

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 20, 2020

I Continuing Review

A041703, A Phase II Study of Inotuzumab Ozogamicin Followed by Blinatumomab for Ph-Negative CD22-Positive B-Lineage Acute Lymphoblastic Leukemia in Newly Diagnosed Older Adults or Adults with Relapsed or Refractory Disease (Protocol Version Date 06/01/20)

II Continuing Review

A091105, A Phase III, Double Blind, Randomized, Placebo-Controlled Trial of Sorafenib in Desmoid Tumors or Aggressive Fibromatosis (DT/DF) (Protocol Version Date 07/17/19)

III Continuing Review

E4412, A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma (Protocol Version Date 07/02/20)

IV Continuing Review

EA4181, A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients \leq 70 years old with Untreated Mantle Cell Lymphoma (Protocol Version Date 05/22/20)

V Continuing Review



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EA5181, Randomized Phase III Trial of MEDI4736 (durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (Protocol Version Date 02/20/20)

VI Continuing Review

NRG-HN004, Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Locoregionally Advanced Head and Neck Cancer with a Contraindication to Cisplatin (Protocol Version Date 10/04/19)

VII Continuing Review

S1404, A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma (Protocol Version Date 06/03/20)

VIII Continuing Review

S1605, Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (Protocol Version Date 03/05/20)

IX Continuing Review

S1827, MRI Brain Surveillance Alone versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK) (Protocol Version Date 01/13/20)

X Amendment

A041501, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Protocol Version Date 07/24/20)



XI Amendment

NCICOVID, NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study (Protocol Version Date 07/21/20)
