Adult CIRB - Late Phase Emphasis Meeting Agenda

April 18, 2024

I  New Study - Initial Review

EA3231, A Randomized Phase III Study of BRAF-Targeted Therapy vs Cabozantinib in RAI-Refractory Differentiated Thyroid Cancer with BRAF V600Em (Version Date 03/11/24)

II  Amendment Prior to Activation

EA7222, A Randomized Phase III Trial of Doxorubicin + Pembrolizumab Versus Doxorubicin Alone for the Treatment of Undifferentiated Pleomorphic Sarcoma (UPS) and Related Poorly Differentiated Sarcomas (Version Date 02/16/24)

III  Continuing Review

A032002, Phase II Randomized Trial of Immunotherapy Versus Immunotherapy and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (IMMORTAL) (Version Date 03/29/24)

IV  Continuing Review

A041702, A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib plus Venetoclax and Obinutuzumab in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Version Date 04/18/22)

V  Continuing Review

EA2197, Optimal Perioperative Therapy For Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial (Version Date 07/20/23)
VI Continuing Review

NRG-HN010, A Controlled, Randomized Phase II Trial of Docetaxel Plus Trastuzumab Versus Ado-Trastuzumab Emtansine for Recurrent, Metastatic, or Treatment-Naïve, Unresectable HER2-Positive Salivary Gland Cancer (Version Date 06/21/22)

VII Continuing Review

NRG-LU002, Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial (Version Date 10/18/23)

VIII Continuing Review

EA5181, Randomized Phase III Trial of MEDI4736 (durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (Version Date 06/07/22)