



WM

## Waldenström macroglobulinemia: Six-year follow-up of phase II trial into front-line BDR in the treatment of newly diagnosed patients



Karl Kemp-O'Brien | Dec 20, 2016

In November 2016, Maria Gavriatopoulou from the National and Kapodistrian University of Athens School of Medicine, Greece, and colleagues published in Blood the results of the six-year follow-up of a multi-center phase II study into the efficacy of chemotherapy-free bortezomib, dexamethasone, and rituximab (BDR) in newly diagnosed WM patients. The study enrolled 59 patients over 10 centers in Europe.

The BDR treatment regimen was 23 weeks long; the first cycle was 21 days with bortezomib IV 1.3mg/m<sup>2</sup> on days 1, 4, 8, and 11. Bortezomib was then administered weekly for a further four 35-day cycles at 1.6mg/m<sup>2</sup>. On cycles 2 and 5, IV dexamethasone and IV rituximab were also delivered at 40mg and 375mg/m<sup>2</sup> doses, respectively.

### Highlights:

- Majority of patients recruited were intermediate (40%) or high (45.5%) according to IPSSWM
- ITT analysis:
  - 85% responded with 3% CR, 7% VGPR, 58% PR, 17% MR
  - Major response rate (PR + VGPR + CR) of 68%
- Median PFS: 43 months (with 17% in remission after a median of 90 months)
- 7-year PFS and 7-year OS by risk:
  - Low IPSSWM = 62.5% and 87.5%
  - Intermediate IPSSWM = 42% and 68.2%
  - High IPSSWM = 15% and 48%
- 7-year overall OS = 66%
- Peripheral neuropathy in 46% patients, but this resolved completely or to grade I

The authors concluded by stating that toxicity was mild and that BDR was an active chemotherapy-free treatment, which was shown to result in durable responses over a 6 year follow-up period.

**Reference:**

1. Gavriatopoulou M. et al. BDR in newly diagnosed patients with WM: final analysis of a phase 2 study after a minimum follow up of 6 years. Blood. 2016 Nov 21. DOI: <https://doi.org/10.1182/blood-2016-09-742411>. [Epub ahead of print].

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