



## SAT0264 CLINICAL EFFICACY OF ETANERCEPT VERSUS SULFASALAZINE IN ANKYLOSING SPONDYLITIS PATIENTS WITH PERIPHERAL JOINT INVOLVEMENT

J. Braun\*<sup>1</sup>, K. Pavelka<sup>2</sup>, C. R. Remus<sup>3</sup>, A. Dimic<sup>4</sup>, B. Vlahos<sup>5</sup>, **A. S. Koenig**<sup>5</sup>, B. Freundlich<sup>5</sup>

<sup>1</sup>Rheumatology Medical Center, Ruhrgebiet, Herne, Ruhr-University, Bochum, Germany, <sup>2</sup>Institute, Rheumatology, Prague, Czech Republic, <sup>3</sup>Unidad de Investigacion en Enfermedades Cronico Degenerativas, Guadalajara, Mexico, <sup>4</sup>Rheumatology Institut, Niska Banja, Serbia, <sup>5</sup>Global Medical Affairs, Wyeth, Collegeville, United States

**Background:** Etanercept (ETN) is a fully human tumor necrosis factor soluble receptor that is effective in the treatment of ankylosing spondylitis (AS).[1, 2] Current guidelines for the management of AS recommend sulfasalazine (SSZ) for AS patients with peripheral arthritis.[3]

**Objectives:** This study compared the efficacy of ETN with SSZ in subjects with AS, including those with peripheral joint involvement.

**Methods:** A post hoc analysis compared the efficacy of ETN 50 mg once weekly with SSZ up to 3 g daily in subjects with and without swollen peripheral joint involvement from a 16-week randomized, double-blind study in subjects with AS [4]. Study design and eligibility criteria have been published [4]. Efficacy endpoints assessed in this analysis included ASAS 20, ASAS 5/6, partial remission, and BASDAI; physical function and mobility were assessed using BASFI and BASMI. LOCF was used for imputation of missing values.

**Results:** Of a total of 566 subjects included in the study [4], 181 (ETN 121; SSZ 60) had  $\geq 1$  swollen peripheral joint and 364 (ETN 250; SSZ 124) had none. Regardless of swollen joint involvement, subjects receiving ETN showed significantly greater improvement than subjects receiving SSZ in all efficacy assessments, including physical function and spinal mobility (Table).

**Table:**

	Efficacy at Week 16 (LOCF)								
	All Patients			Patients With Swollen Joints at Baseline			Patients With No Swollen Joints at Baseline		
	ETN n/N (%) Improvement)	SSZ n/N (%) Improvement)	P value**	ETN n/N (%) Improvement)	SSZ n/N (%) Improvement)	P value**	ETN n/N (%) Improvement)	SSZ n/N (%) Improvement)	P value**
<b>ASAS 20</b>	287/378 (75.9)	99/187 (52.9)	<0.001	83/121 (68.6)	30/60 (50.0)	0.020	197/249 (79.1)	68/124 (54.8)	<0.001
<b>ASAS 5/6</b>	166/365 (45.5)	38/179 (21.2)	<0.001	48/119 (40.3)	10/56 (17.9)	0.002	115/239 (48.1)	28/121 (23.1)	<0.001
<b>Partial Remission</b>	126/379 (33.3)	29/187 (15.5)	<0.001	42/121 (34.7)	9/60 (15.0)	0.006	82/250 (32.8)	19/124 (15.3)	<0.001
	Mean (%) Improvement)	Mean (%) Improvement)		Mean (%) Improvement)	Mean (%) Improvement)		Mean (%) Improvement)	Mean (%) Improvement)	
<b>BASDAI</b>	27.2 (54.1)	39.4 (33.4)	<0.001	31.1 (51.9)	43.8 (28.1)	0.001	25.7 (55.2)	37.6 (36.1)	<0.001
<b>BASFI</b>	28.7 (47.8)	39.4 (28.5)	<0.001	32.2 (43.5)	42.4 (25.9)	0.011	27.2 (50.0)	37.9 (30.2)	<0.001
<b>BASMI</b>	2.8 (25.0)	3.3 (6.9)	<0.001	2.4 (31.7)	3.1 (6.0)	0.001	3.0 (23.6)	3.3 (7.8)	<0.001

**Conclusion:** In this post hoc analysis, etanercept was significantly more effective than SSZ at improving the clinical symptoms of AS in subjects with and without swollen joints at baseline. These findings support the role of etanercept as a key therapy for the management of subjects with AS with or without associated peripheral joint involvement.

\*\*ETN vs SSZ. Cochran-Mantel-Haenszel Test for ASAS criteria and partial remission; ANCOVA model for BASDAI, BASFI and BASMI.

**References:** References:

1. Calin A, et al. Ann Rheum Dis 2004; 63(12): 1594-600.
2. Davis JC, Jr., et al. Arthritis Rheum 2003; 48(11): 3230-6.
3. Zochling J, et al.: Ann Rheum Dis 2006; 65(4): 442-52.
4. Braun J, et al. Arthritis Rheum 2008; 58 (9):S415.

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