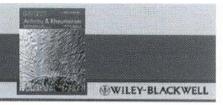
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Arthritis & Rheumatism, Volume 65, October 2013 Abstract Supplement

Abstracts of the 2013 American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting

San Diego, CA October 25-30, 2013.

Final 5-Year Safety And Efficacy Results Of A Phase 3, Randomized Placebo-Controlled Trial Of Golimumab In Patients With Active Rheumatoid Arthritis Despite Prior Treatment With Methotrexate.

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Background/Purpose:

The safety and efficacy of subcutaneous golimumab (GLM)+/-MTX has been evaluated through 2yrs in a phase 3 trial (GO-FORWARD) of pts with active rheumatoid arthritis (RA) despite MTX therapy. Final safety and efficacy results through 5yrs are reported.

Methods:

Pts in GO-FORWARD were randomized to placebo (PBO)+MTX, GLM 100mg+PBO, GLM 50mg+MTX, or GLM 100mg+MTX q4w. PBO+MTX pts crossed over to GLM+MTX at wks 16 (blinded early escape) or 24 (crossover). Pts continued treatment at wk52 (start of long-term extension). After the last pt completed wk52 and unblinding occurred, MTX and corticosteroid use could be adjusted, and a one-time GLM dose increase (50 à 100mg) or decrease (100 à 50mg) was permitted based on investigator judgment. The last GLM injection was at wk252. Observed efficacy results (ACR20/50/70, DAS28-CRP, HAQ-DI, radiographic) by randomized treatment group and cumulative safety data are reported through wks 256 and 268, respectively.

Results:

A total of 444 pts were randomized; 313 pts continued treatment through wk252, and 131 pts withdrew (64 for AE, 25 for lack of efficacy, 1 protocol violation, 6 lost to follow-up, 32 for other reasons, 3 deaths). 301 completed the safety follow-up through wk268. Efficacy results are presented in the table. At wk256, 76.0% of all pts had an ACR20, 89.5% had a DAS28-CRP EULAR response, and 68.5% had improvement in HAQ-DI ≥0.25. Changes from baseline in mean total vdH-S scores were small; 54% of pts randomized to GLM+MTX had no radiographic progression (DvdH-S≤0). The most common AEs were upper respiratory tract infection



Meeting Menu 2013 ACR/ARHP Meeting Authors Meeting Abstracts (32.9%), nasopharyngitis (17.1%), and bronchitis (17.1%); 9.2% of pts had an injection-site reaction. Through wk268, 172/434 pts (39.6%) had an SAE; 14.1% of pts discontinued study agent due to AEs. The rates of serious infections, malignancies, and death were 11.5%, 6.2%, and 1.8%, respectively. Of 429 pts with available samples, 33 (7.7%) were positive for antibodies to GLM.

Table. Efficacy results at wk256

3%) 57/74 (77.09) 6%) 40/74 (54.19) 28/74 (37.89) 65/73 (89.09) 65/73 (47.99) 67/3 (47.99) 63.09 1%) 46/73 (63.09) 63.09 4%) 55/74 (74.39)	4 (%) 44 (%) 28 (4 (%) 15 (3 (%)) 32 (3 (%)) 37 (3 (%)) 38 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4	/60 (28.3%)	241/317 (76.0%) 159/317 (50.2%) 91/317 (28.7%) 281/314 (89.5%) 141/314 (44.9%) 83/315 (26.3%) 199/315 (63.2%)
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1	70)		217/317 (68.5%)
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0.3 ±	1.2 0.7	7 ± 2.2	0.7 ± 2.0
1.7 ±	6.1 3.3	3 ± 10.2	3.3 ± 9.4
		/65 (46.2%)	172/338 (50.9%)
4	1.7 ± 47/79 (59.5	1.7 ± 6.1 3.3 47/79 (59.5%) 30 0 mg or 100mg, and MT	1.7 ± 6.1 3.3 ± 10.2

dChange in vdH-S score divided by GLM treatment duration per pt.

Conclusion:

The retention rate was high (70.5%), and improvements in signs/symptoms of RA and in physical function with GLM+MTX therapy were maintained long-term. Radiographic progression appeared controlled with small changes in mean vdH-S scores observed through 5yrs. The long-term safety of GLM is consistent with other anti-TNFa agents.

Disclosure: E. Keystone, Abbott, Amgen, AstraZeneca, Baylis Medical, Bristol-Myers Squibb, F-Hoffman-LaRoche, Janssen, Lilly Pharmaceuticals, Novartis, Pfizer, Sanofi-Aventis, UCB, 2, Abbott, AstraZeneca, Baylis Medical, Biotest, Bristol-Myers Squibb, F-Hoffman-LaRoche, Genentech, Janssen, Lilly Pharmaceuticals, Merck, Nycomed, Pfizer, UCB, 5, Abbott, Amgen, AstraZeneca, Bristol-Myers Squibb Canada, F-Hoffman-LaRoche, Janssen, Pfizer, UCB, 8; M. C. Genovese, Janssen Research & Development, LLC., 2, Janssen Research & Development, LLC., 5; S. Hall, Janssen Research & Development, LLC., 9; P. Miranda, Janssen, HGS, Medimmune, Celltrion, Sanofi, Roche, Pfizer, and MSD, 9, Pfizer Inc, 9; S. C. Bae, Janssen Research & Development, LLC., 9; C. Han, Janssen Global Services, LLC., 3; T. A. Gathany, Janssen Global Services, LLC, 3; Y. Zhou, Janssen Research & Development, LLC., 3; S. Xu, Janssen Research & Development, LLC., 3; E. C. Hsia, Janssen Research & Develpment, LLC., 3.

To cite this abstract, please use the following information:
Keystone, Edward, Genovese, Mark C., Hall, Stephen, Miranda, Pedro,
Bae, Sang-Cheol, Han, Chenglong, et al; Final 5-Year Safety and Efficacy
Results Of a Phase 3, Randomized Placebo-Controlled Trial Of Golimumab
In Patients With Active Rheumatoid Arthritis Despite Prior Treatment With
Methotrexate. [abstract]. Arthritis Rheum 2013;65 Suppl 10:1414
DOI: 10.1002/art.2013.65.issue-s10

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