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.

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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.

Disclosure of Interests: None declared

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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.