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AB0711 **IXEKIZUMAB IMPROVES SIGNS AND SYMPTOMS AND SPINAL INFLAMMATION OF ANKYLOSING SPONDYLITIS/RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS 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 (89%) 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			
Mean (± SD) change from baseline, Week 52	IXE Q4W (N=81)	IXE Q2W (N=83)	
mBOCF (intent-to-treat)			
ASAS-CRP	-1.7 (1.2)	-1.6 (1.0)	
BASDAI ^a	-3.3 (2.5)	-3.1 (2.3)	
C-Reactive Protein (mg/L)	-9.2 (12.4)	-9.6 (14.5)	
BASFI	-2.8 (2.5)	-2.8 (2.4)	
SF-36 PCS ^b	8.3 (9.5)	8.1 (7.5)	
ASAS Health Index	-2.7 (3.3)	-3.3 (3.6)	
SPARCC Spine Score (observed) ^c	-8.8 (17.3)	-8.5 (15.9)	
Response (%)	PBO/All (N=86)	ADA/All (N=86)	All IXE/All (N=164)
NRI, extended treatment period population ^d	IXE (N=86)	IXE (N=86)	IXE (N=164)
ASAS40			
Week 16	18.6	36.0	50.0
Week 52	46.5	51.2	51.8

^aBASDAI items were scored on a 0-10 numeric rating scale
^bSF-36 analyses based on 2009 US norms
^cSPARCC Spine: N=72 (IXE Q4W), N=68 (IXE Q2W)
^dPatients who received ≥1 dose of IXE during Weeks 16-52
ADA=adalimumab; BASFI=Bath Ankylosing Spondylitis Functional Index; IXE=ixekizumab; mBOCF=modified Baseline Observation Carried Forward; NRI=nonresponder imputation; PBO=Placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; SF-36 PCS=Medical Outcomes Study 36-Item Short-Form Health Survey Physical Component Summary; SPARCC=Spondyloarthritis Research Consortium of Canada

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 received 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

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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