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Poster Discussion Session (Board #17), Mon, 1:15 PM-5:15 PM and  
4:45 PM-5:45 PM**Secondary efficacy subanalysis by histology from the phase III BRIGHT study: First-line bendamustine-rituximab (BR) compared with standard R-CHOP/R-CVP for patients with advanced indolent non-Hodgkin lymphoma (NHL) or mantle cell lymphoma (MCL).**

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**Background:** BR was previously reported to be statistically noninferior to R-CVP/R-CHOP for complete response rate in the treatment of patients with indolent NHL or MCL. Evaluation of time-to-event outcomes is immature. This subanalysis reports response by histology. **Methods:** Indolent NHL or MCL was histologically confirmed <6 months before study enrollment in patients who were therapy-naïve. Patients were stratified according to predetermined standard treatment (R-CHOP or RECVP) and lymphoma type, then assigned to receive BR (28-day cycles: bendamustine 90 mg/m<sup>2</sup> on days 1 and 2, rituximab 375 mg/m<sup>2</sup> on day 1) or standard treatment (21-day cycles at standard doses) for 6-8 cycles. Responses were assessed by a blinded independent review committee. The primary efficacy measure was noninferiority of BR complete response (CR) rate for evaluable patients with ≥1 postbaseline efficacy assessment. If the noninferiority threshold was met, superiority was assessed. Secondary measures included tolerability. **Results:** Of 447 patients enrolled in the study, 213 receiving BR and 206 receiving R-CHOP/R-CVP were evaluable with postbaseline data (Table). BR achieved a statistically noninferior CR rate compared with R-CHOP/R-CVP in patients with indolent NHL and MCL. **Conclusions:** In patients with treatment-naïve indolent NHL and MCL, BR achieved the primary endpoint of noninferior CR rate. Most CR rates were numerically, but not significantly, higher with BR. Small subgroup results should be interpreted with caution. Support: Teva BPP R&D, Inc. Clinical trial information: NCT00877006.

**Response rates.**

| n/N (%)           | CR          |              |                   | CR + partial response |              |
|-------------------|-------------|--------------|-------------------|-----------------------|--------------|
|                   | BR          | R-CHOP/R-CVP | CR ratio [95% CI] | BR                    | R-CHOP/R-CVP |
| Indolent NHL      | 49/178 (28) | 43/174 (25)  | 1.11 [0.78, 1.59] | 173/178 (97)          | 160/174 (92) |
| Follicular        | 45/148 (30) | 37/149 (25)  | 1.23 [0.85, 1.78] | 147/148 (>99)         | 140/149 (94) |
| Lymphoplasmacytic | 0/5         | 1/6 (17)     | 0.39 [0.02, 7.88] | 3/5 (60)              | 6/6 (100)    |
| Marginal zone     | 5/25 (20)   | 4/17 (24)    | 0.84 [0.26, 2.66] | 23/25 (92)            | 12/17 (71)   |
| MCL               | 17/34 (50)  | 9/33 (27)*   | 1.76 [0.91, 3.42] | 32/34 (94)            | 28/33 (85)*  |

\* R-CHOP, n = 22.