

Retention rate and long-term safety of biosimilar CT-P13 in patients with ankylosing spondylitis: data from the Korean College of Rheumatology Biologics registry

Supplementary File

Suppl. Table SI. Adverse events resulting in changing from CT-P13 or discontinuation of CT-P13.

	CT-P13		
	Overall (n=244)	First line (n=203)	≥ Second line (n=41)
Total number of patients who changed or discontinued therapy due to adverse events, n (%)	18 (7.4)	13 (6.4)	5 (12.2)
Changed	10 (4.1)	7 (3.4)	3 (7.3)
Discontinued	8 (3.3)	6 (3.0)	2 (4.9)
Adverse event cases in patients who changed therapy, n			
Infusion/injection reaction	8	5	3
Uveitis	1	1	–
Skin rash	2	2	–
Adverse event cases in patients who discontinued therapy, n			
Infusion/injection reaction	2	1	1
Conception	1	1	–
Urticaria	1	–	1
Pulmonary <i>Mycobacterium tuberculosis</i> infection	2	2	–
Gastrointestinal disturbances	1	1	–
Headache	2	2	–

Suppl. Table SII. ASDAS scores, ASAS20 response rates, and ASAS40 response rates at first and second follow-up visits in the overall patient population and those patients who received first-line CT-P13 treatment.

Overall patient population	Year 1 (n=191)	Year 2 (n=123)
ASAS20, n (%)	109 (57.1)	74 (60.2)
ASAS40, n (%)	86 (45.0)	57 (46.3)
ASDAS improvement criteria, n (%)		
Major improvement	108 (56.5)	70 (56.9)
Clinically important improvement	157 (82.2)	105 (85.4)
Patients receiving first-line CT-P13	Year 1 (n=157)	Year 2 (n=106)
ASAS20, n (%)	89 (56.7)	63 (59.4)
ASAS40, n (%)	68 (43.3)	48 (45.3)
ASDAS improvement criteria, n (%)		
Major improvement	94 (59.9)	58 (54.7)
Clinically important improvement	132 (84.1)	91 (85.8)

ASAS Response Criteria (ASAS20) is defined as an improvement of at least 20% and an absolute improvement of at least 10 units on a 0–100 scale in at least three of the following domains: patient global assessment, pain assessment, function (BASFI), and inflammation (last two questions of BASDAI).

ASAS40 is defined as for ASAS20 above, but with improvements of at least 40%.

Clinically important or major changes in ASDAS scores defined as ≥ 1.1 or ≥ 2 -point improvements, respectively.

ASAS: Assessment in Ankylosing Spondylitis Response Criteria; ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index.

Suppl. Table SIII. Summary of AEs.

	CT-P13 (n=244)
Patients reporting AEs, n (%)	118 (48.4)
Patients with biologic-related AEs, n (%)	41 (16.8)
AE cases, n*	313
AE cases according to severity, n	
Mild/grade 1	195
Moderate/grade 2	101
Severe/grade 3	12
Undefined	5
AE cases according to relationship with treatment, n	
Related	72
First-line treatment	63
Second-line or subsequent treatment	9
Unrelated	206
Indeterminate	34
Unspecified	1

*Number of events.

AE: adverse event.