

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

**June 20, 2023**

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**I New Study - Initial Review**

**10590**, NORM: Nodular Lymphocyte-predominant Hodgkin Lymphoma Patients Treated in a Randomized Phase 2 Trial with Either Rituximab or Mosunetuzumab (Version Date 05/03/23)

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**II New Study - Initial Review**

**10614**, A Phase 1/2 Study of Nivolumab and Ipilimumab in Combination with Sirolimus and Prednisone in Kidney Transplant Recipients with Selected Unresectable or Metastatic Cutaneous Cancers (Version Date 05/10/23)

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**III Amendment**

**10347**, A phase I study with an expansion cohort of duvelisib and nivolumab in mycosis fungoides (MF) and Sézary syndrome (SS) (Version Date 05/08/23)

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**IV Amendment**

**10216**, A Phase Ib Study of Osimertinib (AZD9291) and Telaglenastat (CB-839) HCl in Patients with EGFR Mutant Non-Small Cell Lung Cancer (Version Date 05/02/23)

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**V Continuing Review**

**ABTC-1801**, Phase I/II Study of Pamiparib (BGB-290) with Temozolomide in Recurrent Gliomas with IDH1/2 Mutations (Version Date 07/07/22)

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## **VI Continuing Review**

**10525**, A Phase 1b Trial of ZEN003694 (ZEN-3694) with Pembrolizumab and Nab-Paclitaxel in Patients with Metastatic Triple-Negative Breast Cancer (Version Date 02/21/23)

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## **VII Continuing Review**

**10466**, A Phase 2 Study of Bevacizumab, Erlotinib and Atezolizumab in Subjects with Advanced Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC) Associated or Sporadic Papillary Renal Cell Cancer (Version Date 06/23/22)

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## **VIII Continuing Review**

**10476**, A Randomized Phase 2 Study of Combination Atezolizumab and CDX-1127 (Varlilumab) With or Without Addition of Cobimetinib in Previously Treated Unresectable Biliary Tract Cancers (Version Date 11/01/22)

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