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OP0142

NETAKIMAB REDUCES ANKYLOSING SPONDYLITIS ACTIVITY IN PATIENTS WITH OR WITHOUT SACROILIITIS ON MRI: RESULTS OF SUBANALYSIS OF PHASE 3 ASTERA TRIAL

I. Gaydukova^{1,2}, V. Mazurov¹, S. Erdes³, T. Dubinina⁴, A. Kundzer⁵, N. Soroka⁶, A. Ereemeeva⁷. ¹Mechnikov North-Western State Medical University, Department of Therapy and Rheumatology of Temporary Disability and Medical Care Quality Expertise, St-Petersburg, Russian Federation; ²Clinical Rheumatology Hospital No 25, Consultative Outpatient Department, St-Petersburg, Russian Federation; ³Nasonova Research Institute of Rheumatology, Laboratory of Spondyloarthritis, Moscow, Russian Federation; ⁴Nasonova Research Institute of Rheumatology, Laboratory of Medical and Social Problems of Rheumatology, Moscow, Russian Federation; ⁵Belarusian Medical Academy of Postgraduate Education, Department of Cardiology and Rheumatology, Minsk, Belarus; ⁶Belarusian State Medical University, Department of Internal Diseases №2, Minsk, Belarus; ⁷JSC BIOCAD, Clinical Development Department, St-Petersburg, Russian Federation

Background: The presence of sacroiliitis in patients (pts) with ankylosing spondylitis (AS) on imaging can be established both by sacroiliac joint (SIJ) X-ray or MRI. Active sacroiliitis on MRI as defined by ASAS is predictor of good treatment response to biological disease modifying anti-rheumatic drugs [1, 2]. Netakimab (NTK) is a humanized anti-interleukin-17A antibody approved for the treatment of AS, psoriatic arthritis, moderate-to-severe plaque psoriasis in Russia and Belarus. The difference in treatment response to NTK in AS pts with and without active sacroiliitis on MRI (MRI+/MRI-) is unclear.

Objectives: To report the changes in AS activity in pts with and without sacroiliitis on MRI at week 16 of NTK treatment.

Methods: ASTERA (NCT03447704) is an ongoing phase 3 placebo (PBO)-controlled clinical study, aimed at evaluating NTK efficacy in AS. All pts fulfilled modified New York criteria. Evaluation of acute inflammation on SIJ MRI was performed at the baseline but was not an inclusion criterion. This analysis includes pts received subcutaneous NTK 120mg every 2 wks with available baseline SIJ MRI. The presence of sacroiliitis on MRI was defined as SPARCC>2. Efficacy endpoints included ASAS20/40, ASAS partial remission (PR), changes from baseline in BASDAI (Bath Ankylosing Spondylitis Disease Activity Index), ASDAS-CRP (Ankylosing Spondylitis Disease Activity Score).

Results: 67 MRI+ and 46 MRI- pts were included into analysis. Baseline characteristics were balanced across both arms. 42.4% of MRI+ pts and 38.3% of MRI- pts achieved ASAS40 at week 16 ($p \geq 0.05$), ASAS20 was observed in 65.2%/55.3% pts in the same arms respectively ($p \geq 0.05$). ASAS PR was reported for 15.2% MRI+ and 17.0% MRI- pts ($p \geq 0.05$). Improvements in BASDAI and ASDAS-CRP were similar across both arms. At wk 16, mean change from baseline in BASDAI was -2.7 vs -3.0 for MRI+ and MRI- pts respectively, mean change in ASDAS-CRP was -1.7 vs -1.4 in the same arms ($p \geq 0.05$ for all), (figure 1).

Figure 1. Clinical improvements in AS disease activity. Mean change from baseline is shown for (A) ASDAS-CRP, and (B) BASDAI

Conclusion: NTK leads to decline of disease activity in AS pts irrespectively of sacroiliitis on MRI.

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OP0143

IMPACT OF ADALIMUMAB VERSUS NON-BIOLOGIC THERAPY ON DISEASE ACTIVITY AND PATIENT-REPORTED OUTCOMES IN ANKYLOSING SPONDYLITIS OVER 24 MONTHS – RESULTS OF THE COMPLETE-AS CANADIAN OBSERVATIONAL STUDY

L. Bessette¹, A. Chow², V. Pavlova³, M. C. Laliberté⁴, M. Khraishi⁵. ¹Laval University, Centre Hospitalier de l'Université Laval, Laval University, Centre Hospitalier de l'Université Laval, Quebec City, Canada; ²University of Toronto, University of Toronto, Toronto, Canada; ³McMaster University, McMaster University, Hamilton, Canada; ⁴AbbVie Corporation, AbbVie Corporation, Montreal, Canada; ⁵Memorial University of Newfoundland, Memorial University of Newfoundland, St. John's, Canada

Background: COMPLETE-AS was an observational study among Canadian biologic-naïve adults with active ankylosing spondylitis (AS) treated with either adalimumab or subsequent non-biologic disease-modifying anti-rheumatic drugs and/or non-steroidal anti-inflammatory drugs (nbDMARD/NSAID) after having switched from initial treatment with a preceding nbDMARD and/or NSAID due to lack of response or intolerance, as per treating physician judgement.

Objectives: To assess the impact of adalimumab on disease activity and patient-reported outcomes among adalimumab- vs. nbDMARD/NSAID-treated patients over 24 months.

Methods: Patients were enrolled between July 2011 and December 2017 and followed for up to 24 months. Treatment was per routine care and all analyses were performed using the intent-to-treat (ITT) approach. Between-group differences for change in patient-reported disease activity (BASDAI), morning stiffness (minutes/day), functional limitation (BASFI), quality of life (QoL: SF-12), depression (BDI-II), and work productivity (WLQ) were assessed with repeated measures models for overall treatment effect; baseline-adjusted estimates (least square means [LSM]) for each visit were produced. Achievement of, and time to the following endpoints were assessed: 50% improvement from baseline in BASDAI (BASDAI50); minimum clinically important improvements (MCII) in BASDAI ($\Delta \geq 1.1$); BASFI ($\Delta \geq 0.6$); SF-12 physical component score (PCS; $\Delta \geq 4.4$) and mental component score (MCS; $\Delta \geq 3.1$); and low disease activity for BASDAI (<4) and BASFI (<3.8).

Results: A total of 452 adalimumab-treated patients and 187 nbDMARD/NSAID-treated patients were enrolled in the study and included in the analyses. At baseline, mean (SD) BASDAI [6.4 (1.8) vs. 5.0 (1.8); $p < 0.001$] and BASFI [5.5 (2.4) vs. 3.7 (2.4)] were however significantly ($p < 0.001$) higher among adalimumab-treated patients compared to nbDMARD/NSAID-treated patients, respectively. Over 24 months, adalimumab-treated patients had significantly lower overall BASDAI scores compared to nbDMARD/NSAID-treated patients [estimate (95% CI): -0.7 (-1.2, -0.3); $p = 0.007$]. BASFI scores were also significantly lower among adalimumab-treated patients over the course of the study [estimate (95% CI): -0.4 (-0.8, 0.0); $p = 0.013$]. Both groups had statistically comparable outcomes for morning stiffness, BDI-II, WLQ, and SF-12.

Adalimumab-treated patients were also at significantly higher odds of achieving therapeutic response thresholds, including BASDAI50 [OR (95% CI): 1.7 (1.2-2.3)], BASDAI<4 [1.8 (1.2-2.7)], MCII for BASDAI [1.9 (1.3-2.9)], and MCII for BASFI [1.6 (1.1-2.2)]. Time to achievement of each threshold was significantly shorter among adalimumab-treated patients for BASDAI50 [HR (95% CI): 1.8 (1.1-2.8)], BASDAI<4 [1.7 (1.6-3.6)], and MCII for BASDAI [1.5 (1.0-2.3)]. Time to achievement of MCII for BASFI was not statistically different between groups; for BASFI<3.8 and MCII for both SF-12 PCS and MCS, both odds of, and time to achievement, were also statistically comparable.

At month 24, baseline-adjusted BASDAI and BASFI was comparable ($p > 0.05$): LSM (95%CI) 3.5 (3.3, 3.8) vs. 3.6 (3.2-4.0), and 2.9 (2.6-3.1) vs. 3.3 (2.9-3.7), respectively, for adalimumab-treated vs. nbDMARD/NSAID-treated patients.

Conclusion: Among Canadian patients with active AS, adalimumab-treated patients reported a greater overall reduction in disease burden related to both self-reported disease activity and functional capacity compared to nbDMARD/NSAID-treated patients, along with higher odds and shorter time to achieving therapeutic response thresholds. Despite the overall beneficial effects observed with adalimumab, residual disease burden, however, is observed for Canadian AS patients even after 24 months of treatment.

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OP0144

EFFICACY AND SAFETY OF UPADACITINIB IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: 1-YEAR RESULTS FROM A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY WITH OPEN-LABEL EXTENSION

A. Deodhar¹, D. Van der Heijde², J. Sieper³, F. Van den Bosch⁴, W. P. Maksymowych⁵, T. H. Kim⁶, M. Kishimoto⁷, A. Ostor⁸, B. Combe⁹, Y. Sui¹⁰,

X. Wang¹⁰, A. Chu¹⁰, I. H. Song¹⁰. ¹Oregon Health, Science University, Portland, United States of America; ²Leiden University, Medical Center, Leiden, Netherlands; ³Charité Universitätsmedizin, Medicine, Berlin, Germany; ⁴Ghent University Hospital, Rheumatology, Ghent, Belgium; ⁵University of Alberta, Rheumatology, Edmonton, Canada; ⁶Hanyang University, Hospital for Rheumatic Diseases, Seoul, Korea, Rep. of (South Korea); ⁷Kyori University, School of Medicine, Tokyo, Japan; ⁸Cabrini Hospital, Monash University & Emeritus Research, Melbourne, Australia; ⁹CHU Montpellier, Montpellier University, Montpellier, France; ¹⁰AbbVie Inc., Rheumatology, North Chicago, United States of America

Background: Upadacitinib (UPA) was efficacious and well tolerated vs placebo (PBO) during the first 14 weeks (wks) of the phase 2/3 SELECT-AXIS 1 study in patients (pts) with active ankylosing spondylitis (AS) who had an inadequate response to NSAIDs.¹

Objectives: To report efficacy and safety of UPA through 1 year in the SELECT-AXIS 1 study.

Methods: In SELECT-AXIS 1 (NCT03178487) pts were randomized 1:1 to UPA 15 mg once daily (QD) or PBO; at wk 14, pts continued in the 90-wk open-label extension and received UPA 15 mg QD; reported here are data up to wk 64. The study enrolled pts (≥ 18 y) with active AS (defined as BASDAI ≥ 4 and pt assessment of back pain ≥ 4 [numeric rating scale, 0–10] at screening and baseline [BL]) who had inadequate response to ≥ 2 NSAIDs or intolerance to or contraindication for NSAIDs and were biologic DMARD naïve. Efficacy assessments included percentage of pts with Assessment of SpondyloArthritis international Society (ASAS) 20/40 response, ASAS partial remission, BASDAI50, AS Disease Activity Score (ASDAS) and change from BL in ASDAS and BASFI. Data are reported as observed and by using non-responder imputation (NRI). Treatment-emergent adverse events (TEAEs) were reported as events per 100 patient-years (PY) up to January 31, 2020.

Results: Of 187 pts, 178 pts (each n=89 for UPA and PBO arms) completed wk 14 on study drug and entered the open-label extension; 160 pts completed wk 64. Efficacy was maintained or continued to improve throughout the study in the continuous UPA group: 85% (95% CI, 77%–93%) of pts achieved ASAS40 at wk 64 in the as-observed analysis and 72% (63%–81%) in the NRI analysis (Figure). Pts who switched from PBO to UPA at wk 14 showed similar speed of onset and magnitude of response vs pts

Figure. Efficacy Endpoints Over Time

AO, as observed; ASAS, Assessment of SpondyloArthritis international Society; ASDAS, Ankylosing Spondylitis Disease Activity Score; ID, inactive disease; MMRM, mixed-effect model repeated measures; NRI, non-responder imputation; PR, partial remission; QD, once daily; UPA, upadacitinib.
Dashed line: all patients randomized to placebo received open-label UPA starting from week 14.
N's below the graphs are for as observed analysis. N's for NRI analysis were 94 for placebo to upadacitinib and 93 for continuous upadacitinib. 160 patients completed week 64; lack of efficacy (n=10) and adverse events (n=4) were the most common reasons for discontinuation between weeks 14 and 64.