Figure 1. Change from baseline in pain over 16 weeks in A) biologic-naïve patients (COAST-19) and B) TNF-experienced patients (COAST-20)

*p<0.001 vs PBO; **p<0.01 vs PBO

ADA, anti-adalimumab; DXE, ixekizumab; LSM, least squares mean; NRS, Numeric Rating Scale; PBO, placebo; Q2W, every 2 weeks; Q4W, every 4 weeks.

Conclusion: IXE significantly improved pain, inflammation, and fatigue in patients with r-axSpA.

REFERENCES:

- [1] Sieper J, et al. *Lancet*. 2017;390:73–84.
- [2] Stebbings SM, et al. *Clin Rheumatol*. 2014;33:1467–74.
- [3] Van der Heijde D, et al. *Lancet*. 2018;392:2411–51.
- [4] Deodhar A, et al. *Arthritis Rheumatol*. 2018 Oct 20. Doi: :10.1002/art.40753.

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FRI0422

HS016, A PROPOSED ADALIMUMAB BIOSIMILAR, SHOWED EQUIVALENT PHARMACOKINETICS AND SIMILAR SAFETY, IMMUNOGENICITY AND TOLERABILITY TO CHINA-LICENSED ADALIMUMAB IN HEALTHY MALE SUBJECTS, ACCORDING TO A 2.3-MONTHS PHASE I STUDY

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Background: HS016, a biosimilar to China-licensed adalimumab, has an identical amino acid sequence, similar physicochemical and in vitro functional properties to China-licensed adalimumab.

Objectives: The primary objective of this study was to demonstrate PK equivalence between HS016 and China-licensed adalimumab. PK characteristics, safety, tolerability and immunogenicity were investigated as secondary objectives.

Methods: The first-in-human study was a randomized, double-blind, parallel-control, single-dose study conducted in 136 healthy male subjects at 1 site in China. Subjects were randomized to receive a 40 mg subcutaneous injection of either HS016 or China-licensed adalimumab and were followed up for 70 days. Blood samples were taken pre-dose and at multiple intervals to day 70.

The primary outcomes were area under the concentration-time curve from time zero to time t (AUC_{0-t}) area under the concentration-time curve from time zero to infinity (AUC_{0-∞}), and maximum concentration (C_{max}). The secondary endpoints were the time taken to reach the maximum concentration (T_{max}), elimination half-life (T_{1/2}) etc. Equivalence for the primary outcomes were to be concluded if the 90% confidence intervals (CIs) for

the ratio of geometric least squares means (LS Means) of the groups compared were completely contained within the pre-defined equivalence margin of 0.8 to 1.25 using analysis of variance (ANOVA).

Safety indicators mainly included physical examination, vital signs, laboratory examination, electrocardiogram, chest X-ray, etc. Immunogenicity evaluation explored kinetics and magnitude of anti-drug antibody (ADA) and its neutralizing ability of Neutralizing ADA.

Results: The 90% confidence intervals of geometric least squares means ratios (GMR) of C_{max}, AUC_{0-∞} and AUC_{0-t} between HS016 and China-licensed adalimumab arms were (0.9855,1.1359), (0.8743,1.0841) and (0.8724, 1.0605). The 90% confidence intervals of all GMRs fell within pre-specified confidence bounds of 80% to 125%.

Table 1. Statistical Analysis of Bioequivalence-Pharmacokinetic Analysis Set

	Statistic	Ismeans	95% CIs	GLSM	95% CIs	HS016 compare with adalimumab 90% CIs
HS016 (N=68)	AUC _{0-t} (hr·ng/mL)	14.66	(14.58, 14.74)	2326562.38	(2142491.09, 2526448.09)	(0.8724, 1.0605)
	AUC _{0-∞} (hr·ng/mL)	14.73	(14.63, 14.82)	2484615.56	(2268102.44, 2721797.02)	(0.8743, 1.0841)
	C _{max} (ng/mL)	8.3	(8.24, 8.36)	4034.86	(3799.95, 4284.29)	(0.9855, 1.1359)
adalimumab (N=68)	AUC _{0-t} (hr·ng/mL)	14.7	(14.62, 14.78)	2418702.15	(2227341.01, 2626504.01)	
	AUC _{0-∞} (hr·ng/mL)	14.75	(14.66, 14.84)	2552064.12	(2331241.56, 2793803.70)	
	C _{max} (ng/mL)	8.25	(8.19, 8.31)	3813.61	(3591.58, 4049.36)	

Of the 136 subjects, 128 had adverse events (AEs) with 63 (92.6%) and 65 (95.6%) AEs occurring in the HS016 and China-licensed adalimumab, respectively. Among these AEs, 172 from 50 subjects (73.5%) in HS016 group and 148 from 55 subject (80.9%) in China-licensed adalimumab were treatment emergent adverse event.

The proportion of confirmed anti-drug antibody responses in the 2 study arms were, 25.0% (17 cases) and 22.1% (15 cases) at day 14, 50.0% (34 cases) and 42.6% (29 cases) at day 42, for the HS016 and China-licensed adalimumab arms, respectively. Neutralizing antibodies were all negative at day 14 for both groups, except 2 cases (3.7%) and 1 case (1.6%) at day 42, for the HS016 and China-licensed adalimumab arms, respectively.

Conclusion: It is concluded that HS016 have shown a similar PK to china -licensed adalimumab in healthy male subjects, and no meaningful differences in safety of immunogenicity were observed.

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Psoriatic arthritis

FRI0423

NAIL ULTRASONOGRAPHY FINDINGS IN GRAYSCALE AND POWER DOPPLER TO DIFFERENTIATE PSORIATIC ARTHRITIS, PSORIASIS AND CONTROL INDIVIDUALS

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Background: The early diagnosis of psoriatic arthritis (PsA) on patients with psoriasis (PsO) is challenging, but may prevent functional impairment. Patients with nail psoriasis have an odds ratio of nearly 3.0 of developing psoriatic arthritis. Ultrasonography is a replicable, radiation-free method that could be used to identify nail changes before clinical manifestations.

Objectives: To verify if nail changes identified via ultrasonography can differentiate between PsA and PsO patients as well as between PsA/PsO patients and a control group.

Methods: Single-center, cross-sectional study. PsA patients were consecutively enrolled, PsO and controls were matched by age and gender with the PsA group. PsO patients must have had the diagnosis of psoriasis of any subtypes. PsA patients had to fulfill the CASPAR criteria. Exclusion criteria, for all groups included: other joint inflammatory disease; dermatological or systemic disease that could modify the nail structure. Ultrasound examination was performed using a MyLab 50 system (Esaote Biomedica, Genova, Italy), equipped with a linear probe of 18 MHz in greyscale (GS) and 8.0 MHz in power doppler (PD). The exams were performed in a room with temperature between 22°C and 26°C, after a 10 minutes rest period. Patients were seated, with hands and fingers in a neutral position over the table. The nails were scanned on a longitudinal plane. The 2nd and 3rd fingernails of both hands were examined. Through GS, the following characteristics were assessed: 1) the trilaminar appearance of the nail plate (NP), that was classified according to Wortsman characterization of changes on psoriatic nails (I – IV), 2) the nail plate thickness (NPT), 3) the nail bed thickness (NBT), and 4) the nail matrix thickness (NMT). The signal of PD in the nail matrix and in the nail bed were evaluated together and classified according to Gutierrez *et al.*'s score (1-3). Comparisons between independent means were analyzed using ANOVA or Kruskal-Wallis test. The association between categorical variables was calculated by chi-squared test or Fisher's exact test.

Results: In the trilaminar structure (TS) evaluation, 137(99.3%) of the nails from control group had no change in the TS; for PsO group, 32 of the analyzed nails presented TS alterations, as follows: 9 type I, 5 type II, 7 type III and 11 type IV. For PsA group, there were also 32 of the analyzed nails that presented TS changes; 4 type I, 15 type II, 9 type III and 4 type IV. The mean NPT± SD (mm) was higher on both PsA and PsO groups when compared to the control group: 0.73 ±0.14 and 0.72 ±0.15 vs.0.67±0.10 (p=0.001), respectively. NBT and NMT means did not differ among groups. There was also no statistical difference between groups regarding the degree of nail PD, as well as no difference in the grayscale and PD evaluated parameters between PsA/PsO nails both with or without clinical involvement.

Conclusion: Alterations of the trilaminar structure of the NP and the NPT show differentiation between psoriatic nails and the control group, but no differentiation between PsO and PsA nails. PD, NMT and NBT means also had no differences between groups. Studies with larger sample sizes are necessary to clarify the utility of these parameters in the evaluation of psoriatic patients.

REFERENCES:

- [1] Wortsman C X, Holm EA, Jemec GB, Gniadecka M, Wulf HC. Ultrasonido de Alta Resolución en el estudio de la uña psoriática. *Rev Chil Radiol.* 2004;10(1).
- [2] Gutierrez M, Di Geso L, Salaffi F, Bertolazzi C, Tardella M, Filosa G, Filippucci E, Grassi W. Development of a preliminary US power Doppler composite score for monitoring treatment in PsA. *Rheumatology.* 2012 Jul;51(7):1261-8.

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FRI0424

DIFFERENCES AND SIMILARITIES ACCORDING TO GENDER IN PATIENTS WITH PSORIATIC ARTHRITIS INITIATING BIOLOGICAL THERAPY

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Background: The evolution of the disease is heterogeneous among patients with psoriatic arthritis (PsA). Specifically, the influence of gender on the disease outcomes (and the need of a more intensive treatment) has been pointed. However, data regarding this are scarce.

Objectives: to analyse the disease profile in male and female patients with PsA starting biological treatment.

Methods: Data from an observational prospective cohort including all patients with PsA initiating biological therapy from 2002-2018 in a university hospital was conducted. Demographic information, laboratory tests, disease presentation (axial presentation, including oligoarticular affection,

and polyarticular presentation), disease activity indexes (ASDAS and DAPSA for axial and peripheral-only presentations, respectively) and concomitant treatment were collected before starting biological drug. Patients were stratified by gender to compare the characteristics of the populations. Chi-squared for categorical and t-student tests for continuous variables were used to analyse the differences between groups.

Results: Out of 109 included patients, 55 (51%) were males and 54 (49%) females. Baseline gender-stratified characteristics are shown in Table 1. Including the whole population of the study, mean age at diagnosis was 57 ± 14.6 years, mean PsA duration was 17.7 ± 9.2 years, and mean Body Mass Index (BMI) was 27.2 ± 4.9. Axial or oligoarticular presentation was shown in 57 patients (52%), whereas 52 patients (48%) had polyarticular manifestations. Mean baseline ASDAS was 3.2 ± 1.0 and mean baseline DAPSA was 25.4 ± 13.6. Biological therapies initiated included etanercept in 42% of the cases, infliximab in 25%, adalimumab in 19%, golimumab in 7% and secukinumab in 6%. No significant differences were observed between genders for most of the characteristics including: age at starting biologic, disease duration, BMI, smoking habit, positive HLA B27 and rheumatoid factor, baseline activity, baseline ESR, baseline CRP, baseline sulfasalazine (SSZ), baseline prednisone (PRD), baseline patient global assessment and biological drug use. However, there were substantial differences between gender in some other characteristics. While males had more frequently a predominant axial disease (p=0.01), females more frequently presented a polyarticular disease (p=0.02) and received methotrexate more frequently (p=0.02). These differences in methotrexate use might be explained by the predominance of peripheral presentation in female patients.

Conclusion: In clinical practice, biological therapy (TNFi and IL-17i) is prescribed in a similar frequency in male and female patients with PsA. Nevertheless, the predominant articular manifestation behind the prescription of the biological therapy is different among genders: while men have predominant axial disease, women have predominant peripheral manifestations. These differences in clinical presentation in both genders may contribute to differences in therapeutic management, such as increased use of methotrexate in women with PsA who initiate biological therapy.

Table 1. Gender-stratified characteristics at the visit starting the biological therapy. Results are shown as mean (standard deviation) or absolute number (percentage).

	Male n=55 (51 %)	Female n= 54 (49 %)	p-value
Age (years)	55.8 (12.2)	58.3 (16.7)	0.2
Disease duration (years)	17.3 (7.3)	18.1 (10.9)	0.6
BMI	27.7 (3.8)	26.7 (5.9)	0.3
Smokers & ex smokers	19 (34.5%)	19 (35.2 %)	1.0
HLA B27	8/28 (28.6 %)	3/20 (15.0 %)	0.3
RF	2/47 (4.3%)	4/48 (8.3%)	0.4
Axial and/or Oligoarticular manifestations	37 (67.3%)	20 (37.2 %)	0.01
Polyarticular manifestations	18 (32.0%)	34 (63.1 %)	0.02
bASDAS	3.1 (1.0)	3.3 (1.0)	0.5
bDAPSA	21.3 (11.8)	29.4 (15.5)	0.08
bESR	19.8 (19.2)	31.6 (19.7)	0.2
bCRP mg/L	11.9 (16.16)	9.6 (10.7)	0.1
Baseline PGA	45.1 (20.8)	50.4 (20.8)	0.4
Baseline MTX	27 (49.1 %)	38 (70.4 %)	0.02
Baseline SSZ	10 (18.2 %)	8 (14.8 %)	0.6
Baseline PRD	14 (25.5%)	20 (37.1 %)	0.2
Infliximab	15 (27.3 %)	12 (22.2 %)	0.9
Adalimumab	6 (10.9 %)	15 (27.8 %)	0.2
Etanercept	24 (43.6 %)	22 (40.7 %)	0.8
Golimumab	6 (10.9 %)	2 (3.7 %)	0.4
Secukinumab	4 (7.3 %)	3 (5.6 %)	0.9

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