Merck, Novartis, Novo Nordisk, Orion, Pfizer, Regeneron, Roche, Sandoz, Sanofi, and UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Hospira, Janssen, Merck, Novartis, Novo Nordisk, Orion, Pfizer, Regeneron, Roche, Sandoz, Sanofi, and UCB, Merete L. Hetland Grant/research support from: BMS, MSD, AbbVie, Roche, Novartis, Biogen and Pfizer, Consultant of: Eli Lilly, Speakers bureau: Orion Pharma, Biogen, Pfizer, CellTrion, Merck and Samsung Bioepis

DOI: 10.1136/annrheumdis-2020-eular.1413

SAT0431 PROPORTIONS OF PATIENTS ACHIEVING A MINIMAL DISEASE ACTIVITY STATE UPON TREATMENT WITH TILDRAKIZUMAB IN A PSORIATIC ARTHRITIS PHASE 2B STUDY

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Background: Tildrakizumab (TIL) is a high-affinity anti–interleukin-23p19 monoclonal antibody approved in the US, EU, and Australia to treat moderate to severe plaque psoriasis. A randomised, double-blind, placebo-controlled, multiple-dose, phase 2b study evaluating the efficacy and safety of TIL was recently completed (NCT02980692).

Objectives: To characterise and evaluate the rate of minimal disease activity (MDA) up to week (W)52 from the phase 2b study.

Methods: Patients (pts) ≥18 years old with active psoriatic arthritis (PsA)[2] and ≥3 tender and ≥3 swollen joints were randomised 1:1:1:1:1 to receive TIL 200 mg every 4 weeks (Q4W) to W52, TIL 200 mg Q12W to W52, TIL 100 mg Q12W to W52, TIL 20 mg Q12W to W24→TIL 200 mg Q12W to W52, or placebo (PBO) Q4W to W24→TIL 200 mg Q12W to W52. MDA was assessed throughout the study; an MDA response was achieved when 5 of 7 criteria were met.[3] Safety was assessed throughout the study and included treatment-emergent adverse event (TEAE) monitoring.

Results: Of 500 pts screened, 391 were randomised and received ≥1 dose of study drug. At baseline (BL), mean age was 48.8 years, 55% were female, 97% were White, mean body mass index was 29.7 kg/m^2, and pts had PsA for a median (range) of 4.4 (0–42.8) years since diagnosis. Baseline disease characteristics related to MDA varied little between study arms (**Table**).

By W24, MDA state was achieved in significantly more pts receiving TIL vs PBO (24%–39% vs 7%; p<0.02 for all groups); the proportion further increased with continued TIL treatment to W52 (45%–64%), including pts who switched from PBO to TIL (47%) (**Figure**).

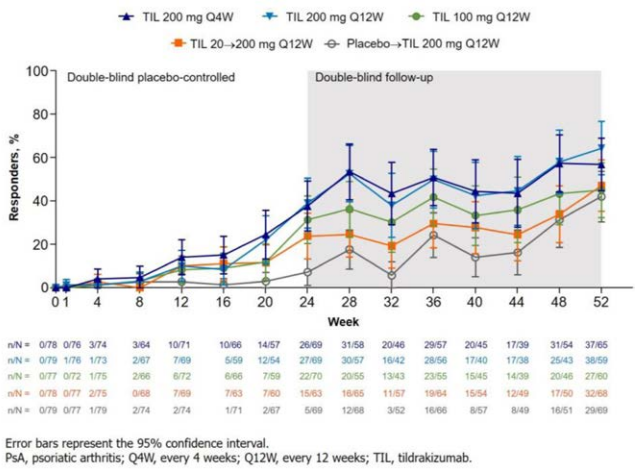
Among the overall pt population from BL→W24/W25→W52, 50.4%/39.9% and 2.3%/1.0% experienced a TEAE and serious TEAE, respectively. From BL→W24, 1 serious infection (chronic tonsillitis) was reported for TIL 20 mg→200 mg Q12W arm. From W25→W52, there was 1 malignancy (TIL 20→200 mg Q12W). There were no reports of candidiasis, uveitis, inflammatory bowel disease, major adverse cardiac events, or deaths from BL→W24 or W25→W52.

Table. Baseline disease characteristics related to minimal disease activity

	TIL 200 mg Q4W n = 78	TIL 200 mg Q12W n = 79	TIL 100 mg Q12W n = 77	TIL 20→200 mg Q12W n = 78	PBO→TIL 200 mg Q12W n = 79
Swollen joint count	10.4	10.0	11.0	9.4	11.8
Tender joint count	16.6	19.5	21.3	19.0	19.7
Patient GADA score	57.8	61.1	60.3	61.9	65.2
Patient pain assessment	55.4	59.6	59.2	60.9	64.2
Enthesitis (LEI) score*	1.9	1.5	2.2	2.2	1.5
PASI†	7.6	6.2	8.8	6.6	5.0
HAQ-DI score	1.0	1.0	1.0	1.1	1.2

Data are reported as mean.
*Total patients analysed (n) = 76, 79, 76, 78, 78, respectively.
†Total patients analysed (n) = 75, 79, 76, 75, 75, respectively.
GADA, global assessment of disease activity; HAQ-DI, Health Assessment Questionnaire Disability Index; LEI, Leeds Enthesitis Index; PASI, Psoriasis Area and Severity Index; PBO, placebo; Q4W, every 4 hours; Q12W, every 12 hours; TIL, tildrakizumab.

Figure. Minimal disease activity response rates from baseline to week 52 in PsA patients across treatments and time points



Error bars represent the 95% confidence interval.
PsA, psoriatic arthritis; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

Conclusion: TIL produced clinically meaningful improvement in pts with PsA, resulting in a large proportion of pts achieving MDA by W52, and was well tolerated through W52.

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Disclosure of Interests: Peter Nash Grant/research support from: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant of: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Michael E Luggen Grant/research support from: AbbVie; Amgen; Eli Lilly; Genentech; Nichi-Iko; Novartis; Pfizer; R-Pharm; and Sun Pharmaceutical Industries, Inc., Consultant of: AbbVie; Amgen; Eli Lilly; Genentech; Nichi-Iko; Novartis; Pfizer; R-Pharm; and Sun Pharmaceutical Industries, Inc., Speakers bureau: AbbVie; Amgen; Eli Lilly; Genentech; Nichi-Iko; Novartis; Pfizer; R-Pharm; and Sun Pharmaceutical Industries, Inc., Luis Espinoza: None declared, Ferran J García Fructuoso Grant/research support from: AbbVie, Eli Lilly, Gedeon Richter, MedImmune, Nichi-Iko, Pfizer, Sanofi-Aventis, Takeda, and UCB, Consultant of: AbbVie, Eli Lilly, Gedeon Richter, MedImmune, Nichi-Iko, Pfizer, Sanofi-Aventis, Takeda, and UCB, Speakers bureau: AbbVie, Eli Lilly, Gedeon Richter, MedImmune, Nichi-Iko, Pfizer, Sanofi-Aventis, Takeda, and UCB, Richard C Chou Consultant of: Sun Pharmaceutical Industries, Inc, Alan M Mendelsohn Shareholder of: Johnson and Johnson, Employee of: Sun Pharmaceutical Industries, Inc, Stephen Rozzo Employee of: Sun Pharmaceutical Industries, Inc, Iain McInnes Grant/research support from: Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Janssen, and UCB, Consultant of: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Gilead, Janssen, Novartis, Pfizer, and UCB

DOI: 10.1136/annrheumdis-2020-eular.3947

SAT0432 EFFECT OF SEX ON DISEASE CHARACTERISTICS AND DISEASE IMPACT IN PATIENTS WITH PSORIATIC ARTHRITIS (PSA): INSIGHTS FROM THE REAL-WORLD, OBSERVATIONAL MULTINATIONAL PSABIO COHORT

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