OPEN ACCESS

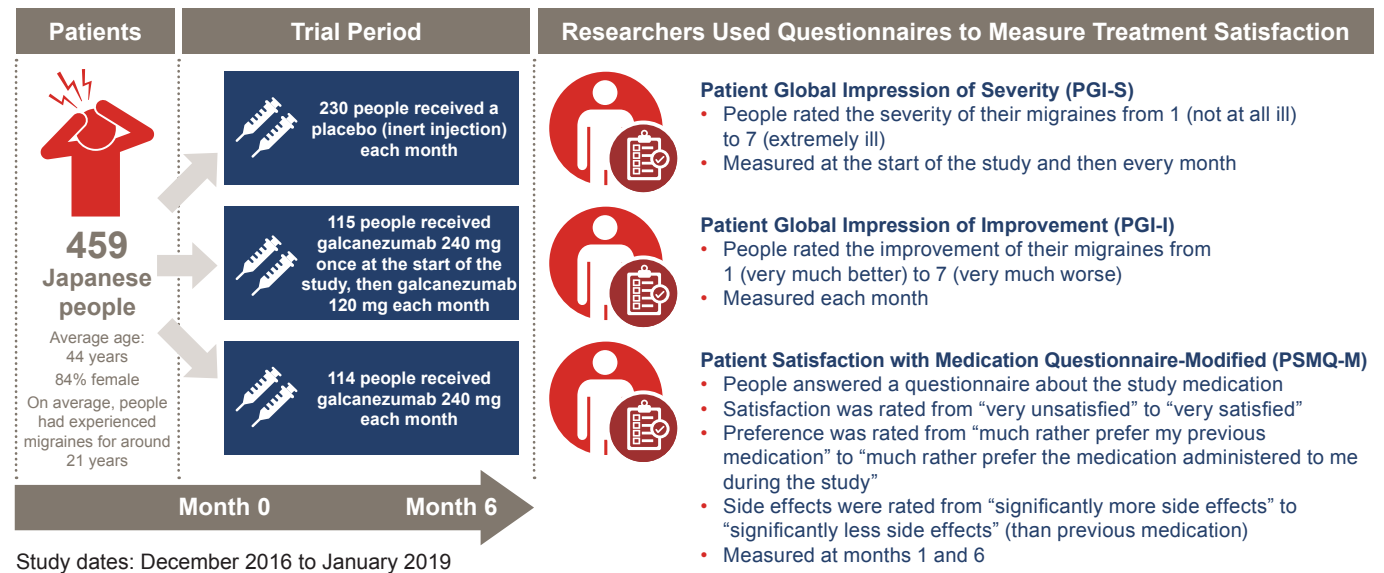# Treatment Satisfaction of Galcanezumab in Japanese Patients with Episodic Migraine: A Phase 2 Randomized Controlled Study

Why did we do this study?

- A migraine causes severe throbbing pain usually on one side of the head. Migraine attacks can last for hours or days
- Currently, the level of satisfaction with preventive treatments for migraine in Japanese people is unknown
- Galcanezumab is an approved treatment for preventing migraine attacks
- In the CGAN study, galcanezumab reduced the number of days people experienced a migraine or severe headache by an average of 2.8–3.0 days each month compared with a placebo (inert injection)
- In this analysis of the CGAN study, we looked at how satisfied people were with galcanezumab treatment for preventing migraine attacks

What did we do?

Patients	Trial Period	Researchers Used Questionnaires to Measure Treatment Satisfaction

459 Japanese people
Average age: 44 years
84% female
On average, people had experienced migraines for around 21 years

Trial Period:
- 230 people received a placebo (inert injection) each month
- 115 people received galcanezumab 240 mg once at the start of the study, then galcanezumab 120 mg each month
- 114 people received galcanezumab 240 mg each month

Month 0 → Month 6

Study dates: December 2016 to January 2019

Patient Global Impression of Severity (PGI-S)
- People rated the severity of their migraines from 1 (not at all ill) to 7 (extremely ill)
- Measured at the start of the study and then every month

Patient Global Impression of Improvement (PGI-I)
- People rated the improvement of their migraines from 1 (very much better) to 7 (very much worse)
- Measured each month

Patient Satisfaction with Medication Questionnaire-Modified (PSMQ-M)
- People answered a questionnaire about the study medication
- Satisfaction was rated from "very unsatisfied" to "very satisfied"
- Preference was rated from "much rather prefer my previous medication" to "much rather prefer the medication administered to me during the study"
- Side effects were rated from "significantly more side effects" to "significantly less side effects" (than previous medication)
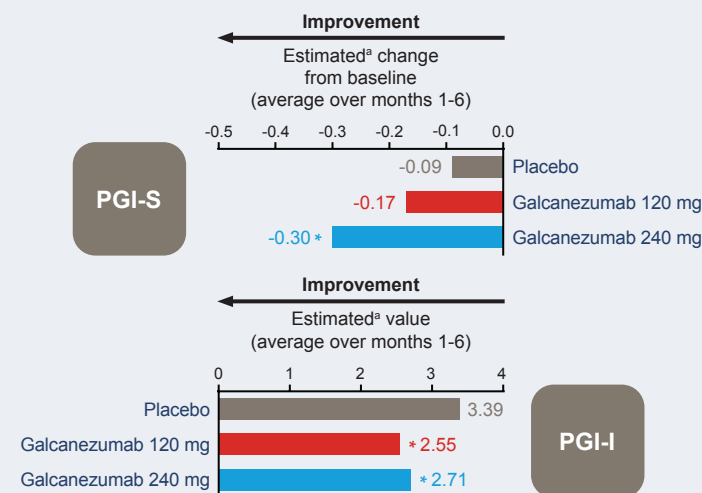- Measured at months 1 and 6

What were the results of this study?

People who received galcanezumab:
- Had less severe migraines (PGI-S)
- Had greater improvement in their migraine disease (PGI-I)
- Were somewhat or very satisfied with galcanezumab at months 1 and 6
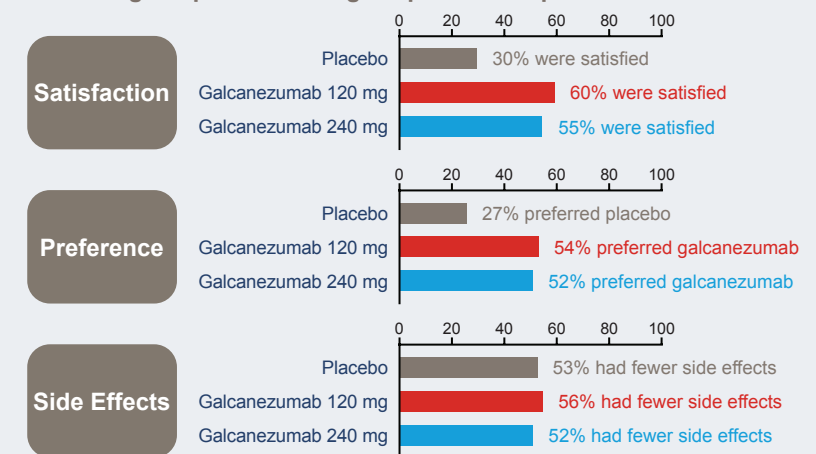- Preferred or much preferred galcanezumab at months 1 and 6

Similar percentages of patients across all groups reported fewer side effects compared with their previous migraine treatment

PGI-S
← Improvement
Estimated[a] change from baseline (average over months 1-6)
-0.5 -0.4 -0.3 -0.2 -0.1 0.0
- Placebo: -0.09
- Galcanezumab 120 mg: -0.17
- Galcanezumab 240 mg: -0.30 *

PGI-I
← Improvement
Estimated[a] value (average over months 1-6)
0 1 2 3 4
- Placebo: 3.39
- Galcanezumab 120 mg: * 2.55
- Galcanezumab 240 mg: * 2.71

*p<0.05 vs. placebo (no adjustments for multiplicity)
[a]These values were estimated using a method known as least squares means

Percentage of patients who gave positive responses[b] at month 1

Satisfaction
0 20 40 60 80 100
- Placebo: 30% were satisfied
- Galcanezumab 120 mg: 60% were satisfied
- Galcanezumab 240 mg: 55% were satisfied

Preference
0 20 40 60 80 100
- Placebo: 27% preferred placebo
- Galcanezumab 120 mg: 54% preferred galcanezumab
- Galcanezumab 240 mg: 52% preferred galcanezumab

Side Effects
0 20 40 60 80 100
- Placebo: 53% had fewer side effects
- Galcanezumab 120 mg: 56% had fewer side effects
- Galcanezumab 240 mg: 52% had fewer side effects

[b]Positive responses: somewhat or very satisfied, preferred or much preferred the study medicine, less or significantly less side effects