

Adult CIRB - Early Phase Emphasis Meeting Agenda

March 17, 2020

I Continuing Review

10089, A Randomized Phase 2 Study of CDX-1127 (Varlilumab) in Combination with Nivolumab in Patients with Relapsed or Refractory Aggressive B-cell Lymphomas (Protocol Version Date 11/07/19)

II Continuing Review

10106, A phase I and randomized phase II study of KW-0761 (Mogamulizumab) and MK-3475 (Pembrolizumab) in relapsed, refractory diffuse large-B cell lymphoma (Protocol Version Date 10/25/19)

III Continuing Review

10132, A Phase I Study of the Wee 1 kinase (Wee 1) inhibitor AZD1775 in combination with Radiotherapy and Cisplatin in Cervical, Upper Vaginal and Uterine Cancers (10041848, 10008224, 10008238, 10046888, 10014735) (Protocol Version Date 06/28/19)

IV Continuing Review

10145, Phase IB Combination Study Of Copanlisib And Nivolumab In Advanced Solid Tumors And Lymphomas (Protocol Version Date 09/04/19)

V Continuing Review

10268, Randomized Phase II Trial of Topotecan plus M6620 (VX-970) vs. Topotecan alone in Patients with Relapsed Small-Cell Lung Cancer (Protocol Version Date 12/12/19)



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VI Continuing Review

10292, DURVA+ : Evaluation of the Safety and Pharmacodynamics of Anti-PD-L1 Antibody MEDI4736 (durvalumab) in Combination with Chemotherapy in Patients with Advanced Solid Tumors (Protocol Version Date 08/29/19)

VII Continuing Review

A011203, A Randomized Phase II Trial of Tamoxifen Versus Z-Endoxifen HCL in Postmenopausal Women with Metastatic, Estrogen Receptor Positive, HER2 Negative Breast Cancer (Protocol Version Date 04/24/18)

VIII New Study - Initial Review

10346, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Protocol Version Date 02/14/20)
