

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

**September 5, 2024**

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**I New Study - Initial Review**

**A012301**, LoTam: A Randomized, Phase III Clinical Trial of Low-Dose Tamoxifen for Selected Patients with Molecular Low-Risk Early-Stage Breast Cancer (Version Date 07/25/24)

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**II New Study - Initial Review**

**EA4232**, A Randomized Phase III Study to Evaluate Benefits of Autologous Stem Cell Transplant in Patients with Peripheral T Cell Lymphoma that Achieved a First Complete Remission (CR1) Following Induction Therapy (PTCL-STAT) (Version Date 07/19/24)

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**III New Study - Initial Review**

**MM1MDS-A01**, A Randomized Phase II Trial of Enasidenib-Based Therapies versus Cedazuridine-Decitabine in Higher-Risk IDH2-Mutated Myelodysplastic Syndrome: A MyeloMATCH Treatment Trial (Version Date 07/30/24)

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**IV Amendment**

**A052101**, A Randomized Phase 3 Trial of Continuous vs Intermittent Maintenance Therapy with Zanubrutinib as Upfront Treatment in Older Patients with Mantle Cell Lymphoma (INTERCON) (Version Date 08/02/24)

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**V Amendment Prior to Activation**

**S1900J**, A Phase II Study of Amivantamab-vmjw in Participants with MET Amplification-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study) (Version Date 07/30/24)

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## **VI Continuing Review**

**EA3161**, A Phase III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPSCC (Version Date 08/18/23)

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## **VII Continuing Review**

**EA3191**, A Phase II Randomized Trial of Adjuvant Therapy with Pembrolizumab after Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma with High Risk Features (Version Date 06/16/23)

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## **VIII Continuing Review**

**S1929**, Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) (Version Date 10/11/23)

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## **IX Continuing Review**

**S2114**, A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-Cell Treatment for Relapsed/Refractory Large B-Cell Lymphoma or Grade IIIB Follicular Lymphoma (Version Date 05/23/23)

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## **X Continuing Review**

**S1905**, A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL) (Version Date 04/17/23)

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