OnabotulinumtoxinA has been shown to reduce headache-days among patients with chronic migraine (CM). The objective of this analysis was to determine whether onabotulinumtoxinA has an impact on headache-day severity in patients with CM among those patients who were deemed non-responders based on reduction in the frequency of headache days alone.

Data from the Phase 3 REsearch Evaluating Migraine Prophylaxis Therapy (PREEMPT) clinical trial program (a 24-week, 2-treatment cycle, double-blind, randomized, placebo-controlled, parallel-group phase, followed by a 32-week, 3-treatment cycle, open-label phase) were pooled for analysis. Patients kept a daily diary to record headache severity on a 4-point scale (from none to severe), and a 6-domain Headache Impact Test (HIT-6) was used to determine the clinical impact of headaches. Analysis was undertaken to assess whether the subset of patients that were headache-day frequency non-responders at week 24 (patients with <50% reduction in headache-day frequency) experienced a reduction in headache severity whilst receiving onabotulinumtoxinA.

For headache-day frequency non-responders, significant reductions in the number of severe headache days, average daily headache severity, pooled percentage of severe headache days and headache severity score were observed at week 24 for patients who had received onabotulinumtoxinA compared with those who had received placebo. The between-group differences were reduced and non-significant at week 56. Similarly, headache-day frequency non-responders receiving onabotulinumtoxinA were found to have an improvement in the clinical impact of headaches using results from the HIT-6.

These results suggest that even those patients with CM who are deemed non-responders based on analysis of headache frequency alone experience clinically meaningful relief from headache intensity following treatment with onabotulinumtoxinA [1].

1)
Matharu M, Halker R, Pozo-Rosich P, DeGryse R, Manack Adams A, Aurora SK. The impact of onabotulinumtoxinA on severe headache days: PREEMPT 56-week pooled analysis. J Headache Pain. 2017 Dec;18(1):78. doi: 10.1186/s10194-017-0784-4. Epub 2017 Aug 1. PubMed PMID: 28766236.