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- as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

(54) Title: ANTI-CGRP ANTIBODY DOSING AND SCREENING METHODS

Infusion 1 predictor at week 12 / over weeks 1-12	PROMISE-1			PROMISE-2		
	Odds ratio	Parameter estimate	p-value	Odds ratio	Parameter estimate	p-value
Percent change in MMDs	0.966	-0.0349	0.0001	0.940	-0.0614	<.0001
Change in HIT-6 total score	N/A	N/A	N/A	0.923	-0.0802	0.0269
PGIC	N/A	N/A	N/A	1.502	0.4067	0.1700
Change in SF-36 bodily pain	1.042	0.0410	0.1131	0.996	-0.0044	0.8589
Change in SF-36 mental health	0.993	-0.0075	0.7964	0.986	-0.0142	0.6248
Change in SF-36 role- emotional	0.957	-0.0436	0.1148	0.997	-0.0033	0.8824
Change in SF-36 role- physical	1.009	0.0090	0.7722	0.983	-0.0174	0.5442
Change in SF-36 social functioning	0.999	-0.0013	0.9578	0.998	-0.0018	0.9497
Change in SF-36 vitality	1.041	0.0401	0.1882	0.987	-0.0127	0.6861
Change in EQ-5D VAS	0.998	-0.0022	0.8864	1.010	0.0095	0.4267
Change in percent of headaches with severe pain	1.017	0.0171	0.0312	0.985	-0.0149	0.0981

HIT-6, 6-item Headache Impact Test; MMD, monthly migraine days; N/A, not applicable (i.e., instrument
not captured in PROMISE-1); PI-MBS, patient-identified most bothersome symptom; SF-36, 36-item
Short-Form Health Survey (v2.0); VAS, visual analog scale.

Figure 1

(57) Abstract: The present invention relates the use of monoclonal anti-calcitonin gene-related peptide (CGRP) antagonist antibodies
or anti-CGRP receptor antibodies in subjects that do not respond adequately to a first dose but respond to the second dose.

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