Efficacy and time to next treatment following lenalidomide/rituximab (R^2) or rituximab/placebo in patients with R/R indolent NHL (AUGMENT).

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Authors:
John G. Gribben, Koji Izutsu, Nathan Hale Fowler, Xiaonan Hong, Huilai Zhang, Fritz Offner, Adriana A. S. Scheliga, Grzegorz S. Nowakowski, Antonio Pinto, Francesca Re, Laura Maria Fogliatto, Phillip Scheinberg, Ian Flinn, Cláudia Moreira, Stacey Anastasia Kalambakas, Pierre Fustier, Chengqing (Alan) Wu, John Paul Leonard; Centre for Haemato-Oncology, Barts Cancer Institute, Queen Mary University of London, London, United Kingdom; National Cancer Center Hospital, Tokyo, Japan; The University of Texas MD Anderson Cancer Center, Department of Lymphoma/Myeloma, Houston, TX; Department of Medical Oncology, Fudan University Shanghai Cancer Center, Shanghai, China; Tianjin Medical University Cancer Institute and Hospital, Tianjin, China; Universitair Ziekenhuis Gent, Ghent, Belgium; INCA Instituto Nacional De Câncer, Rio De Janeiro, Brazil; Mayo Clinic, Rochester, MN; Istituto Nazionale Tumori "Fondazione G.Pascale"- IRCCS, Naples, Italy; Azienda Ospedaliero-Universitaria di Parma, Parma, Italy; Hospital de Clinicas de Porto Alegre, Porto Alegre, Brazil; Hospital A Beneficência Portuguesa de São Paulo, São Paulo, Brazil; Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN; Instituto Portugues de Oncologia Do Porto Francisco Gentil Epe, Porto, Portugal; Celgene Corporation, Summit, NJ; Celgene Corporation, Boudry, Switzerland; Meyer Cancer Center, Weill Cornell Medical College, New York-Presbyterian Hospital, New York, NY

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Abstract Disclosures

Background:
Relapse is expected in treated indolent lymphoma patients, and an unmet need exists to prolong remission with effective therapies. Lenalidomide + rituximab (R^2) may improve the efficacy of next treatment by their unique mechanisms.

Methods:
The AUGMENT phase III study evaluated patients with R/R FL gr 1-3a (82%) and MZL (18%) after ≥ 1 prior systemic therapy (not rituximab refractory). Randomization was 1:1 to R^2 (lenalidomide PO 20 mg/d, d1-21/28 X12 cycles [c] + rituximab [R] IV 375 mg/m^2/wk, c1, d1, 8, 15, 22 and c2-5, d1) and R/placebo (same dosing schedule). The primary endpoint was PFS by 2007 IWG; secondary/exploratory

analyses were time to next antilymphoma/chemotherapy treatment (TTNLT/TTNCT) and response to next treatment. Per regulatory guidance, PFS2 was defined as time from randomization to first PD or death from any cause after next antilymphoma treatment, or initiation of a third antilymphoma treatment.

Results:

Median PFS was superior for R^2 over R/placebo (39.4 vs 14.1 mo; HR = 0.46; *P*< 0.0001). As of 22June2018, median TTNLT, TTNCT, and PFS2 were not reached for R^2, and were significantly longer than R/placebo (HR = 0.54, 0.50, and 0.52, respectively). For 49/178 (28%) R^2 and 80/180 (44%) R/placebo patients receiving next antilymphoma therapy, response was generally higher with R^2 (57% ORR; 31% CR) than R/placebo (36% ORR; 16% CR; Table).

Conclusions:

These analyses suggest that R^2 (vs R/placebo) prolonged time to subsequent treatment and is associated with longer PFS2, enabling greater response to next therapy. Although patient numbers were modest, it is hypothesized that patients who received R^2 were generally more sensitive to subsequent therapy than those treated with R/placebo. Clinical trial information: NCT01938001

Response to next treatment after R^2 and R/placebo.

	Response after R^2		Response after R/placebo	
Treatment (R^2 n/ R/placebo n)	ORR, %	CR, %	ORR, %	CR, %
Single agent chemo (n = 8/14)	63	38	36	21
Other R-Chemo combo (n = 7/11)	43	29	64	18
Other (n = 9/10)	44	22	40	30
Combo chemo (n = 2/15)	0	0	27	0
Single agent targeted therapy (n = 7/8)	43	14	13	0
R-Benda (n = 5/10)	100	40	40	30
R monotherapy (n = 3/4)	67	67	25	0
O-Chemo (n = 3/3)	100	67	67	33
R-CHOP (n = 3/2)	67	33	0	0
Combo targeted therapies (n = 2/3)	50	0	33	33