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Supplementary Material

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Two-Year Safety and Efficacy Experience in Patients with Methotrexate-Resistant Active Rheumatoid Arthritis Treated with Etanercept and Conventional Disease-Modifying Anti-rheumatic Drugs in the Latin American Region

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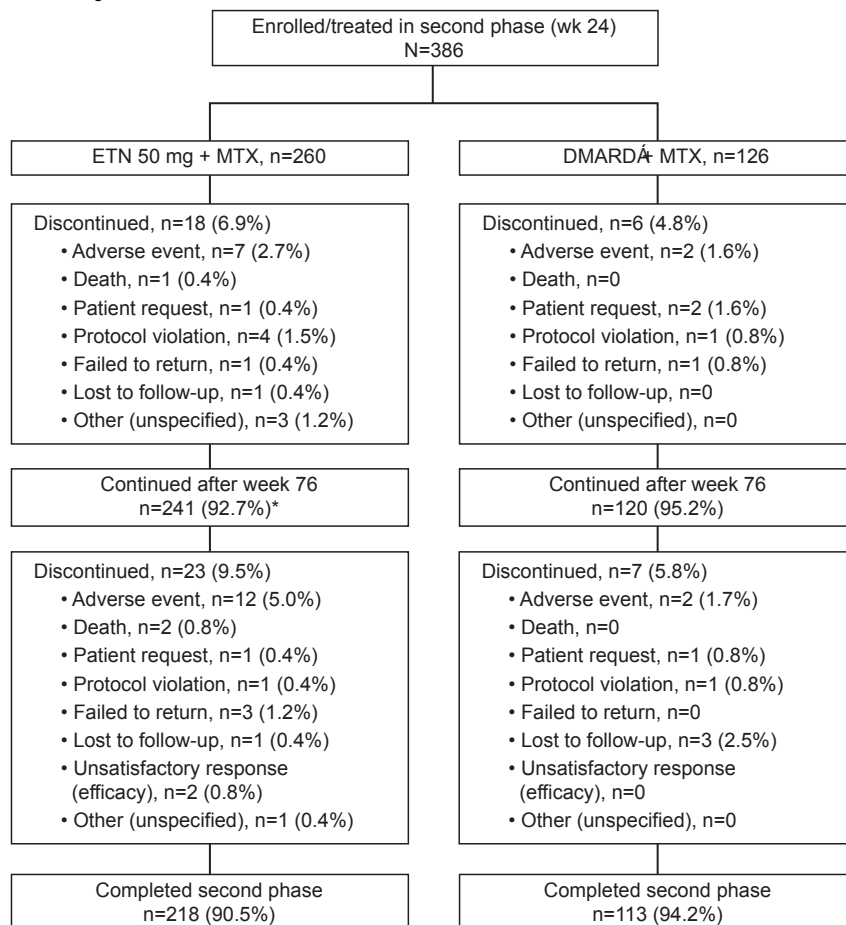
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Supplementary Content 1



*1 patient completed the first 52-week period of the extension but discontinued before entering the second 52-week period of the extension.

Fig. (1). Patient disposition in the extension.

Supplementary Content 2

Table 1. Summary of changes in randomized therapy at the start of the extension.

Change From Phase 1 Treatment Regimen	No. of Patients (%)	
	Etanercept + Methotrexate (n=260)	DMARD + Methotrexate ^a (n=126)
No change		
Etanercept	259 (100)	
Methotrexate	260 (100)	126 (100)
Hydroxychloroquine		29 (45)
Sulfasalazine		11 (18)
Added therapy		
Etanercept	1 (1) ^b	105 (83)
Hydroxychloroquine	8 (3)	
Sulfasalazine	3 (1)	
Discontinued therapy		
Hydroxychloroquine		35 (55)
Sulfasalazine	1 (1) ^b	51 (82)

DMARD, disease-modifying anti-rheumatic drug.

^aHydroxychloroquine + methotrexate, n=64; sulfasalazine + methotrexate, n=62.

^bData reflects actual exposure: one patient was randomized to the etanercept-plus-methotrexate group in phase 1 but mistakenly received sulfasalazine.

Supplementary Content 3

Table 2. Summary of treatment-emergent adverse events in phase 2 (safety population).

Adverse Event	No. of Patients (%)	
	Etanercept + Methotrexate	DMARD + Methotrexate
	n=260	n=126
Any adverse event, n (%)	192 (73.8)	92 (73.0)
Any serious adverse event	27 (10.4)	6 (4.8)
Any adverse event causing withdrawal	21 (8.1)	4 (3.2)
Most common adverse events		
Nasopharyngitis	20 (7.7)	14 (11.1)
Bronchitis	25 (9.6)	12 (9.5)
Urinary tract infection	22 (8.5)	9 (7.1)
Influenza	16 (6.2)	10 (7.9)
Nausea	9 (3.5)	7 (5.6)
Pharyngitis	14 (5.4)	7 (5.6)
Sinusitis	13 (5.0)	1 (0.8)
Back pain	8 (3.1)	6 (4.8)
Headache	8 (3.1)	6 (4.8)

DMARD, disease-modifying anti-rheumatic drug.