J-C Health Care Ltd.

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יולי 2021

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא בתכשיר:

TREMFYA (Guselkumab 100 mg)

התוויה:

Plaque psoriasis
Tremfya is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Psoriatic arthritis
Tremfya, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

4.8 Undesirable effects

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Transaminases Increased

In two phase III psoriatic arthritis clinical studies, through the placebo-controlled period, adverse events of increased transaminases (includes ALT Increased AST Increased, Hepatic Enzyme Increased, Transaminases Increased, Liver Function Test Abnormal, Hypertransaminasaemia) were reported more frequently in the Tremfya-treated groups (8.6% in the q4w group and 8.3% in the q8w group) than in the placebo group (4.6%). Through 1 year, adverse events of increased transaminases (as above) were reported in 12.9% of patients in the q4w group and 11.7% of patients in the q8w group.

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Neutrophil count decreased

In two phase III psoriatic arthritis clinical studies, through the placebo-controlled period, the adverse event of decreased neutrophil count was reported more frequently in the Tremfya-treated group (0.9%) than in the placebo group (0%). Through 1 year, the adverse event of decreased neutrophil count was reported in 0.9% of patients treated with Tremfya. In most cases, the decrease in blood neutrophil count was mild, transient, not associated with infection and did not lead to discontinuation of treatment.

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Injection site reactions

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Through 1 year, the proportion of subjects reporting 1 or more injection site reactions was 1.6% and 2.4% in the Tremfya q8w and q4w groups respectively.

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5.1 Pharmacodynamic properties

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Clinical response was maintained up to Week 52 as assessed by ACR 20/50/70, DAS 28 (CRP), MDA, IGA and PASI 90 response rates (see Table 9).

Table 9: Clinical Responses in DISCOVER 1 and DISCOVER 2 at Week 52[a]

	DISCOVER 1		DISCOVER 2	
	guselkumab 100 mg q8w	guselkumab 100 mg q4w	guselkumab 100 mg q8w	guselkumab 100 mg q4w
ACR 20				

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N[b] % Response	112 67.9%	124 75.8%	234 79.1%	228 75.9%
ACR 50				
N[b] % Response	113 43.4%	124 55.6%	234 51.3%	228 49.1%
ACR 70				
N[b] % Response	114 28.9%	124 29.8%	234 29.5%	228 28.1%
DAS 28 (CRP) change from baseline				
N[c] Mean (SD)	112 -2.03 (1.250)	123 -1.99 (1.062)	234 -2.08 (1.121)	227 -2.11 (1.128)
MDA				
N[b] % Response	112 33.9%	124 40.3%	234 32.9%	228 36.8%
Patients with ≥3% BSA and IGA ≥2 at baseline				
IGA Response				
N[b] % Response	75 69.3%	88 83.0%	170 77.1%	173 84.4%
PASI 90				
N[b] % Response	75 66.7%	88 76.1%	170 77.1%	173 81.5%

[a] There was no placebo arm beyond Week 24.
[b] Evaluable subjects with an observed response status.
[c] Subjects have an observed change from baseline.

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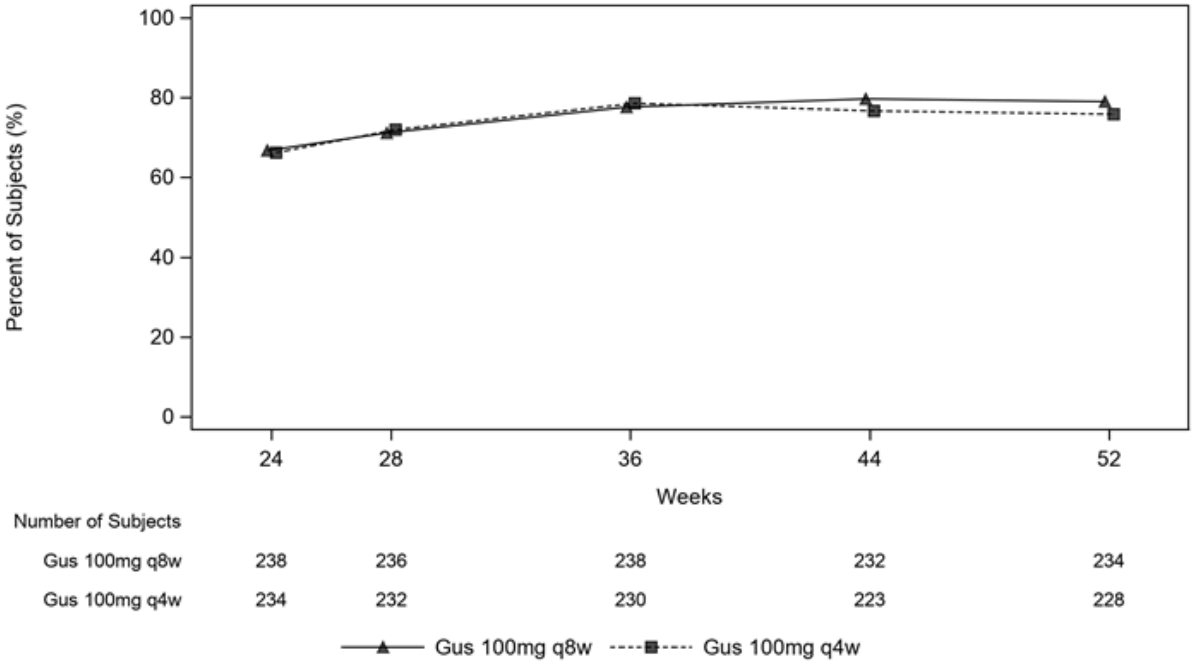
In DISCOVER 2, for subjects receiving continuous guselkumab treatment, ACR 20 response was maintained from Week 24 to Week 52 (see Figure 6).

Figure 6: ACR 20 Response by Visit Through Week 52 in DISCOVER 2



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In DISCOVER 1 and 2, improvements were shown in all components of the ACR scores including patient assessment of pain. At Week 24 in both studies, the proportion of patients achieving a modified PsA response criteria (PsARC) response was greater in the guselkumab groups compared to placebo. PsARC responses were maintained from Week 24 to Week 52.

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Dactylitis and enthesitis were assessed based on pooled data from DISCOVER 1 and 2. At Week 24, among patients with dactylitis at baseline, the proportion of subjects with dactylitis resolution was greater in the guselkumab q8w group (59.4%, nominal $p < 0.001$) and q4w group (63.5%, $p = 0.006$) compared to placebo (42.2%). At Week 24, among patients with enthesitis at baseline, the proportion of subjects with enthesitis resolution was greater in the guselkumab q8w group (49.6%, nominal $p < 0.001$) and q4w group (44.9%, $p = 0.006$) compared to placebo (29.4%). At Week 52, the proportions of subjects with dactylitis resolution (81.2% in q8w group and 80.4% in q4w group) and enthesitis resolution (62.7% in q8w group and 60.9% in q4w group) were maintained.

In DISCOVER 1 and 2, patients treated with guselkumab who had spondylitis with peripheral arthritis as their primary presentation, demonstrated greater improvement from baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) compared to placebo at Week 24. Improvement in BASDAI was maintained from Week 24 to Week 52.

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Physical function and health-related quality of life

In DISCOVER 1 and 2, guselkumab treated patients showed significant improvement ($p < 0.001$) in physical function compared to placebo as assessed by the Health Assessment Questionnaire-Disability Index (HAQ-DI) at Week 24. Improvements in HAQ-DI were maintained from Week 24 to Week 52.

A significantly greater improvement from baseline in the SF-36 Physical Component Summary (PCS) score was observed in guselkumab treated patients compared to placebo at Week 24 in DISCOVER 1 ($p < 0.001$ for both dose groups) and DISCOVER 2 ($p = 0.006$ for q4w group). At Week 24, a greater increase from baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) score was observed in guselkumab treated patients compared to placebo in both studies. In DISCOVER 2, greater improvements in health-related quality of life as measured by the Dermatology Life Quality Index (DLQI) were observed in guselkumab treated patients compared to placebo at Week 24. Improvements in SF-36 PCS, FACIT-F and DLQI scores were maintained from Week 24 to Week 52.

כלל השינויים מסומנים בעלון המצורף כאשר הטקסט המודגש באדום הוסף לעלון ואילו הטקסט המחוק הוסר.
העלון לרופא נשלח לפרסום במלואו למאגר התרופות שבאתר משרד הבריאות.

כמו כן, ניתן לקבל מודפס בפניה אלינו לטלפון 09-9591111 .

להלן העדכונים.

בברכה,
אלינה ורמן
רוקחת ממונה