

LS1681: A Phase I Trial of AR160 (Abraxane/Rituximab 160nm nanoparticle) in Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (NHL) including Transformed Follicular Lymphoma

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Background:

Relapsed refractory B-cell lymphoma is a clinically significant problem in all B-cell malignancies. New therapeutic approaches are required. AR160 is a macromolecular complex consisting of a clinical grade paclitaxel-containing nanoparticle (nab-paclitaxel, Abraxane®) that is non-covalently coated with clinical grade rituximab (Rituxan®, anti-CD20 recombinant monoclonal antibody). Preclinical testing of the AR160 nano-immunoconjugate demonstrated significant antitumor activity with evidence of targeted delivery into a mouse model of non-Hodgkin lymphoma (Nevala et al. Sci Rep. 2017;45682).

Methods:

Patients age ≥ 18 years with a histological confirmation of relapsed/refractory B-cell non-Hodgkin lymphoma who failed or are intolerant to 2 or more lines of established therapy or for whom no other treatment options are available in the opinion of the investigator with at least 1 lesion ≥ 1.5 cm in one diameter with an ECOG performance status of 0-2 are eligible. A standard 3 + 3 phase I clinical trial design was chosen to determine the primary endpoint of the maximally tolerated dose and secondary goals to assess toxicity profile, pharmacokinetics, complete response rate, progression free survival, and overall survival. Patients are treated for a maximum of 12 cycles with each cycle length of 28 days. AR160 is administered on days 1, 8, and 15 every 28 days. Dose level 0 was 100 mg/m² of abraxane and 40 mg/m² of rituximab. A maximum of 2 dose reductions are allowed. CTCAE v. 5.0 is incorporated to assess adverse events.

Clinical trial information: NCI-2016-01984; NCT03003546