

Gary Schwartz, MD

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Date: April 18, 2017

To: Experimental Therapeutics and Rare Tumor Committee

From: Gary Schwartz, MD

Pamela Munster, MD

Re: Experimental Therapeutics and Rare Tumor Committee Meeting

Date: Friday, May 12, 2017

Time: 3:00pm - 6:30pm Central

Location: Loews Chicago O'Hare - Rosemont, IL 60018

Room TBD

Call-In Information: (800) 501-8979 / Access Code: 8087368

AGENDA

1. Status update on activated current trials: *Munster*

| · | Status update on activated current trials. Munster | | | | |
|----|--|--|---------------|--|--|
| | A091101 | Carboplatin-paclitaxel Induction Chemotherapy and | | | |
| | | ABT-888 (Veliparib) – A Phase 1/Randomized Phase 2 | | | |
| | | Study in Patients with Locoregionally Advanced | | | |
| a. | | Squamous Cell Carcinoma of the Head and Heck | J. de Souza | | |
| | A091202 | A Phase II Study of the Peroxisome Proliferator- | | | |
| | | Activated Receptor Gamma Agonist, Efatutazone in | | | |
| | | Patients with Previously Treated, Unresectable Myxoid | | | |
| b. | | Liposarcoma | M. Pishvaian | | |
| | A091302 | Randomized Phase II study of Sorafenib With or | | | |
| | | Without Everolimus in Patients with Radioactive Iodine | | | |
| c. | | Refractory Hürthle Cell Thyroid Cancer | E. Sherman | | |
| | A091304 | A Phase I/Randomized Phase II Study of MLN-0128 vs. | | | |
| | | Pazopanib in Patients with Advanced/Unresectable | | | |
| d. | | and/or Metastatic Sarcoma | W. Tap | | |
| | A091305 | A Phase 2 Study of Efatutazone, an Oral PPAR Agonist, | | | |
| | (suspended to | in Combination with Paclitaxel in Patients with | | | |
| e. | registration) | Advanced Anaplastic Thyroid Cancer | R. Smallridge | | |

| | A091401 | Randomized Phase II Study of Nivolumab With or | |
|----|--------------------|--|-------------|
| | (suspended to pre- | Without Ipilimumab in Patients with Metastatic or | |
| f. | registration) | Unresectable Sarcoma | S. D'Angelo |
| | A091404 | A Phase II Study of Enzalutamide for Patients with | |
| g. | | Androgen Receptor Positive Salivary Cancers | A. Ho |

2. Status update on current trials in development: *Schwartz*

| | | A Randomized Trial of Adjuvant Nivolumab or Expectant | |
|----|---------|--|---------------|
| | | Observation following Neoadjuvant Ipilimumab plus | |
| | | Nivolumab and Surgical Resection of High-Risk Localized or | A. Shoushtari |
| a. | A091603 | Locoregionally Advanced Mucosal Melanoma. | R. Carvajal |
| | | Stereotactic Body Radiotherapy + anti-PD1 antibody | J. Luke |
| b. | A091605 | (pembrolizumab) in advanced Merkel Cell Carcinoma | S. Chmura |
| | | A randomized phase II study of CDX-1401 in combination | |
| | | with Atezolizumab in patients with locally advanced or | |
| c. | A091607 | metastatic NY-ESO-1 positive synovial sarcoma | S. Robinson |

3. Status of Concepts: Munster

| | Reversing Resistance to Pazopanib with Histone Deacetylase Inhibition: A | |
|----|--|--------------|
| a. | Randomized Phase 2 Study (A091702) | P. Munster |
| | Phase II Randomized Study of Atezolizumab (PDL-1 inhibitor) alone or in | |
| | combination with Obinutuzumab (anti-CD20) for Recurrent-Metastatic HPV | |
| | positive tumors, following progression of disease on previous lines of | |
| b. | therapy. | M. Matsangou |
| | A Phase II trial randomized trial of Avelumab plus Necitumumab vs. | |
| | Necitumumab alone in advanced cutaneous squamous cell carcinoma of the | |
| c. | skin (cSCC (A091701) | D. Zandberg |
| | An Open-Label Phase II Study with Safety Lead-In of MLN0128 in Children | |
| | and Young Adults with Relapsed/Refractory Rhabdomyosarcoma, Ewing | |
| d. | sarcoma, and Osteosarcoma | E. Slotkin |