Adult CIRB - Late Phase Emphasis Meeting Agenda

November 21, 2019

I Continuing Review

A091802, Phase II Randomized Trial of Avelumab Plus Cetuximab versus Avelumab Alone in Advanced Cutaneous Squamous Cell Carcinoma of the Skin (cSCC) (Protocol Version Date 08/09/19)

II Continuing Review

E1A06, An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) Versus Melphalan, Prednisone and Lenalidomide (Revlimid TM) (MPR) in Newly Diagnosed Multiple Myeloma Patients Who Are Not Candidates for High-Dose Therapy (Protocol Version Date 06/15/16)

III Continuing Review

E4512, A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein (Protocol Version Date 02/08/19)

IV Continuing Review

E5508, Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC (Protocol Version Date 10/12/18)

V Continuing Review

NRG-BN001, Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma (Protocol Version Date 02/16/17)
VI  Continuing Review


VII   New Study - Initial Review

A031803,  Phase II Trial of Intravesical Gemcitabine and MK-3475 (pembrolizumab) in the Treatment Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer  (Protocol Version Date 10/18/19)

VIII  New Study - Initial Review

A071702,  A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermutated Recurrent Glioblastoma  (Protocol Version Date 10/09/19)

IX    Amendment ReReview

S1608,  Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma  (Protocol Version Date 10/16/19)

X     Amendment

S1609,  DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors  (Protocol Version Date 10/21/19)