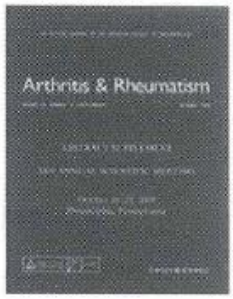
Arthritis & Rheumatism
AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION · TREATMENT · RESEARCH
WILEY-BLACKWELL

Arthritis & Rheumatism, Volume 60, October 2009 Abstract Supplement

The 2009 ACR/ARHP Annual Scientific Meeting
Philadelphia October 16-21, 2009.



Golimumab In Rheumatoid Arthritis: GO-FORWARD Week 52 Results

Keystone[1], Edward C., Genovese[2], M.C., Klareskog[3], L., Hsia[4], E. C., Hall[5], S., Miranda[6], P.C., Pazdur[7], J.

Professor of Medicine/University of Toronto, Toronto, ON,
Centocor R&D, Inc, Malvern, PA
Stanford U, Palo Alto, CA,
Karolinska Institutet, Stockholm, Sweden,
Centocor R&D, Inc/U of Penn School of Med, Malvern, PA,
Cabrini Medical Center, Malvern, Victoria, Australia,
U of Chile/Hosp San Juan de Dios, Santiago, Chile,
Instytut Reumatologii, Warszawa, Poland,
Hanyang University Hospital, Seoul, South Korea,
Westroads Medical group, Omaha, NE,

Purpose:

To assess efficacy and safety of golimumab (GLM) + MTX vs MTX alone in pts with active RA despite MTX.

Methods:

Pts were randomized to PBO + MTX (Grp 1), GLM 100mg + PBO (Grp 2), GLM 50mg + MTX (Grp 3), and GLM 100mg + MTX (Grp 4). At wk16, pts in Grps 1, 2, and 3 who had < 20% improvement in tender and swollen joints entered early escape (EE). At wk 24, pts in Grp 1 crossed over to 50mg + MTX.

Results:

Through wk52, 4%, 10%, 12%, and 16% had a sustained clinical response (ACR70 at 6 consecutive monthly visits) in Grps 1 to 4, respectively; sustained remission (DAS 28 remission at 6 consecutive monthly visits), was observed in 15%, 16%, 29%, and 28% of the respective grps. SAEs were reported in 11%, 17%, 14%, and 18% of pts in Grps 1 through 4, respectively & 2%, 6%, 2%, and 8%, respectively, had serious infections. Between wks 24 and 52, 9 serious infections were reported: 2 in Grp1 EE, 4 in Grp2, 1 in Grp3, & 2 in Grp4. During this period 4 pts had malignancies: squamous and basal cell cancer (Grp1), basal cell cancer (Grp4), breast cancer (Grp 3 and Grp 4).

Conclusion:

GLM efficacy was sustained through 1 yr with many pts achieving sustained remission and sustained clinical response. More pts in grps receiving GLM 100 mg had SAEs and serious infections.

Table. Wk52 Efficacy*

	Group 1: PBO + MTX (wk 0–20) and GLM 50 mg + MTX	Group 2: GLM 100	Group 3: GLM 50	Group 4: GLM 100

Assessment	(wk 24–52)	mg + PBO	mg + MTX	mg + MTX
Pts randomized	133	133	89	89
ACR 20	58(43.6%) [81(62.3%)]	60(45.1%) [75(59.1%)]	57(64.0%) [63(70.8%)]	52(58.4%) [51(58.0%)]
ACR 50	37(27.8%) [49(37.7%)]	38(28.6%) [45(35.2%)]	39(43.8%) [41(46.1%)]	40(44.9%) [39(44.3%)]
ACR 70	20(15.0%) [27(20.8%)]	23(17.3%) [27(21.1%)]	22(24.7%) [22(24.7%)]	30(33.7%) [29(33.0%)]
DAS28 (CRP) Good and Mod responders	72(54.1%) [95(73.1%)]	81(60.9%) [101(78.9%)]	65(73.0%) [76(86.4%)]	70(78.7%) [68(78.2%)]
DAS28 (CRP) remission (< 2.6)	42(31.6%) [52(40.0%)]	38(28.6%) [50(39.1%)]	43(48.3%) [47(53.4%)]	41(46.1%) [41(47.1%)]
Proportion of pts achieving HAQ improvement >0.25	58(43.6%) [69(53.1%)]	57(42.9%) [67(52.3%)]	50(56.2%) [55(61.8%)]	60(67.4%) [59(67.0%)]

* Intent-To-Treat (ITT) analysis [observed analysis] for pts achieving the respective endpoint. ITT analyses considered pts entering EE as non-responders (NR) for categorical endpoints and used LOCF for continuous endpoints. Observed analyses (for Grps 1–3) included all the rules of the ITT analysis except pts entering EE were not considered NR automatically and the observed data at wk 52 were used. Pts entering EE at wk16 received: Grp 1 (42 pts) GLM 50mg +MTX, Grp 2 (36 pts) GLM 100 mg+MTX, & Grp 3 (15 pts) GLM 100mg+MTX. No EE for Grp4.

To cite this abstract, please use the following information: Keystone, Edward C., Genovese, M.C., Klareskog, L., Hsia, E. C., Hall, S., Miranda, P.C., et al; Golimumab in Rheumatoid Arthritis: GO-FORWARD Week 52 Results [abstract]. Arthritis Rheum 2009;60 Suppl 10 :1667 DOI: 10.1002/art.26741