

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

**January 17, 2023**

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**I New Study - Initial Review**

**10546**, Phase I Study Targeting DNA Methyltransferases in Metastatic Triple-Negative Breast Cancer (Version Date 11/22/22)

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**II New Study - Initial Review**

**10553**, A Phase 2 Study of Darolutamide in Combination with Leuprolide Acetate in Hormone-Therapy Naïve Recurrent and/or Metastatic Androgen Receptor (AR) Positive Salivary Gland Cancer (Version Date 11/30/22)

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**III Amendment**

**10449**, A Phase 1 Study of ZEN003694 in Combination with Binimetinib in Solid Tumors with RAS Pathway Alterations and Triple Negative Breast Cancer (Version Date 11/21/22)

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**IV Memos**

**9673**, PART A: A Multi-Institutional Phase 2 Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal PART B: A Multi-Institutional Phase 2 Study of Nivolumab or Nivolumab in Combination with Ipilimumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal (Version Date )

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**V Amendment**

**9673**, PART A: A Multi-Institutional Phase 2 Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal PART B: A Multi-Institutional Phase 2 Study of Nivolumab or Nivolumab in Combination with Ipilimumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal (Version Date 11/14/22)

## **VI Continuing Review**

**9466**, Phase I/II study of dabrafenib, trametinib, and navitoclax in BRAF mutant melanoma (Phase I and II) and other solid tumors (Phase I only) (Version Date 07/06/22)

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## **VII Continuing Review**

**10329**, Phase I Sequential Trial of Agents Against DNA Repair (STAR) (Version Date 11/14/22)

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## **VIII Continuing Review**

**S1320**, A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma (Version Date 07/22/22)

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## **IX Continuing Review**

**10382**, A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination with Copanlisib in Patients with Metastatic Triple Negative Breast Cancer (Version Date 09/21/22)

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## **X Continuing Review**

**10512**, A Phase 2 Randomized Study of the BER Inhibitor TRC102 in Combination with Standard Pemetrexed-Platinum-Radiation in Stage III Non-Squamous Non-Small Cell Lung Cancer (Version Date 03/01/22)

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## **XI Continuing Review**

**9706**, Randomized phase II study to assess the role of Nivolumab as single agent to eliminate minimal residual disease and maintain remission in acute myelogenous leukemia (AML) patients after chemotherapy (REMAIN Trial) (Version Date 03/12/21)

## **XII Continuing Review**

**9898**, A Phase I Trial of AZD9291 and Necitumumab in EGFR-Mutant Non-Small Cell Lung Cancer After Progression on a Previous EGFR Tyrosine Kinase Inhibitor (Version Date 12/07/20)

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