Pixantrone: An Overview of Phase II and Phase III Studies in Non-Hodgkin’s Lymphoma

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BACKGROUND

Antiangiogenic

• Among the most active class of agents in non-Hodgkin’s lymphoma (NHL) in recent years. Several agents in this class are in clinical development including CC-4016, CC-1406, bevacizumab, and SU5416.

• The standard of care for 1st line aggressive NHL is CHOP-R.

• Infrequently used in relapsed NHL, even in sensitive patients, due to cumulative cardiac toxicity.

PAL: 16 mg/m2 Days 1, 8, 15 or 28 days.

Study Design – Single Agent

• Study Type: Intergroup phase II study.

• Inclusion criteria: 60-70 years of age; Eastern Cooperative Oncology Group (ECOG) ≤ 1; histologically documented & evaluable NHL; ≥ 10% increase in tumor size or symptoms.

• Exclusion criteria: prior chemotherapy, radiotherapy; myelosuppression ≥ grade 3; any significant organ dysfunction.

• Treatment: Palifermin 100 mcg/kg subcutaneously on the first and fourth day of treatment.

• Endpoints: ORR per modified World Health Organization (WHO) criteria. Durable complete remission (CR) defined as > 1 year in duration.

• Randomization: 1:1 ratio: Palifermin vs. no Palifermin.

• Follow-up: 5 years.

• Palifermin: CR 25.7% (20/78); CRu 0.0% (0/78). No CRu in either group.

• No significant differences were observed between the two groups for any of the endpoints.

• Conclusion: Palifermin does not appear to improve the efficacy of chemotherapy in this patient population.

REFERENCES

1. Schiffer CA et al, J Clin Oncol 2005

2. Rowinsky et al, J Clin Oncol 2006