ePoster #: 55

Efficacy of galcanezumab in adults with treatment resistant migraine and concomitant pain disorders: Post-hoc subpopulation analyses from the randomized, double-blind, placebo-controlled CONQUER study

Charles Argoff (Presenter)[1], Yan Dong[2], Lily Li[2], Peter Wright[2], Meredith Barad[3]

[1]Albany Medical College, New York, USA; [2]Eli Lilly and Company, Indianapolis, Indiana, USA; [3]Stanford University, Stanford, California, USA

BACKGROUND

- Study CONQUER (NCT03559257)
- Phase 3, multicenter, randomized, double-blind, parallel, placebo-controlled study to assess the efficacy and safety of galcanezumab 120 mg/month
- Patients with treatment-resistant migraine*

*Patients were considered to have treatment-resistant migraine if they experienced 2 to 4 migraine preventive medication category failures in the past 10 years due to insufficient efficacy or safety/tolerability reasons. This population is of particular interest due to evidence of decreased quality of life and increased economic burden among people with migraine that is inadequately managed

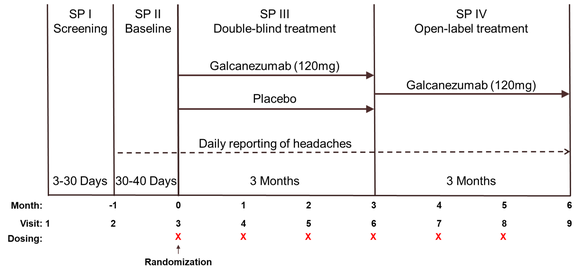
OBJECTIVE

- To evaluate the efficacy of galcanezumab compared to placebo in patients with treatment-resistant migraine (EM or CM) who had 1 or more concomitant pain disorders

CONQUER STUDY DESIGN

Randomization

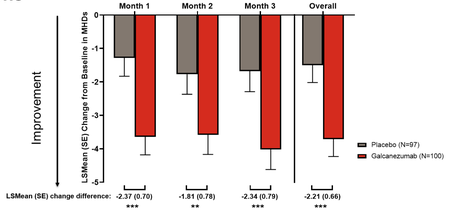
- Patients were randomized (1:1) to receive galcanezumab 120 mg/month (with 240-mg loading dose) or placebo during a 3-month double-blind treatment period



KEY RESULT

- Galcanezumab-treated patients had significantly greater mean reduction in the number of monthly MHDs compared to placebo-treated patients as early as Month 1 and continued through Month 3

Change from Baseline in Monthly Migraine Headache Days in Patients with Treatment Resistant Migraine† and Comorbid Pain Conditions



† Patients were considered to have treatment-resistant migraine if they experienced 2 to 4 migraine preventive medication category failures in the past 10 years due to insufficient efficacy or safety/tolerability reasons
** P ≤0.01; *** P≤0.001 vs. placebo
Abbreviations: LS=least square; MHD= migraine headache days; SE=Standard error

CONCLUSIONS

- In treatment-resistant migraine in patients who had at least one concomitant pain condition:
  - Galcanezumab was effective in reducing monthly migraine headache days compared to placebo
  - Overall, galcanezumab-treated patients had a higher 50%, 75% and 100% response rates than placebo
  - Galcanezumab was also effective in improving functional quality of life compared to placebo

Limitations

- This is a post hoc analysis with a small sample size. Additional study needs to be conducted for further evaluation

References

Martelletti P, Schwedt T, Lantéri-Minet M, et al. My Migraine Voice survey: a global study of disease burden among individuals with migraine for whom preventive treatments have failed. J Headache Pain 2018;19:115.
Ford J, Schroeder K, Nyhuis A, Foster SA, Aurora S. Cycling through migraine preventive treatments: implications to all-cause total direct costs and disease-specific costs. J Manag Care Spec Pharm. 2019;25(1):46-59.

CONQUER Study Design (NCT03559257)

Randomization

Endpoints evaluated (Months 1–3)

- Change from baseline in number of monthly migraine headache days
- Response rates for ≥50%, ≥75%, or 100% reduction from baseline in monthly migraine headache days
- Migraine-Specific Quality of Life - Role Function Restrictive (MSQ-RFR) domain score
- Continuous variables with repeated measures were analyzed using a mixed model repeated measures (MMRM) analysis. Binary variables with repeated measures were analyzed with generalized linear mixed model (GLIMMIX)

Analysis Population

- Patients who had treatment resistant migraine and at least 1 concomitant pain disorder (Placebo n=97; Galcanezumab 120mg n=100)

Key Inclusion Criteria

- Patients 18 to 75 years of age
- IHS ICHD-3 diagnosis of migraine with or without aura
- ≥4 migraine headache days and >1 headache-free day per month
- Documented failure of 2 to 4 standard-of-care migraine preventive medication categories due to inadequate efficacy and/or safety reasons in the past 10 years

Key Exclusion Criteria

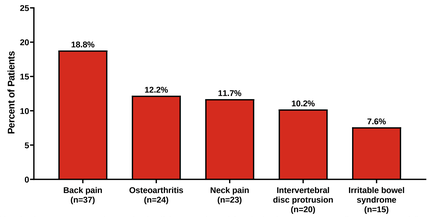
- Enrolled in another clinical study not compatible with this one
- Prior use of galcanezumab or another CGRP antibody or CGRP receptor antibody
- Currently receiving migraine prevention medications

Baseline Demographics and Disease Characteristics

Patient Characteristics in adults with treatment resistant migraine and at least 1 comorbid pain condition	Placebo (N=97)	Galcanezumab 120mg (N = 100)
Age (years); *mean (SD)*	47 (12)	49 (11)
Female *n (%)*	88 (91%)	85 (85%)
Race: White* *n (%)*	78 (83%)	79 (79%)
Episodic migraine *n (%)*	46 (47%)	52 (52%)
Chronic migraine *n (%)*	51 (53%)	48 (48%)
Patients with: 1 prior migraine medication category failure in 10 years; *n(%)*	2 (2.1%)	0 (0%)
2 prior migraine medication category failure in 10 years; *n(%)*	58 (60%)	62 (62%)
3 prior migraine medication category failure in 10 years; *n(%)*	32 (33%)	26 (26%)
4 prior migraine medication category failure in 10 years; *n(%)*	5 (5.2%)	12 (12%)
Number of failed migraine meds (10 year); *mean (SD)*	3.59 (2.0)	3.4 (1.7)
Number of comorbid pain conditions; *mean (SD)*	6.2 (4.3)	5.7 (4.4)
Monthly migraine headache days; *mean (SD)*	14 (5.9)	14 (6.5)
Monthly days with abortive med use; *mean (SD)*	13 (6)	13 (6.5)
MSQ-RFR; *mean (SD)*	40 (20)	47 (18)

*For race, N=94 and 100 for placebo and galcanezumab, respectively
Abbreviations: MSQ-RFR: Migraine-specific quality of life questionnaire - Role function-Restrictive; SD: Standard deviation

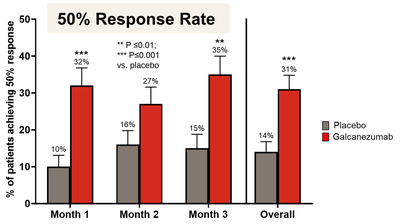
Baseline Top 5 Most Common Comorbid Pain Conditions in Patients With Treatment-Resistant Migraine† and Disease Characteristics



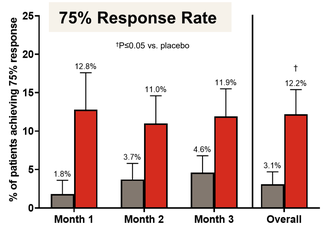
† Patients were considered to have treatment-resistant migraine if they experienced 2 to 4 migraine preventive medication category failures in the past 10 years due to insufficient efficacy or safety/tolerability reasons.
It is possible for a patient to be counted in multiple concomitant pain disorder groups. This does not include all conditions considered in this analysis; only the most common ones.

Patients with Treatment-Resistant Migraine† and Comorbid Pain Conditions

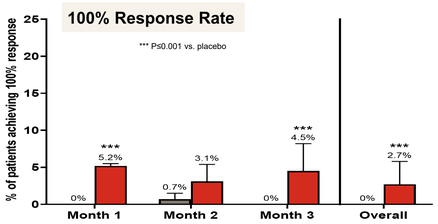
(†2 to 4 migraine preventive medication category failures in the past 10 years due to insufficient efficacy or safety/tolerability reasons)



- More galcanezumab-treated patients experienced at least 50% response compared to placebo over 3 months
- The 50% response rate for galcanezumab group is significantly greater than placebo at Months 1 and 3



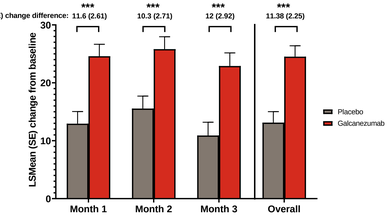
- Galcanezumab-treated patients had significantly higher overall 75% response rates compared to placebo over Months 1 to 3
- The 75% response rate for the galcanezumab group is numerically greater than placebo from Month 1 to Month 3



- Galcanezumab-treated patients had a higher 100% response rates compared to placebo over time
- The overall response rate across Month 1 to Month 3 was significantly greater in the galcanezumab treatment group as well at Month 1 and Month 3

Mean Improvement in MSQ-RFR Score

- Galcanezumab-treated patients had a significantly higher improvement in MSQ-RFR score compared to placebo at Months 1, 2, and 3



*** P≤0.001 vs. placebo
Abbreviations: LS=least square; MSQ-RFR=Migraine-Specific Quality of Life Questionnaire - Role Function-Restrictive; SE=Standard error

Disclosure

Previously presented at 62nd American Headache Society Annual Meeting (AHS); Virtual 2020; June 15-30, 2020

Scan or use this URL
https://lillysource.lilly.com/congress/painweek2020
for a list of all Lilly content presented at the congress

PAINWeek 2020