Arthritis & Rheumatism
AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION · TREATMENT · RESEARCH
WILEY-BLACKWELL

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.

Keystone[1], Edward, Genovese[2], Mark C., Hall[3], Stephen, Miranda[4], Pedro, Bae[5], Sang-Cheol, Han[6], Chenglong, Gathany[6], Timothy A.

University of Toronto/Mount Sinai Hospital, Toronto, ON,
Stanford University, Palo Alto, CA,
Cabrini Medical Centre, Melbourne, Australia,
Universidad de Chile and Centro de Estudios Reumatologicos, Santiago de Chile, Chile,
Hanyang University Hospital for Rheumatic Diseases, Seoul, South Korea,
Janssen Global Services, LLC., Malvern, PA,
Janssen Research & Development, LLC., Spring House, PA,
Janssen Research & Development, LLC./U of Penn, Spring House/Philadelphia, PA.

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 à100mg) or decrease (100 à50mg) 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

(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

Efficacy at wk256	PBO+MTXa	GLM100mg+PBOb	GLM 50mg+MTXb	GLM 100mg+MTXb	Total
ACR20	69/91 (75.8%)	71/93 (76.3%)	57/74 (77.0%)	44/59 (74.6%)	241/317 (76.0%)
ACR50	43/91 (47.3%)	48/93 (51.6%)	40/74 (54.1%)	28/59 (47.5%)	159/317 (50.2%)
ACR70	21/91 (23.1%)	27/93 (29.0%)	28/74 (37.8%)	15/59 (25.4%)	91/317 (28.7%)
DAS28-CRP EULAR Response	81/90 (90.0%)	83/92 (90.2%)	65/73 (89.0%)	52/59 (88.1%)	281/314 (89.5%)
DAS28-CRP Remission (<2.6)	38/90 (42.2%)	41/92 (44.6%)	35/73 (47.9%)	27/59 (45.8%)	141/314 (44.9%)
SDAI ≤3.3	25/90 (27.8%)	21/92 (22.8%)	20/73 (27.4%)	17/60 (28.3%)	83/315 (26.3%)
DAS28-CRP ≤3.2	56/90 (62.2%)	59/92 (64.1%)	46/73 (63.0%)	38/60 (63.3%)	199/315 (63.2%)
HAQ-DI improvement ≥0.25	61/91 (67.0%)	59/93 (63.4%)	55/74 (74.3%)	42/59 (71.2%)	217/317 (68.5%)
Radiographic results at wk256.					
Estimated annual progression rate at baselinec	5.3 ± 7.8	5.6 ± 8.9	4.7 ± 6.9	5.4 ± 13.7	5.3 ± 9.3
Mean ± SD annual rate of progression through 5yrsd	0.7 ± 2.0	1.0 ± 2.3	0.3 ± 1.2	0.7 ± 2.2	0.7 ± 2.0
Mean ± SD change in vdH-S score	3.2 ± 9.2	4.6 ± 10.9	1.7 ± 6.1	3.3 ± 10.2	3.3 ± 9.4
Change in vdH-S score ≤0	52/95 (54.7%)	43/99 (43.4%)	47/79 (59.5%)	30/65 (46.2%)	172/338 (50.9%)
aPts switched to GLM at wk16 or 24.					
bAfter wk52 pts could receive GLM50 mg or 100mg, and MTX could be added/adjusted.					
c vdH-S score divided by the disease duration per pt.					
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-TNFα 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