Golimumab in Rheumatoid Arthritis: 52-week results of the GO-FORWARD study

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Objective: To assess the efficacy and safety of golimumab (GLM) + methotrexate (MTX) compared with MTX alone in patients with active RA despite MTX through 52 wks.

Methods: Patients 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, patients in Grps 1, 2, and 3 who had < 20% improvement in tender and swollen joints entered early escape (EE). At wk 24, patients in Grp 1 crossed over to 50mg + MTX.

Results: See Table. Through wk52, 4.2%, 9.9%, 12.3%, and 16.2% had a sustained clinical response (ACR70 at 6 consecutive monthly visits) in Grps 1 through 4, respectively; sustained remission (DAS 28 remission at 6 consecutive monthly visits between wks 4 and 52), was observed in 15.4%, 16.5%, 29.2%, and 28.4% of the respective groups. Of the patients who entered EE at wk16 in Grps 1(23pts), 2(15pts), and 3(6pts), 59.0%, 48.4%, 40.0% achieved ACR20 at wk 52. Of the patients who did not require EE, 71.6%, 69.0% and 82.9%, respectively, achieved ACR20.

Table: Summary of Wk 52 Efficacy*

Assessment	Group 1: PBO + MTX (wk 0-20) and GLM 50 mg + MTX (wk 24-52)	Group 2: GLM 100 mg + PBO	Group 3: GLM 50 mg+MTX	Group 4: GLM 100 mg+MTX
Patients 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 (ESR) Good and Mod responders	70(52.6%) [93(71.5%)]	77(57.9%) [97(75.8%)]	65(73.0%) [74(83.1%)]	69(77.5%) [68(77.3%)]
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%)]
DAS28 (ESR) remission(<2.6)	21(15.8%) [28(21.5%)]	20(15.0%) [22(17.2%)]	25(28.1%) [26(29.2%)]	25(28.1%) [25(28.4%)]
Median (IQ range) improvement from baseline in HAQ	0.25(-0.13, 0.63) [0.38(0.00, 0.75)]	0.13(-0.13, 0.75) [0.38(0.00,0.88)]	0.38(0.13,0.88) [0.50(0.13,0.88)]	0.50(0.25,0.88) [0.50(0.19,0.88)]
Proportion of patients achieving HAQimprovement >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%)]

*Presented as results of Intent-To-Treat (ITT) analysis [observed analysis] for patients achieving the respective endpoint. ITT analyses considered patients entering EE as non-responders for categorical endpoints and used last observation carried forward for continuous endpoints. Observed analyses (for Grps 1-3) included all the rules of the ITT analysis except patients

entering EE were not considered non-responders and the observed data at wk 52 were used. Patients entering EE at wk16 received GLM 50mg +MTX (Grp1), GLM 100 mg+MTX (Grp2), and GLM 100mg+MTX (Gp3). No EE for Grp4.

Serious adverse events were reported in 10.5%, 17.3%, 13.5%, and 18.0% of patients in Grps 1 through 4, respectively and 2.3%, 6.0%, 2.2%, and 7.9%, respectively, had serious infections. Between wks 24 and 52, 9 serious infections including 2 pts in Grp1 EE (TB pleurisy and pneumonia), 4 pts in Grp2 [pyrexia/pneumonia, sinusitis, bronchitis and cellulitis), 1 pt in Grp3 (cellulitus), and 2 pts Grp4 (acute pneumopathay and sepsis). In addition to the 3 GLM-treat pts with malignancies through wk 24, 4 additional pts had malignancies through wk 52 [squamous and basal cell carcinoma (Grp1), basal cell carcinoma (Grp4), breast cancer (Grp 3 and Grp 4)].

Conclusion: GLM efficacy was sustained through 1 yr with a substantial proportion of patients achieving sustained remission and sustained clinical response. More patients in groups receiving GLM 100 mg had serious adverse events and serious infections.