

***Blood* Abstracts: 54th ASH Annual Meeting Abstracts; Vol. 120, Issue 21, 16 Nov 2012**

Abstract 2739 Bendamustin-Rituximab Induction Followed by Observation or Rituximab Maintenance for Newly Diagnosed Patients with Waldenström's Macroglobulinemia: Results From a Prospective, Randomized, Multicenter Study (StiL NHL 7-2008 – MAINTAIN-; ClinicalTrials.gov Identifier: NCT00877214)

Mathias J. Rummel, MD^{1*}, Christian Lerchenmüller, MD^{2*}, Richard Greil, MD³, Martin Görner^{4*}, Manfred Hensel, MD⁵, Erik Engel^{6*}, Ulrich Jaeger, MD⁷, Friedhelm Breuer^{8*}, Bernd Hertenstein^{9*}, Otto Prummer, MD, PhD¹⁰, Christian Buske, MD¹¹, Juergen Barth^{12*}, Alexander C. Burchardt, MD^{13*} and Wolfram Brugger¹⁴

¹Dept. of Hematology & Oncology, Justus-Liebig Universität Giessen, Giessen, Germany

²Hämatologisch-onkologische Gemeinschaftspraxis, Münster, Germany

³Department of Internal Medicine III, University Hospital Salzburg, Salzburg, Austria

⁴Städtische Kliniken, Bielefeld, Germany

⁵Mannheimer Onkologie Praxis, Mannheim, Germany

⁶Hämatologische Praxis Hamburg Altona (HOPA), Hamburg, Germany

⁷Hematology, Medical University of Vienna, Vienna, Austria

⁸Praxis, Frechen, Germany

⁹Hämatologie und Onkologie, Klinikum Bremen Mitte, Bremen, Germany

¹⁰Klinikum Kempten-Oberallgäu, Kempten, Germany

¹¹University Hospital of Ulm, Institute of Experimental Cancer Research, Ulm, Germany

¹²Hematology, Justus-Liebig Universität Giessen, Giessen, Germany

¹³Hematology, University Hospital of Gießen, Giessen, Germany

¹⁴Hospital Villingen-Schwenningen, Villingen-Schwenningen, Germany

Background: Bendamustine-rituximab (B-R) has demonstrated substantial efficacy in the primary treatment of indolent lymphomas. A multicenter prospective randomized trial was initiated to investigate the impact of adding rituximab maintenance following B-R first-line induction. The trial included patients (pts) with Waldenström's Macroglobulinemia (WM), marginal zone, small lymphocytic and mantle cell lymphomas. Here we present first and preliminary results for pts with WM.

Methods: Treatment consisted of a maximum of 6 cycles of B-R (bendamustine 90 mg/m², rituximab 375 mg/m²) administered every 28 days plus 2 cycles of rituximab every 4

weeks. Responding pts (\geq PR) were eligible for further treatment and were randomized to observation or 2 years of rituximab maintenance every two months. The primary endpoint is PFS.

Results: From April 2009 to July 2012, 57 centers included a total of 162 pts with newly diagnosed WM with a median age of 67 years (31% < 60 years, 69% > 60 years). At baseline/inclusion/screening, the median values for b₂-microglobulin (b₂M), hemoglobin and IgM were 3.3 mg/L, 10.1 g/dL and 2110 mg/dL (max. 13400 mg/dL), respectively. To date (Aug 2012) 116 pts are evaluable for response (43 women [37%] and 73 men [63%]). 100 pts have responded to B-R leading to an overall response rate (ORR) of 86%. At the time of response evaluation, the median Hb was 12.6 g/dl and the median IgM was 380 mg/dl.

90 pts have undergone randomization to date, 43 to observation and 47 to maintenance. Randomization is ongoing. No results can be reported from that ongoing part of the trial. No uncommon toxicities were observed during B-R induction.

Conclusion: Initial results of our trial confirm that for patients with Waldenström's macroglobulinemia, treatment with B-R is an efficacious treatment with a manageable safety profile. The role of rituximab maintenance in this disease is under investigation.

Disclosures: No relevant conflicts of interest to declare.

[Back to Category: Lymphoma - Therapy with Biologic Agents, excluding Pre-Clinical Models](#)
[<< Go to Previous Abstract](#) || [Go to Next Abstract >>](#)

* *signifies non-member of ASH*