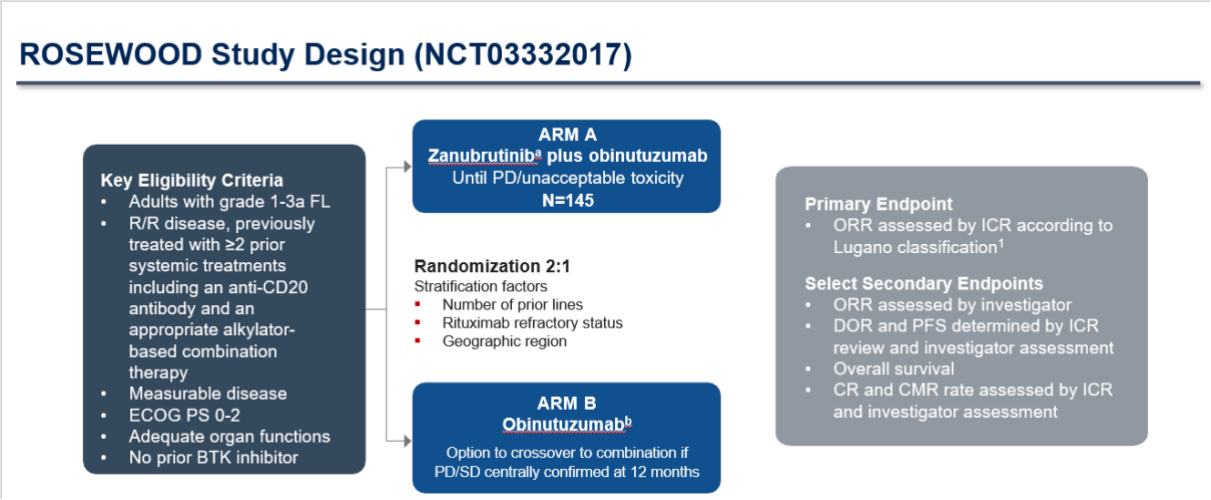
THE ROSEWOOD TRIAL (NCT03332017) – A Global Phase 2 Trial Comparing Zanubrutinib Combined With Obinutuzumab Compared to Obinutuzumab Monotherapy in Relapsed/Refractory (R/R) Follicular Lymphoma

ABOUT THE TRIAL

The ROSEWOOD trial examines zanubrutinib plus obinutuzumab versus obinutuzumab monotherapy in patients with R/R follicular lymphoma (FL) who have received ≥2 prior lines of therapy.

TRIAL DESIGN[i]



- Randomized, open-label, Phase 2 trial comparing the highly selective next generation BTK inhibitor zanubrutinib combined with obinutuzumab compared to obinutuzumab monotherapy.
- 2:1 assignment of patients to receive oral zanubrutinib 160 mg twice daily + obinutuzumab or obinutuzumab alone (both arms in 28-day cycles, at 1000 mg IV on days 1, 8, and 15 of cycle 1; day 1 of cycles 2-6; and then once every 8 weeks) until progressive disease (PD), toxicity or a maximum of 30 mo of obinutuzumab.
- Stratified randomization by prior therapies (2-3 vs >3), rituximab-refractory status and geographic region.
- Patients in the obinutuzumab arm may cross over to the combination arm if progressive disease or stable disease is centrally confirmed after 12 months.
- A total of 217 patients were enrolled from research sites in Asia, Australia, North America and Europe.

Primary Efficacy Endpoint:
Overall Response Rate assessed by Independent Committee Review according to Lugano classification[ii]
Key secondary endpoints: Overall Response Rate assessed by investigator; Duration of Response and Progression Free Survival determined by ICR review and investigator assessment; Overall Survival; Complete Response and Complete Metabolic Response rates assessed by ICR and investigator assessment.

[i] Fowler, Nathan H., Judith Trotman, Rebecca Auer, et.al. *Blood* 134 (2019): 5252.
[ii] Cheson BD. *J Clin Oncol.* 2014;32(27):3059-3068