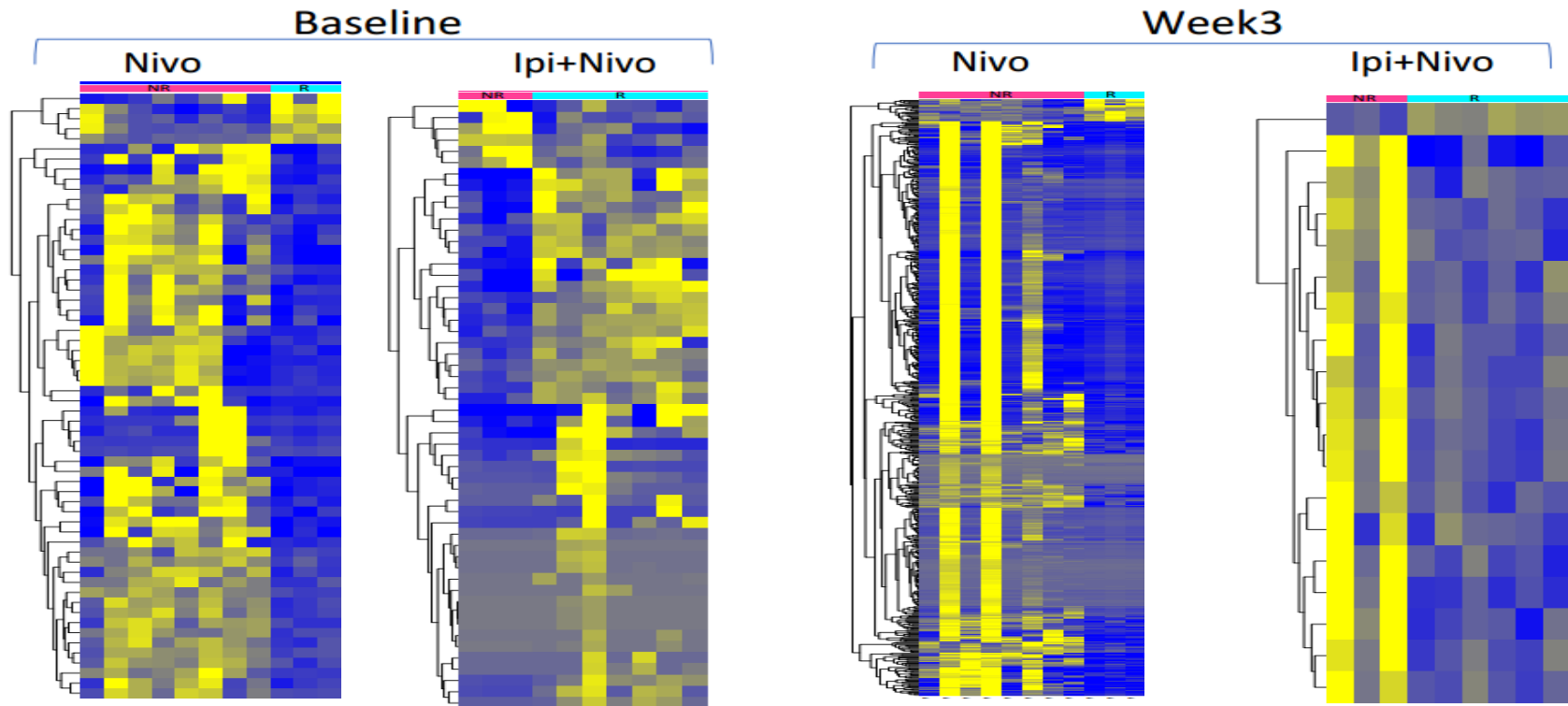
**Secondary Endpoints:**  
-RECIST 1.1  
measurement  
-Toxicity



# Key Data



# Key Data



# Take Home

- Challenging arm = Nivo (progression prior to surgery)
- Surgery feasible post Ipi / Nivo
- Profiling data invaluable



# Questions

- What about neo-adjuvant Ipi / Nivo in pts with oligo-metastatic disease?
- LT outcome
- MOA / MOR