M16-788: Debulking Regimens Prior to Initiating Venetoclax and Obinutuzumab Combination Therapy in Frontline CLL

Staged Debulking

- **1L CLL N = 100**
- 2 Months Debulking
- Low-Risk Patients Begin Treatment
- CT/ALC
- 2 Months Debulking
- CT/ALC
- 2 Months Debulking

Treatment (1 year)

- Obinutuzumab (Gazyva) x 5 months + Venetoclax x 12 months

Endpoints

1° Endpoint
- % patients to achieve low tumor burden at end of cycle 2/4/6
- Overall safety and efficacy (CR/CRi rate) of the regimen

2° Endpoints
- ORR, PFS, DOR, TTP, OS, MRD in the peripheral blood

Dosing

**Staged Debulking**
- Obinutuzumab (IV): Loading 1st cycle as per label, followed by 1,000 mg day 1, cycle 2-6 as needed
- *Bendamustine (IV): 900 mg/m² days 1 and 2, or days 2 and 3 cycles 1-6 as needed

**Treatment**
- Obinutuzumab (IV): 1,000 mg for 5 cycles
- Venetoclax (po): Ramp up per label for 1st cycle then 400 mg daily for 11 additional months (12 total)

* Bendamustine recommended for patients with bulky LAD or del(11q)

Eligibility

- Untreated CLL requiring treatment per iwCLL criteria
- Medium or High-Risk for TLS
- Absence of del(17)


To learn more about our pipeline, please visit www.abbvie.com/oncology

Venetoclax is being investigated for indications that have not been approved by Regulatory Health Agencies. Safety and Efficacy have not been established in unapproved indications.

To learn more about these studies, please visit https://ClinicalTrials.gov or email abbvieclinicaltrials@abbvie.com