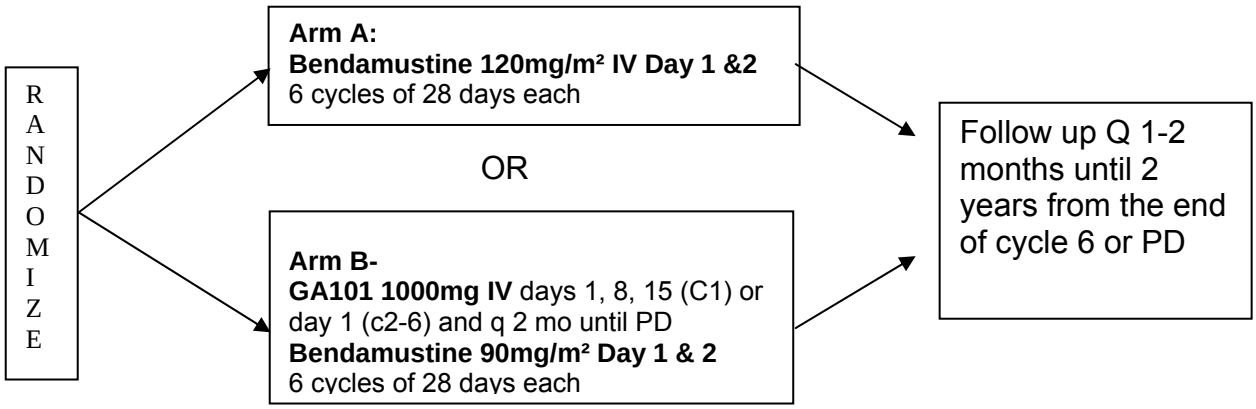
**HO09414--AN OPEN-LABEL PH III STUDY OF BENDAMUSTINE COMPARED WITH BENDAMUSTINE + RO5072759 (GA101) IN PATIENTS WITH RITUXIMAB-REFRACTORY, INDOLENT NON-HODGKIN'S LYMPHOMA**




MAJOR ELIGIBILITY CRITERIA:

- Histologically documented CD 20+, indolent NHL (including follicular lymphoma, grades 1-3a; marginal zone (splenic, nodal and extra-nodal) and small lymphocytic lymphoma with an absolute lymphocyte count <5000
- Refractory to a regimen containing rituximab, defined as no response to, or progression within 6 months of completion of last dose of rituximab therapy, (as monotherapy or in combination with chemotherapy). Qualifying Rituximab therapy does not have to be most recent therapy
- Previously treated with a maximum of 3 unique chemotherapy-containing treatment regimens (a regimen = at least 2 cycles). Prior auto transplant or radioimmunotherapy is permitted if completed at least 6 mo prior to entry
- Bidimensionally measurable disease with at least 1 lesion ≥ 1.5cm in its largest dimension
- Must have a tissue block or slides from a biopsy available for central review for CD20+
- Hematologic, hepatic and renal function parameters satisfying the following:
    - AST ≤2.5 times upper limit of normal(ULN) and ALT≤2.5 times ULN
    - Total bilirubin ≤ 3 times ULN
    - Serum creatinine ≤1.5 times ULN
    - Hemoglobin ≥10.0 g/dL
    - ANC≥1500 $x10^9$ unless due to disease as established by extensive bone marrow disease
    - PLT≥75,000 $x10^9$ unless due to disease as established by extensive bone marrow disease
    - No + HBsAg (hepatitis B surface antigen), HB core antibody, or HCV (hepatitis C) serology, no known history of seropositive HIV status, no HTLV 1 virus
- 18 years or older, ECOG PS≤2
- No prior use of a monoclonal (except antiCD20) within 3 months
- No chemo or other investigational therapy within 28 days prior to the start of C1D1
- No ongoing corticosteroid use > 30mg/day prednisone or equivalent
- No CNS lymphoma or histologic evidence of transformation to high grade or DLBCL
- No vaccination with live vaccines for a minimum of 28 days prior to randomization
- No known *active* bacterial, viral, fungal, mycobacterial, parasitic, or other infection requiring treatment with IV antibiotics or hospitalization within 4 weeks of the start of Cycle 1
- No evidence of significant, uncontrolled concomitant diseases that could affect compliance with protocol, such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within 6 months, unstable arrhythmias or angina or pulmonary disease (COPD or history of brochospasm)

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- Prior malignancies: curatively treated basal or squamous cell carcinoma of the skin or in situ carcinoma of the cervix are generally eligible. Other malignancies treated and in remission for at least 2 years are allowable.

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