

Thursday, November 16, 2017
9:00 am – 12:40 pm (Eastern)

I. Initial Review

A091605, Randomized Phase II Study of Stereotactic Body Radiotherapy + Anti-PD1 Antibody MK-3475 (Pembrolizumab) in Advanced Merkel Cell Carcinoma (Protocol Version Date 10/20/17)

II. Initial Review

EA5152, A Randomized Phase II Trial of Nivolumab, Cabozantinib Plus Nivolumab, and Cabozantinib Plus Nivolumab Plus Ipilimumab in Patients with Previously Treated Non-Squamous NSCLC (Protocol Version Date 10/17/17)

III. Initial Review

NRG-HN004, Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Stage III-IVB Head and Neck Cancer with a Contraindication to Cisplatin (Protocol Version Date 10/25/17)

IV. Continuing Review

E5204, Intergroup Randomized Phase III Study of Postoperative Oxaliplatin, 5-Fluorouracil, and Leucovorin vs Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Pre-Operative Chemoradiation (Protocol Version Date 08/19/10)

V. Continuing Review

S1605, Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (Protocol Version Date 05/22/17)

VI. Reports of Expedited Reviews October 2017

- Late Phase Emphasis CIRB Local Context Subcommittee Report
 - Expedited Reviews and Study Acknowledgements
 - Study Activation Acknowledgements
 - Amendment Activation Acknowledgements
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