ALLERGY, GENETICS

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Table 2-2. Baseline Demographics

	Total AMG 282 SC/IV HS (N = 48)	Cohort 9 AMG 282 [redacted] IV AAS (N = 2)	Placebo SC/IV HS (N = 16)	Cohort 9 Placebo AAS (N = 4)
Sex - n (%)				
Male	47 (97.9)		15 (93.8)	
Female	1 (2.1)		1 (6.3)	
Ethnicity - n (%)				
Hispanic/Latino	9 (18.8)		8 (50.0)	
Not Hispanic/Latino	39 (81.3)		8 (50.0)	
Race - n (%)				
Asian	5 (10.4)		0 (0.0)	
Black	22 (45.8)		5 (31.3)	
Native Hawaiian or Other Pacific Islander	2 (4.2)		0 (0.0)	
White	17 (35.4)		10 (62.5)	
Other	1 (2.1)		0 (0.0)	
Multiple	1 (2.1)		1 (6.3)	
White – Asian	1 (2.1)		0 (0.0)	
Age (years)				
Mean	30.9	36.0	27.7	32.5
SD	7.4	9.9	5.8	4.9

AAS = atopic asthma subjects; HS = healthy subjects; IV = intravenous; SC = subcutaneous

Efficacy Results: Efficacy endpoints were exploratory in nature and were not analyzed in this study because of the small sample size in cohort 9.

Pharmacokinetic Results: AMG 282 exposure was greater than dose-proportional in the dose range of [redacted] mg after single-dose SC administration to healthy subjects, with C_{max} and AUC_{last} increasing 316- and 5095-fold, respectively, for a 200-fold increase in dose. However, in the dose range from [redacted] SC, a 6-fold increase in dose resulted in a 7.1-fold increase in C_{max} and 12-fold increase in AUC_{last}, suggesting that approximately dose-proportional exposure, as assessed by C_{max} and AUC_{last}, may be observed for doses of [redacted] and higher and was consistent with target-mediated disposition processes. The median t_{max} ranged from 2.0 to 7.0 days after a single SC dose. Mean apparent clearance, apparent volume of distribution, and half-life ranged from 229 to 557 mL/day, 3850 to 8290 mL, and 7.41 to 12.0 days across all SC cohorts, respectively.

After a single 1-hour IV infusion of [redacted] to healthy subjects in cohorts 7 and 8, median t_{max} was 0.083 days. Mean clearance, volume of distribution, and half-life ranged from 189 to 210 mL/day, 3360 to 4990 mL, and 11.1 to 18.7 days across both IV infusion cohorts, respectively.

Mean bioavailability after a single [redacted] SC or IV dose was estimated to be 60%.