**Trial in Progress: Phase 3 Randomized Study of Investigational Drug Alisertib (MLN8237) vs Investigator’s Choice in Patients (pts) with Relapsed/Refractory (rel/ref) Peripheral T-cell Lymphoma (PTCL): The LUMIERE Trial**

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**Background:** PTCL is an aggressive form of non-Hodgkin lymphoma (NHL), accounting for 5–10% of NHL diagnoses. Standard NHL therapies developed primarily for B-cell lymphomas are not optimal for PTCL and early relapse is common. Only a minority of pts are eligible for bone marrow transplantation and the majority of transplanted pts will relapse. Approved therapies for rel/ref PTCL in the USA include pralatrexate and romidepsin; elsewhere, gemcitabine is frequently used although not approved for this indication. The oral, investigational drug alisertib is a selective inhibitor of Aurora A kinase (AAK) – a key mitotic regulator overexpressed or amplified in various human tumors. Phase 2 data on single-agent alisertib in rel/ref aggressive T-cell lymphoma (Friedberg et al, J Clin Oncol 2014) support this phase 3 trial in rel/ref PTCL.

**Trial design:** This open-label phase 3 study (NCT01482962) will enroll up to 354 adults with rel/ref PTCL after ≥1 prior systemic cytotoxic therapy at approximately 140 centers in 27 countries worldwide. Pts will be randomized 1:1 to alisertib 50 mg twice daily as an enteric coated tablet on d 1–7 of 21-d cycles, or to investigator’s choice of: pralatrexate 30 mg/m² IV once weekly for 6 weeks in 7-week cycles; romidepsin 14 mg/m² IV on d 1, 8, 15 of 28-d cycles; or gemcitabine 1000 mg/m² IV on d 1, 8, 15 of 28-d cycles. Disease subtype must be centrally confirmed. Pts having previously received all comparator drugs are ineligible. Pts will not receive a comparator drug previously received. Crossover to alisertib is not permitted. Primary endpoints are overall response rate and progression-free survival by International Working Group criteria assessed by central review. Secondary endpoints include complete response rate, overall survival, time to progression, time to response, response duration, safety, and quality of life. Exploratory endpoints include candidate biomarker (e.g. AAK, Ki-67) evaluation in tumor biopsies. 205 pts have been randomized as of 15 April 2014. This abstract was accepted and previously presented at the Pan-Pacific Lymphoma Conference in Hawaii on 21/25 July 2014.

**Disclosure:** H. Liu, X. Zhou, C. Dansky Ullmann, V. Kelly and E.J. Leonard: Employment: Takeda; O’Connor: Advisory board membership: Takeda Honoraria: Takeda, Seattle Genetics Research funding: Takeda. All other authors have declared no conflicts of interest.