

**Adult CIRB - Late Phase Emphasis Meeting Agenda**

**April 20, 2023**

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**I New Study - Initial Review**

**S2212**, Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study (Version Date 03/10/23)

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**II Continuing Review**

**A082002**, A Randomized Phase II/III Trial of Modern Immunotherapy Based Systemic Therapy with or without SBRT for PD-L1-Negative, Advanced Non-small Cell Lung Cancer (Version Date 03/21/23)

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**III Continuing Review**

**EA4151**, A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease-Negative First Complete Remission (Version Date 12/10/21)

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**IV Continuing Review**

**EA6141**, Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma (Version Date 01/20/23)

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**V Continuing Review**

**NRG-GU009**, Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT) (Version Date 11/03/22)

## **VI Continuing Review**

**S2000**, A Randomized Phase II Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Symptomatic Brain Metastases (Version Date 02/03/23)

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## **VII Continuing Review**

**EA2176**, A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients (Version Date 04/22/22)

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## **VIII Continuing Review**

**EA2186**, A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT) (Version Date 04/04/22)

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