Adult CIRB - Late Phase Emphasis Meeting Agenda

March 17, 2022

I  Continuing Review

A031902, CASPAR - A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer (Protocol Version Date 12/10/21)

II  Continuing Review

A071801, Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared with Fractionated SRS (FSRS) for Resected Metastatic Brain Disease (Protocol Version Date 08/30/21)

III  Continuing Review

A091902, A Multicenter Phase II Trial of Paclitaxel with and without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects with Angiosarcoma (Protocol Version Date 09/07/21)

IV  Continuing Review

EA2182, A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE) (Protocol Version Date 01/27/21)

V  Continuing Review

NRG-HN005, A Randomized Phase II/III Trial of De-intensified Radiation Therapy for Patients with Early-Stage, p16-Positive, Non-Smoking Associated Oropharyngeal Cancer (Protocol Version Date 02/16/21)

VI  Continuing Review

S1619, A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma (Protocol Version Date 06/02/21)
VII  Continuing Review

S1900C, A Phase II Study of Talazoparib plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (LungMAP Sub-Study) (Protocol Version Date 04/07/21)

VIII  Continuing Review

S1931, Phase III Trial Of Immunotherapy-Based Combination Therapy With Or Without Cytoreductive Nephrectomy For Metastatic Renal Cell Carcinoma (Probe Trial) (Protocol Version Date 10/15/21)

IX  New Study - Initial Review

A042001, A Randomized Phase II Study Comparing Inotuzumab Plus Chemotherapy versus Standard Chemotherapy in Older Adults with Philadelphia-Chromosome-Negative B-cell Acute Lymphoblastic Leukemia (Protocol Version Date 02/10/22)

X  New Study - Initial Review

NRG-GY027, Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Paclitaxel and Carboplatin with Ipatasertib as Initial Therapy of Ovarian Cancer PTMA 100805 (Protocol Version Date 01/21/22)