BL up to wk 52 according to clinical routine. Real-world effectiveness of secukinumab was assessed prospectively and analyzed as observed.

Results: At BL, 641 PsA pts were included of whom 385 (60.1%) completed 52 wks so far (i.e. at the time of data cut-off for this interim analysis). 58.5% (n=375) of the pts were female and 41.5% (n=266) were male, mean age was 52.6 years. About 66% (n=424) were pre-treated with biologics. Mean PhGA improved from 5.3 at BL (n=571, 89.1%) to 2.5 at wk 52 (n=341, 53.2%). Mean absolute PASI improved from 8.1 at BL (n=211, 32.9%) to 1.2 at wk 52 (n=147, 22.9%). More than half of the documented pts (51 out of 94) achieved a 100% reduction (PASI 100) in skin symptoms at wk 52. The mean number of tender/swollen joints (ACR) was reduced from 7.6 (n=436, 68.0%)/3.9 (n=437, 68.2%) to 3.0 (n=241, 37.6%)/0.7 (n=242, 37.8%) at wk 52. The percentage of pts with CRP >5mg/L dropped from 43.0% at BL (n=230) to 36.6% at wk 52 (n=112). Mean PsAID-12 improved from 5.0 at BL (n=602, 93.9%) to 3.3 at wk 52 (n=343, 53.5%). The percentage of PsA pts with high disease activity (score $\geq$ 5) assessed by PsAID-12 dropped from 61.0% at BL (n=367) to 26.2% at wk 52 (n=90). MOS sleep scales did not change relevantly over time. With respect to pts with a BDI-II reduction of at least 3 score points, the mean value improved from 16.4 (mild depression) at BL to 8.0 (no depression) at wk 52 (n=123, 19.2%).

Conclusion: Secukinumab reduced disease activity and improved QoL already within this subgroup of PsA pts. Thus, real-world data from the AQUILA study show that, in clinical routine, secukinumab treatment up to one year provides a clear benefit for PsA pts in clinical and QoL parameters.

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FRI0406

AQUILA STUDY IN GERMANY – REAL WORLD DATA ON SECUKINUMAB'S EFFECTIVENESS IN ANKYLOSING SPONDYLITIS PATIENTS – RESULTS FROM AN INTERIM ANALYSIS

Uta Kiltz¹, Daniel Peterlik², Veronika Winkelmann², Hans-Peter Tony³, on behalf of the AQUILA Study Group. ¹Rheumazentrum Ruhrgebiet, Herne, and Ruhr University, Bochum, Germany; ²Novartis Pharma GmbH, Clinical Research Immunology, Hepatology and Dermatology, Nürnberg, Germany; ³Medizinische Klinik II, Universitätsklinik, Rheumatology/Immunology, Würzburg, Germany

Background: Ankylosing spondylitis (AS) is characterized by chronic inflammation of the spine and is at high risk to cause inflammation, pain, and stiffness extraspinal as well. Thus, important aims in therapy of AS are pain reduction and maintenance of physical functioning. Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin (IL)-17A, has already shown significant efficacy in the treatment of AS in clinical trials¹.

Objectives: The aim of this interim analysis is to evaluate the effectiveness of secukinumab on disease activity, physical functioning and quality of life in AS patients (pts) in a real world setting.

Methods: AQUILA is an ongoing, multi-center, 52-week (wk) non-interventional study enrolling 2000 pts with active AS and psoriatic arthritis in Germany. Here, we report interim results of effectiveness in a subgroup of AS pts treated with secukinumab.

Validated questionnaires were used to measure the effectiveness of secukinumab on:

- disease activity
- o Physician's Global Assessment (PhGA: 0=no disease activity, 10=most intense disease activity),
- o Bath Ankylosing Disease Activity Index (BASDAI),
- o C-reactive protein (CRP)
- physical functioning
- o global functioning: Assessment of Spondyloarthritis Health Index, (ASAS-HI),
- and key aspects of sleep
- o Medical Outcomes Study Sleep Scale (MOS),

- severity of depression
- o Beck's Depression Inventory Version II (BDI-II).

Pts who were already under secukinumab treatment or just about initiating secukinumab therapy, based on medical therapeutic need, were included; in both scenarios, disease activity at start of secukinumab treatment was used as starting point for analysis. Treatment decision was made independently of participating in this study. Pts were observed from BL up to wk 52 according to clinical routine. Real-world effectiveness of secukinumab was assessed prospectively and analyzed as observed.

Results: This interim analysis describes 311 AS pts who were included at BL and of whom 178 (57.2%) have completed wk 52 so far (i.e. at the time of data cut-off for this interim analysis). 63.3% (n=197) of the pts were male and 36.7% (n=114) female, mean age was 47 years. About 70% (n=221) of the pts were pre-treated with biologics. Physicians reported a mean PhGA value of 5.9 at BL (n=282, 90.7%) which improved to 2.6 at wk 52 (n=168, 54.0%). Mean BASDAI value was reduced from 5.6 at BL (n=301, 96.8%) to 4.0 at wk 52 (n=171, 55.0%). With regard to inflammation parameters, the percentage of pts with a CRP of >5mg/L decreased from 54.7% (n=140) to 40.0% (n=58) at wk 52. Further, mean ASAS-HI value decreased over time from 8.2 at BL (n=274, 88.1%) to 6.3 at wk 52 (n=156, 50.2%). MOS sleep scale did not change over time, yet only few BL documentations for these scales were available (range n=26 to 44). Regarding depressive mood of the pts, while at BL 40.7% (n=101) of the pts suffered from mild to severe depression (BDI-II score between 14 and 63), 30.3% (n=46) did so in wk 52. This is reflected by a drop of mean BDI-II value from 13.0 at BL (n=248, 79.7%) to 10.6 at wk 52 (n=152, 48.9%).

Conclusion: Within this limited subset of AS pts, secukinumab reduced disease activity and improved quality of life for up to one year as assessed by validated physicians' as well as pt-reported outcomes. Overall, this interim analysis gives promising insights into treatment effects of secukinumab on pts' physical and mental well-being under real-world conditions.

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FRI0407

TWO-YEAR ULTRASOUND CONTROLLED STUDY OF HYALINE CARTILAGE AND SYNOVIAL LAYER STRUCTURE OF HIP JOINTS IN PATIENTS WITH ANKYLOSING SPONDYLITIS DURING TREATMENT WITH ADALIMUMAB

Andriy Petrov¹, Anife Gaffarova¹, Aleksey Petrov¹, Jana Shevnina². ¹Crimean Federal University. Medical Academy, Simferopol, Russian Federation; ²Crimean Clinical Hospital n.a. N.A. Semashko, Simferopol, Russian Federation

Background: The impairment of hip joints has significant prognostic value on functional status of patients with Ankylosing spondylitis (AS) [1]. One of possible yearly marker of hip joints structure damage in patients with AS may be changing in volume of hyaline cartilage [2]. Objectives.

Objectives: To investigate changes in width of hyaline cartilage and synovial layer of hip joints in patients with coxitis, associated with AS under treatment with adalimumab (ADA) during 2 years.

Methods: The 28 patients with AS and clinical, ultrasound and radiographic signs of coxitis (21 male, 7 female, average age is 35.4 years old, duration of disease is 12-132 months) were included into study. All patients were being treated by NSAIDs at least 3 months before they started to take ADA (40 mg subcutaneously every 2 weeks). Treatment with ADA was continued during 24 months. Patients were observed at month 0, 12 and 24 months of treatment including measurements of pain visual analog scale (VAS) in hip movements, maximal distance between ankles, pelvic X-ray and sonography of hip joints by 10-18 MHz probe. BASRI-Hips index was applied for radiographic estimation of structural damage of hip joints [3]. During sonography width of hip joint capsule and hyaline cartilage were measured. The Mann-Whitney-U test was used for comparison of changes in clinical and sonographic data between two groups of patients.

Results: It was determined that pain VAS at hip movements was decreased (23.1 [12.3; 32.3] mm at month 12 and 19.7 [11.8; 32.9] mm at month 24 vs 73.7 [59.5; 82.6] mm at month 0, $p < 0.05$) and maximal distance between ankles was increased (112.5 [94.7; 122.2] mm at month 12 and 116.2 [91.2; 125.0] mm at month 24 vs 78.7 [63.4; 98.5] mm at month 0, $p < 0.05$) in observed patients under treatment with ADA. It was also found that ultrasound measured width of hip joint capsule was decreased from 11.8 [10.3; 12.7] mm at month 0 to 8.7 [8.1; 9.4] mm at month 12 ($p < 0.05$) and 7.5 [6.6; 8.5] mm at month 24 ($p < 0.05$). The ultrasound measured width of hyaline cartilage in observed patients was increased from 0.8 [0.6; 1.1] mm at month 0 to 1.0 [0.8; 1.2] mm at month 12 ($p > 0.1$) and 1.2 [1.0; 1.7] mm at month 24 ($p < 0.05$) under treatment with ADA. The BASRI-Hips index had not changed in observed patients at the end of 24-months period. The differences in changes of hip cartilage width between patients with joint capsule width at month 24 less than 9 mm and more than 9 mm was determined ($p < 0.05$): +0.6 [0.3; 0.8] mm vs +0.1 [-0.1; 0.2] mm.

Conclusion: Treatment with ADA leads to decrease of clinical and sonographic signs of coxitis in patients with AS and improves of hyaline cartilage structure. The increase of width of hip hyaline cartilage was observed in patients with absence of ultrasound signs of hip joints synovial inflammation in patients with AS. MRI-controlled studies are needed to confirm ability of THF α inhibitors to restore cartilage volume in patients with coxitis, associated with AS.

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FRI0408

EARLIER TREATMENT OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS WITH CERTOLIZUMAB PEGOL RESULTS IN IMPROVED CLINICAL OUTCOMES

Martin Rudwaleit¹, Lianne S. Gensler², Atul Deodhar³, Jonathan Kay⁴, Walter P. Maksymowich⁵, Nigil Haroon⁶, Robert B.M. Landewé⁷, Simone Auteri⁸, Natasha de Peyrecave⁹, Thomas Kumke⁹, Désirée van der Heijde¹⁰. ¹Klinikum Bielefeld, Bielefeld, Germany; ²University of California San Francisco, San Francisco, CA, United States of America; ³Oregon Health and Science University, Portland, OR, United States of America; ⁴UMass Memorial Medical Center and University of Massachusetts Medical School, Worcester, MA, United States of America; ⁵University of Alberta, Edmonton, Canada; ⁶Krembil Research Institute, and University of Toronto, Toronto, Canada; ⁷Academic Medical Center and Zuyderland Medical Center, Heerlen, Netherlands; ⁸UCB Pharma, Brussels, Belgium; ⁹UCB Pharma, Monheim, Germany; ¹⁰Leiden University Medical Center, Leiden, Netherlands

Background: Patients (pts) with axial spondyloarthritis (axSpA) often experience delayed diagnosis, which leads to treatment delay.¹ Whilst certolizumab pegol (CZP) has been shown to improve the signs and symptoms of non-radiographic (nr)-axSpA,² whether earlier CZP treatment is beneficial in these pts is unclear.

Objectives: To report clinical outcomes in pts with nr-axSpA treated with CZP or placebo (PBO) over 52 weeks (wks) by their symptom duration.

Methods: Post-hoc analyses of disease outcomes in pts stratified by symptom duration (<5 vs ≥ 5 yrs at baseline [BL]) from C-axSpA (NCT02552212) were performed. In this 52-week, phase 3, multicentre, double-blind, PBO-controlled study, pts were randomised 1:1 to PBO or CZP (400mg at Wks 0/2/4, then 200mg every 2 wks), and could adjust non-biologic background medication or switch to open-label biologics at any point.² Outcomes reported: responder rates for Ankylosing Spondylitis Disease Activity Score – major improvement (ASDAS-MI), ASAS 40% improvement (ASAS40) and ASAS partial remission (ASAS-PR); the proportion of pts who reached ASDAS-inactive/low disease (ASDAS-ID/LD) or ASDAS<2.1; and change from BL (CFB) in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). Missing values or values observed after discontinuing double-blind study treatment were considered to be non-response for categorical measures or, for quantitative measures, imputed by carrying forward the last observation from double-blind treatment.

Table: Clinical outcomes in patients treated with PBO or CZP stratified by symptom duration

	Wk	CZP (n=159)		PBO (n=158)	
		Symptom duration: <5 yrs (n=80)	Symptom duration: ≥ 5 yrs (n=79)	Symptom duration: <5 yrs (n=77)	Symptom duration: ≥ 5 yrs (n=81)
ASDAS-MI [a]	0	–	–	–	–
% (n)	12	46.3 (37)	24.1 (19)	9.1 (7)	3.7 (3)
	52	55.0 (44)	39.2 (31)	7.8 (6)	6.2 (5)
ASAS40 [a]	0	–	–	–	–
% (n)	12	58.8 (47)	36.7 (29)	11.7 (9)	11.1 (9)
	52	65.0 (52)	48.1 (38)	18.2 (14)	13.6 (11)
ASAS-PR [a]	0	–	–	–	–
% (n)	12	32.5 (26)	12.7 (10)	3.9 (3)	1.2 (1)
	52	43.8 (35)	24.1 (19)	2.6 (2)	6.2 (5)
ASDAS-ID [b]	0	–	–	–	–
% (n/N)	12	20.3 (16/79)	12.8 (10/78)	1.3 (1/77)	1.2 (1/81)
	52	40.5 (32/79)	17.9 (14/78)	2.6 (2/77)	6.2 (5/81)
ASDAS-LD [b]	0	–	–	–	–
% (n/N)	12	39.2 (31/79)	24.4 (19/78)	14.3 (11/77)	9.9 (8/81)
	52	25.3 (20/79)	34.6 (27/78)	16.9 (13/77)	11.1 (9/81)
ASDAS<2.1 [b]	0	–	–	–	–
% (n/N)	12	59.5 (47/79)	37.2 (29/78)	15.6 (12/77)	11.1 (9/81)
	52	65.8 (52/79)	52.6 (41/78)	19.5 (15/77)	17.3 (14/81)
BASDAI [b]	0	6.7 (1.3; 80)	7.0 (1.5; 79)	6.9 (1.3; 77)	6.7 (1.3; 81)
Mean (SD; n)	12	3.4 (2.1; 79)	4.5 (2.2; 78)	5.8 (2.1; 77)	5.6 (2.1; 81)
	52	2.8 (2.3; 79)	3.7 (2.5; 78)	5.5 (2.4; 77)	5.4 (2.2; 81)

[a] Missing values imputed using non-responder imputation; [b] Missing values imputed using double-blind last observation carried forward. ASDAS: Assessment in SpondyloArthritis international Society; ASDAS: Ankylosing Spondylitis Disease Activity Score; ASDAS-ID: ASDAS inactive disease (ASDAS<1.3); ASDAS-LD: ASDAS low disease (ASDAS ≤ 1.3 , <2.1); ASDAS-MI: ASDAS major improvement (ASDAS reduction of ≥ 2.0 or lowest possible score [0.6]); ASAS40: ASAS 40% improvement; ASAS-PR: ASAS partial remission (score ≤ 2 in all 4 domains); BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; CZP: certolizumab pegol; PBO: placebo; pt: patient; yrs: years.

Results: Of 317 recruited pts, 159 were randomised to CZP, and 158 to PBO. The mean (standard deviation [SD]) BL symptom duration was 7.8 (7.7) yrs for CZP-treated pts and 8.0 (7.5) yrs for PBO pts. 50.3% (80/159) CZP pts and 48.7% (77/158) PBO pts had a symptom duration <5 yrs. At Wks 12 and 52, ASDAS-MI, ASAS40 and ASAS-PR responder rates, the proportions of pts reaching ASDAS-ID and ASDAS<2.1, and mean CFB in BASDAI, were substantially better among CZP-treated pts with shorter symptom duration (<5 yrs at BL) vs longer symptom duration (Table). Amongst PBO pts, responses were low and there was no consistent trend in outcomes by symptom duration (Table).

Conclusion: In this post-hoc analysis, CZP-treated nr-axSpA pts with shorter symptom duration (<5 vs ≥ 5 yrs) showed greater improvements across multiple signs and symptoms of disease. These results indicate that early CZP treatment for nr-axSpA may be beneficial to pts.

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