Spondyloarthritis – treatment

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EFFECTIVENESS AND SAFETY OF CERTOLIZUMAB PEGOL FOR THE TREATMENT OF AXIAL SPONDYLOARTHRITIS IN REAL-WORLD CLINICAL PRACTICE IN EUROPE: RESULTS FROM A PROSPECTIVE NON-INTERVENTIONAL 12-MONTH COHORT STUDY

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Background: Certolizumab pegol (CZP) is an Fc-free, PEGylated anti-TNF with an established efficacy and safety profile in axial spondyloarthritis (axSpA) in clinical trial settings.¹

Objectives: To report CZP effectiveness and safety in patients (pts) with axSpA, including ankylosing spondylitis (AS; radiographic axSpA) and non-radiographic (nr-) axSpA subpopulations, in routine clinical practice in Europe.

Methods: CIMAX (NCT02354105) was a non-interventional multicentre prospective cohort study observing CZP treatment response and safety over 12 months in a real-world clinical cohort of axSpA pts newly prescribed CZP. The primary outcome was change from baseline (CFB) in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) to Week (Wk) 52 in pts with available data, with additional outcomes pertaining to effectiveness and safety. Outcomes were evaluated for AS and nr-axSpA subpopulations (diagnosed according to local practice). Pts who received ≥ 1 dose CZP were followed up for adverse events (AEs) (Safety Set [SS]); those with baseline and ≥ 1 post-baseline BASDAI assessment were included in the effectiveness analyses (Full Analysis Set [FAS]). Outcomes are reported using observed case data with no imputation.

Results: 682 axSpA pts were enrolled from 101 European sites, of whom 490 (71.8%) completed the study. Of those enrolled, 672 formed the SS (AS: 469; nr-axSpA: 201) and 564 the FAS (AS: 384; nr-axSpA: 179); 2 (SS)/1(FAS) pts with unconfirmed AS/nr-axSpA were included in the overall axSpA population. 27.5% (185/672[SS]) axSpA pts had previous anti-TNF exposure (AS: 31.1% [146/469]; nr-axSpA: 18.4% [37/201]). BASDAI data were available for 77.8% (439/564) pts at Wk52. In pts with available data, all clinical outcomes were improved at Wk52 in both subpopulations (Table). At baseline, the mean BASDAI was 6.1. At Wk52, the mean BASDAI CFB in pts with available data (n=439) was -2.9 (AS: -2.9 [n=301]; nr-axSpA: -2.8 [n=137]). For pts with and without prior anti-TNF exposure, BASDAI at baseline was 6.1 in both groups (n=165 vs n=399, respectively), and at Wk52, the mean BASDAI CFB was -2.6 (n=127) vs -3.0 (n=312) (AS: -2.7 vs -3.0; nr-axSpA: -2.2 vs -3.0). In the SS, 37.9% (255/672) pts experienced AEs; 20.7% (139/672) experienced drug-related AEs and 6.3% (42/672) serious AEs (1.8% [12/672] reported serious infections); these data were comparable between AS and nr-axSpA (Table).

Conclusion: This is the first multicentre European study to evaluate CZP effectiveness and safety in both axSpA subpopulations in routine practice. Improvements were observed in all signs and symptoms in pts who remained on treatment to Wk52; >70% of those enrolled completed the study. No new safety signals were identified following application of CZP to real-world rheumatological practice.

Table: Clinical and safety outcomes at Week 52 for patients with axSpA in CIMAX

Clinical outcomes (FAS)	AS (n=384)		nr-axSpA (n=179)		Overall axSpA (n=564)	
	BL	Wk52	BL	Wk52	BL	Wk52
BASDAI	6.1 (1.8)	3.2 (2.1)	6.1 (1.7)	3.2 (2.2)	6.1 (1.8)	3.2 (2.2)
Mean (SD)	n=384	n=301	n=179	n=137	n=564	n=439
BASDAI CFB	-	-2.9 (2.2)	-	-2.8 (2.4)	-	-2.9 (2.3)
Mean (SD)	-	n=301	-	n=137	-	n=439
ASAS20	-	72.8 (209/289)	-	64.3 (181/226)	-	69.7 (200/286)
% (n/N) [95% CI]	-	[67.2, 77.5]	-	[55.9, 72.7]	-	[65.3, 74.1]
ASAS40	-	51.5 (150/291)	-	48.4 (62/128)	-	50.3 (112/220)
% (n/N) [95% CI]	-	[45.8, 57.3]	-	[39.6, 57.1]	-	[45.7, 55.3]
ASDAS (CRP) (n)	3.7 (0.9)	2.1 (1.0)	3.5 (0.8)	2.0 (1.0)	3.6 (0.9)	2.1 (1.0)
Mean (SD)	n=345	n=267	n=158	n=115	n=504	n=383
ASDAS-SD	0.9	24.1	0.6	25.6	0.8	24.5
% (n/N)	(1/351)	(65/270)	(1/160)	(10/117)	(4/512)	(95/388)
BASFI	5.4 (2.4)	3.1 (2.4)	5.1 (2.3)	2.9 (2.5)	5.1 (2.4)	3.1 (2.4)
Mean (SD)	n=383	n=301	n=179	n=137	n=563	n=439
Total back pain (n)	6.8 (2.2)	3.3 (2.3)	6.6 (2.4)	3.3 (2.6)	6.7 (2.3)	3.3 (2.4)
Mean (SD)	n=382	n=297	n=177	n=137	n=560	n=435
PRISDA	6.9 (2.3)	3.2 (2.4)	6.9 (1.8)	3.3 (2.6)	6.9 (2.1)	3.2 (2.3)
Mean (SD)	n=384	n=295	n=177	n=135	n=562	n=431
PRISDA	6.3 (1.7)	2.4 (1.9)	6.2 (1.7)	2.1 (1.9)	6.4 (1.7)	2.3 (1.9)
Mean (SD)	n=378	n=295	n=177	n=135	n=556	n=431
Safety outcomes (SS), % (n)	AS (n=469)		nr-axSpA (n=201)		Overall axSpA (n=672)	
	BL	Wk52	BL	Wk52	BL	Wk52
Any AE	16.1 (17)	79.8 (101)	79.8 (101)	77.4 (122)	77.4 (122)	77.4 (122)
Serious AEs	6.2 (29)	6.3 (13)	6.3 (13)	6.3 (12)	6.3 (12)	6.3 (12)
Serious infections	1.5 (7)	2.5 (5)	2.5 (5)	1.8 (12)	2.5 (5)	1.8 (12)
Drug-related AEs	18.6 (87)	24.9 (32)	24.9 (32)	20.7 (139)	20.7 (139)	20.7 (139)

Observed data are presented. (n) includes 1 patient with unconfirmed AS/nr-axSpA classification; (n) CRP values ≥ 2 were reduced with 1 to complete ASDAS (n) Measured using a numerical rating scale where 0 = 'no pain' and 10 = 'worst possible pain'. All adverse events: AE: any adverse event; ASDAS: ASDAS20/ASDAS40; ASDAS (CRP): ASDAS (CRP) International Society 2004/ASDAS response; ASDAS: Ankylosing Spondylitis Disease Activity Index; ASAS20: ASAS20 Inactive Disease Index; nr-axSpA: non-radiographic axSpA; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BL: baseline; CFB: change from BL; CI: confidence interval; CZP: certolizumab pegol; FAS: Full Analysis Set; nr-axSpA: non-radiographic axSpA; PRISDA: Physician's Global Assessment of Disease Activity; SD: standard deviation; SS: Safety Set; Wk: week.

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EFFECT OF SWITCHING BETWEEN TUMOR NECROSIS FACTOR INHIBITOR IN SPONDYLOARTHRITIS

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Background: The introduction of new drugs, in particular tumour necrosis factor inhibitor (TNFi) has revolutionized the treatment of spondyloarthritis (SpA). Meanwhile, about 30% of patients do not react to first-line TNFi. To date, there is no recommendations available for the treatment of SpA patients after first TNFi failure.

Objectives: In this study we assessed the effectiveness of a second and third biotherapy in patients with SpA with an inadequate response to previous TNFi and to analyze the survival of the second biotherapy

Methods: This study included patients with SpA who had had at least two biotherapies. Treatment response was noted at 3 months. At 6 months, we assessed the maintaining of effectiveness in SpA. We studied the elements of a good response to the second biotherapy.

Results: Our population of study included 30 SpA. During the second treatment, response rate was achieved by 80% after 3 months. No difference was noted between first and second TNFi among switchers. 86, 7% maintained response at twelve months. For axial forms, decrease in BASDAI was significant at 3 months. For peripheral forms, an improvement of the swollen and tender joint counts was observed and was significant at 3 months. Four patients have received a third TNFi. Response rate was achieved by all of them after 3 months. All of them maintained response at 6 months. The elements of a good response founded were: the early age of the SpA starting (<30y.o), the high value of initial CRP, the use of ESSG criteria, the SpA type, the extra articular signs, the first biotherapy and the response at 3 months to it, the drugs taken when second biotherapy were initiated a low initial EVA and BASFI.

Conclusion: These real-life data show that, after discontinuation of a first TNFi, switching to a second biotherapy in SpA is related to significantly improving of clinical effectiveness compared to a first TNFi.

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none

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