PRA-216, a long-acting bispecific IL-4Rα/TSLP antibody, demonstrates favorable safety, extended exposure, and durable pharmacodynamic activity in a Phase 1 study of healthy volunteers

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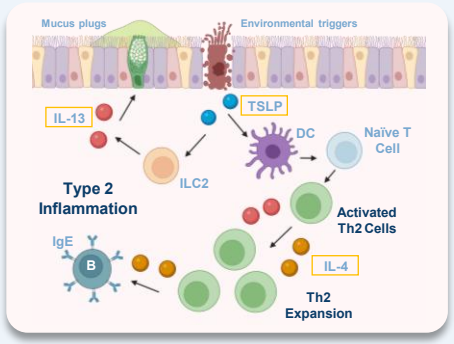
INTRODUCTION

Background

- IL-4, IL-13, and TSLP are central drivers of inflammation and validated therapeutic targets in respiratory diseases. Dual inhibition of IL-4Rα and TSLP may provide broader suppression of upstream and downstream inflammation than either mechanism alone.
- PRA-216 is a fully human, half-life extended bispecific antibody targeting IL-4Rα and TSLP, developed on Prana's INSPIRE platform. Interim Phase 1 results are reported here.

PRA-216 is a long-acting IL-4Rα/TSLP bispecific antibody that blocks multiple critical pathways in the inflammatory cascade



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AIMS & METHODS

Study Objective

- The primary aims of this study were to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of PRA-216 in healthy adults.

Study Design

- This Phase 1 study enrolled 57 healthy adults across seven single- and multiple-ascending-dose cohorts.
- Participants were randomized 6:2 to receive PRA-216 at doses up to 1200 mg, or placebo. Safety, PK, and PD assessments were performed.

RESULTS

Baseline Demographic Characteristics

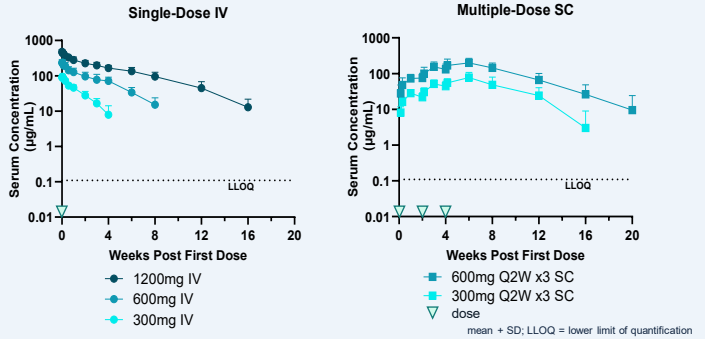
	Single Ascending Dose					Multiple Ascending Dose		All
Characteristics	300 mg IV N=9	300 mg SC N=8	600 mg IV N=8	600 mg SC N=8	1200 mg IV N=8	300 mg SC N=8	600 mg SC N=8	TOTAL N=57
Age (yrs)	37	39	35.5	33	41.6	42.9	42.1	38.73
Female	4	5	5	5	3	1	2	23
Caucasian	7	4	3	6	6	7	8	41
Asian	2	4	3	1	2	1	0	13
Other	0	0	2	1	0	0	0	3
Weight (kg)	70.7	69.2	76.2	70.2	69.6	81.3	80.1	73.9

Safety Summary Across SAD/MAD Cohorts

	Single Ascending Dose					Multiple Ascending Dose		All
Characteristics	300 mg IV N=9	300 mg SC N=8	600 mg IV N=8	600 mg SC N=8	1200 mg IV N=8	300 mg SC N=8	600 mg SC N=8	TOTAL N=57
≥ 1 Serious TEAE (SAEs)	0	0	0	0	0	0	0	0
≥ 1 Grade 3 or higher TEAE	0	0	0	0	0	0	0	0
≥ 1 Drug-related TEAE	0	0	0	0	0	0	1	1
Discontinued study due to TEAE	0	1*	0	0	0	0	0	1*

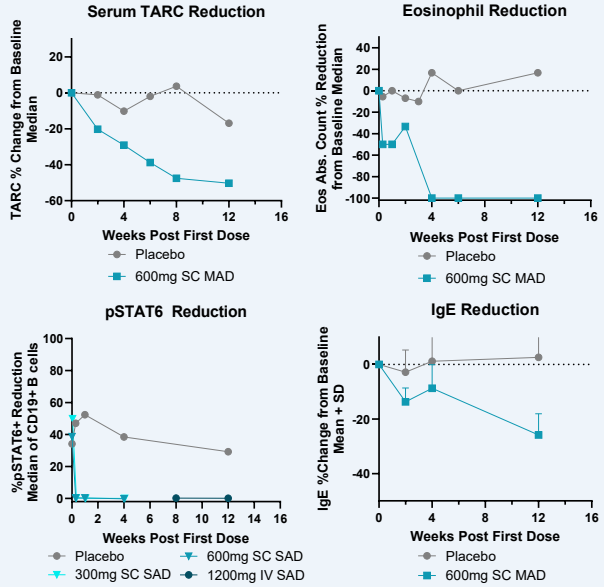
*1 subject discontinued due to flu symptoms, unrelated to study drug

PRA-216 achieves high, sustained exposure with robust target coverage and 85% subcutaneous bioavailability



mean + SD; LLOQ = lower limit of quantification

PRA-216 demonstrates rapid, deep, and durable responses in key Type 2 biomarkers



CONCLUSIONS

PRA-216 demonstrated favorable safety, extended exposure, and rapid, durable pharmacodynamic activity. These results support the potential for PRA-216 to be a best-in-disease therapeutic with infrequent dosing up to Q12W across respiratory and inflammatory diseases. Ph2 studies in asthma and COPD are currently enrolling.

Conflict of interest: IP: Scientific advisor; HA and RD: Consultants; RS, MS, CT, SG, and HO: Full-time employees of Prana Therapies. | **ERS Congress** September 5 – 9, 2026; Barcelona, Spain | **Poster: 5809**