A phase 1 trial of alisertib and romidepsin for relapsed/refractory aggressive B-cell and T-cell lymphomas

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Dose Level	Alisertib	Romidepsin
Level 1	20 mg orally BID on days 1-7	8 mg/m^2 IV on days 1 and 8
Level 2	20 mg orally BID on days 1-7	10 mg/m^2 IV on days 1 and 8
Level 3	40 mg orally BID on days 1-7	10 mg/m^2 IV on days 1 and 8
Level 4	40 mg orally BID on days 1-7	12 mg/m^2 IV on days 1 and 8
Level 5	20 mg orally BID on days 1,2, 3, 8, 9, 10, 15, 16, and 17	10 mg/m^2 IV on days 2, 9, and 16
Level 6	30 mg orally BID on days 1,2, 3, 8, 9, 10, 15, 16, and 17	10 mg/m^2 IV on days 2, 9, and 16
Level 7	30 mg orally BID on days 1,2, 3, 8, 9, 10, 15, 16, and 17	12 mg/m^2 IV on days 2, 9, and 16
Level 8	40 mg orally BID on days 1,2, 3, 8, 9, 10, 15, 16, and 17	12 mg/m^2 IV on days 2, 9, and 16

Supplemental Table 1. Treatment regimen.

Cycles were repeated every 21 days for levels 1-4, and amended to every 28 days for levels 5-8 (due to observation of prolonged count recovery), provided resolved cytopenias: ANC $\geq 1.0 \times 10^9$ /L and platelet count $\geq 75 \times 10^9$ /L. Patients with an ANC $<1.0 \times 10^9$ /L were eligible to receive granulocyte-colony stimulating factor at the discretion of the treating physician.

Patients who were considered to be transplant candidates received a minimum of 2 cycles prior to proceeding on with mobilization chemotherapy for autologous SCT or conditioning chemotherapy for an allogeneic SCT. Patients assessed to not be a transplant candidate could receive up to 8 cycles of therapy.