Chugai, Eli Lilly, Grünenthal, Janssen, MSD, Novartis, Pfizer, Roche, and UCB. Consultant for: Abbvie, Chugai, Eli Lilly, Grünenthal, Janssen, MSD, Novartis, Pfizer, Roche, and UCB. There were no payments made to any of the authors. Employee of: Eli Lilly and Company, Yan Dong Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Ann Leung Employee of: Syneos Health, David Sandoval Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Luis Leon Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Vbke Beke Strand Consultant for: Abbvie, Amgen, Bayer, BMS, Boehringer Ingelheim, Celgene, celltrion, CORRONA, Crescendo, EMD Serono, Genentech/Roche, GSK, Horizon, Inmedix, Janssen, Kezar, Lilly, Merck, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi, Servier, UCB.


AB0711

IKEXIZUMAB IMPROVES SIGNS AND SYMPTOMS AND SPINAL INFLAMMATION OF ANKYLOSING SPONDYLITIS/RADIODIAGNOSTIC AXIS SPONDYLOARTHROPATHY THROUGH ONE YEAR OF TREATMENT IN BIOLOGIC DISEASE MODIFYING ANTI-RHEUMATIC DRUG-NAÏVE PATIENTS

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Background: During 16 weeks (wks) of blinded treatment, ixekizumab (IXE) and an adalimumab (ADA) active reference arm were superior to placebo (PBO) in improving signs and symptoms of radiographic axial spondyloarthritis (r-axSpA).1

Objectives: To assess the safety and efficacy of continuous treatment with IXE through 52 wks in patients (pts) with r-axSpA and to describe clinical response at Wk 52 for pts who switched to IXE following 16 wks of treatment with either ADA or PBO.

Methods: Participants were biologic disease-modifying anti-rheumatic drug (bDMARD)-naïve adult pts with active r-axSpA per Assessment of Spondyloarthritis (SpA) international Society (ASAS) criteria (sacroiliitis centrally defined by modified New York criteria and ≥ 1 SpA feature) and inadequate response or intolerance to non-steroidal anti-inflammatory drugs. Pts were randomized 1:1:1:1 to receive 80 mg IXE every 2 (Q2W) or 4 wks (Q4W), 40 mg adalimumab (ADA) Q2W (active reference arm), or PBO. At Wk 16, pts assigned to IXE continued their assigned treatment and pts receiving PBO or ADA were re-randomized 1:1 to IXE Q2W or IXE Q4W through Wk 52.

Results: Of 164 pts initially randomized to IXE, 146 (99%) completed Wk 52. IXE Q4W and IXE Q2W led to persistent improvements in disease activity, function, objective inflammation (MRI and C-reactive protein), quality of life, health status, and overall functioning for up to 52 wks (Figure and Table). For pts initially assigned to PBO or ADA, ASAS40 response showed a numerical increase upon switching to IXE (Table). Frequencies of treatment-emergent adverse events (AEs) were similar between IXE dosing regimens. Among pts with ≥ 1 dose of IXE (N=336), serious AEs occurred in 20 (6%) pts. There were no deaths and 11 (3%) pts discontinued due to AEs.

Efficacy of IXE in bDMARD-naïve patients with active r-axSpA

<table>
<thead>
<tr>
<th></th>
<th>IXE Q4W</th>
<th>IXE Q2W</th>
</tr>
</thead>
<tbody>
<tr>
<td>mBOCF (intent-to-treat)</td>
<td>(N=86)</td>
<td>(N=164)</td>
</tr>
<tr>
<td>ASDAS-CRP</td>
<td>-1.7 (1.2)</td>
<td>-1.6 (1.0)</td>
</tr>
<tr>
<td>BASDAI</td>
<td>-3.3 (2.5)</td>
<td>-3.1 (2.3)</td>
</tr>
<tr>
<td>C-Reactive Protein (mg/L)</td>
<td>-9.2 (12.4)</td>
<td>-9.6 (14.5)</td>
</tr>
<tr>
<td>BASFI</td>
<td>-2.8 (2.5)</td>
<td>-2.8 (2.4)</td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td>8.3 (9.5)</td>
<td>8.1 (7.5)</td>
</tr>
<tr>
<td>ASAS Health Index</td>
<td>-2.7 (3.3)</td>
<td>-3.3 (9.6)</td>
</tr>
<tr>
<td>SPARC Spine Score (observed)</td>
<td>-8.8 (17.3)</td>
<td>-8.5 (15.9)</td>
</tr>
<tr>
<td>Response (%)</td>
<td>PBO/All</td>
<td>ADA/All</td>
</tr>
<tr>
<td>IXE/All</td>
<td>(N=86)</td>
<td>(N=86)</td>
</tr>
</tbody>
</table>

Conclusion: Persistent improvements in the signs and symptoms of r-axSpA were observed through Wk 52 in pts who received continuous treatment with IXE. ASAS40 response rates at Wk 52 were numerically similar between pts who switched to continuous treatment with IXE and pts who switched from ADA to IXE. No unexpected safety signals were observed through 52 wks of treatment.

REFERENCES

1 van der Heijde, et al. Lancet, 2018


Spondyloarthritis – clinical aspects (other than treatment)

AB0712

RETINAL AND CHOROIDAL VASCULAR STRUCTURES ARE AFFECTED IN AXIAL SPONDYLOARTHRITIS: AN OPTICAL COHERENCE TOMOGRAPHY STUDY

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Background: Axial spondyloarthritis (axSpA) is a chronic inflammatory disease that mainly affects axial skeleton. Ocular inflammation is one of the most common extra-articular manifestations of axSpA, mainly form of acute anterior uveitis (AAU). However posterior segment of the eye was rarely evaluated. The inaccessibility of posterior structures like choroid and retina to direct examination led clinicians to use non-invasive imaging technics. Optical coherence tomography (OCT) is an imaging technology to...

**Methods:** In total 70 (66% male; mean age 39.7 ± 10.4 years) axSpA patients (105.8 vs 113.3) this difference did not reach significance in the ganglion cell complex (GCC) were measured by spectral domain optical coherence tomography (SD-OCT) by the same experienced operator. Other disease related characteristics including the ones related to morbidity and epidemiological were collected from the charts. Balance was assessed by Berg Balance Scale (BBS). The following instruments were applied: ASDAS (Ankylosing Spondylitis Disease Activity Score)-ESR, ASDAS-CRP, BASDAI (Bath Ankylosing Spondylitis Disease Activity Index), BASFI (Bath Ankylosing Spondylitis Functional Index), BASMI (Bath Ankylosing Spondylitis Metrology Index) and ASQoL (Ankylosing spondylitis quality of life questionnaire). The number of falls in the last year was collected.

Results: In this sample, 30.9% had high risk of falls by the BBS and 25.4% recalled having at least one fall in the last years. The BBS values were lower in those with white ethnic background (p<0.01) and with HL-A-B27 (p=0.03) and correlated inversely with BASDAI (r=−0.28), ASDAS-ESR (r=−0.32) and ASDAS-CRP (r=−0.33).


**AB0711**

**MAGNETIC RESONANCE IMAGING AND ULTRASONOGRAPHIC MEASUREMENTS OF THE FEMORAL CARTILAGE THICKNESS IN PATIENTS WITH ANKYLOSING SPONDYLITIS**

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Background: Ankylosing spondylitis (AS) is a progressive inflammatory disease involving cartilaginous structures in the spine and peripheral joints.

**Objectives:** To examine the role of musculoskeletal ultrasound (MSUS) and magnetic resonance imaging (MRI) in assessing femoral cartilage thickness in patients with AS and healthy controls, and to study the correlation between femoral cartilage thickness measurements and disease parameters.

**Methods:** Twenty five patients with AS (17 males and 8 females), and twenty five age, sex and BMI matched healthy individuals were included. For all patients assessment of disease activity, spinal mobility, functional limitation and radiological changes were done. Thickness of the femoral articular cartilage was measured by MSUS using a 10-18 MHz linear probe, three mid-point measurements were taken from each knee at the lateral condyle, intercondylar area, and medial condyle. Thickness of the femorotibial arthralgia cartilage was measured by MRI using 1.5 Tesla MR machine.

Results: Patients with ankylosing spondylitis seem to have thinner femoral cartilage thickness than healthy controls. Correlations of knee cartilage thickness measurements either assessed by MSUS or MRI was negatively correlated with age, age at onset of the disease, and measures of disease activity and radiological changes. Positive correlation between ultrasonographic total femoral cartilage thickness and MRI total femoral cartilage thickness was found (r=0.49, p=0.02).


**AB0714**

**BALANCE AND FALLS IN AXIAL SPONDYLOARTHITIS: A CROSS SECTIONAL STUDY**

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Background: Spondyloarthropathy (SpA) patients may suffer of balance loss predisposing them to falls. Objectives: To study balance impairment and falls in SpA patients and its association with clinical and epidemiological variables, disease activity, functional and metrology indexes.

**Methods:** Cross sectional study of 55 SpA patients with axial disease. Clinical and epidemiological were collected from the charts. Balance was accessed by Berg Balance Scale (BBS). The following instruments were applied: ASDAS (Ankylosing Spondylitis Disease Activity Score)-ESR, ASDAS-CRP, BASDAI (Bath Ankylosing Spondylitis Disease Activity Index), BASFI (Bath Ankylosing Spondylitis Functional Index), BASMI (Bath Ankylosing Spondylitis Metrology Index) and ASQoL (Ankylosing spondylitis quality of life questionnaire). The number of falls in the last year was collected.

Results: In this sample, 30.9% had high risk of falls by the BBS and 25.4% recalled having at least one fall in the last years. The BBS values were lower in those with white ethnic background (p<0.01) and with HL-A-B27 (p=0.03) and correlated inversely with BASDAI (r=−0.28), ASDAS-ESR (r=−0.32) and ASDAS-CRP (r=−0.33).


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