Single-Dose and Repeat Single-Dose Ascending Dose Study Evaluating Safety, Tolerability, and Pharmacokinetics of Subcutaneous and Intramuscular CD388, a Novel Long-acting Drug-Fc Conjugate for Universal Prevention of Seasonal and Pandemic Influenza

Shawn Flanagan, PhD

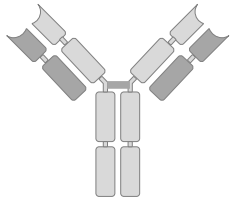
VP Clinical Pharmacology & Early Development

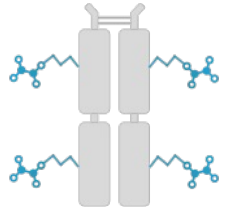
Co-Authors	Affiliations (at the time of study conduct)
Ozlem Equils	Cidara Therapeutics, San Diego, United States
Roxana E. Rojas	Johnson and Johnson, Brisbane, United States
Tristan Baguet	Johnson and Johnson, Beerse, Belgium
Sy-Shi Wang	Johnson and Johnson, Brisbane, United States
Voon Ong	Cidara Therapeutics, San Diego, United States
Taylor Sandison	Cidara Therapeutics, San Diego, United States

ID Week 2024 Abstract ID: 1826357 18 October 2024

CD388: A DRUG-Fc CONJUGATE AGAINST INFLUENZA

IN DEVELOPMENT FOR SINGLE-DOSE, SEASONAL, BROAD INFLUENZA PROPHYLAXIS





Needs	Vaccines	Monoclonal Antibodies	CD388 DFC
Universal Protection	No	No	Yes
Potential to protect all high-risk groups	Low	High	High
Potential for dual prevention and treatment	No	Limited	Yes

CD388 has the potential[1] for

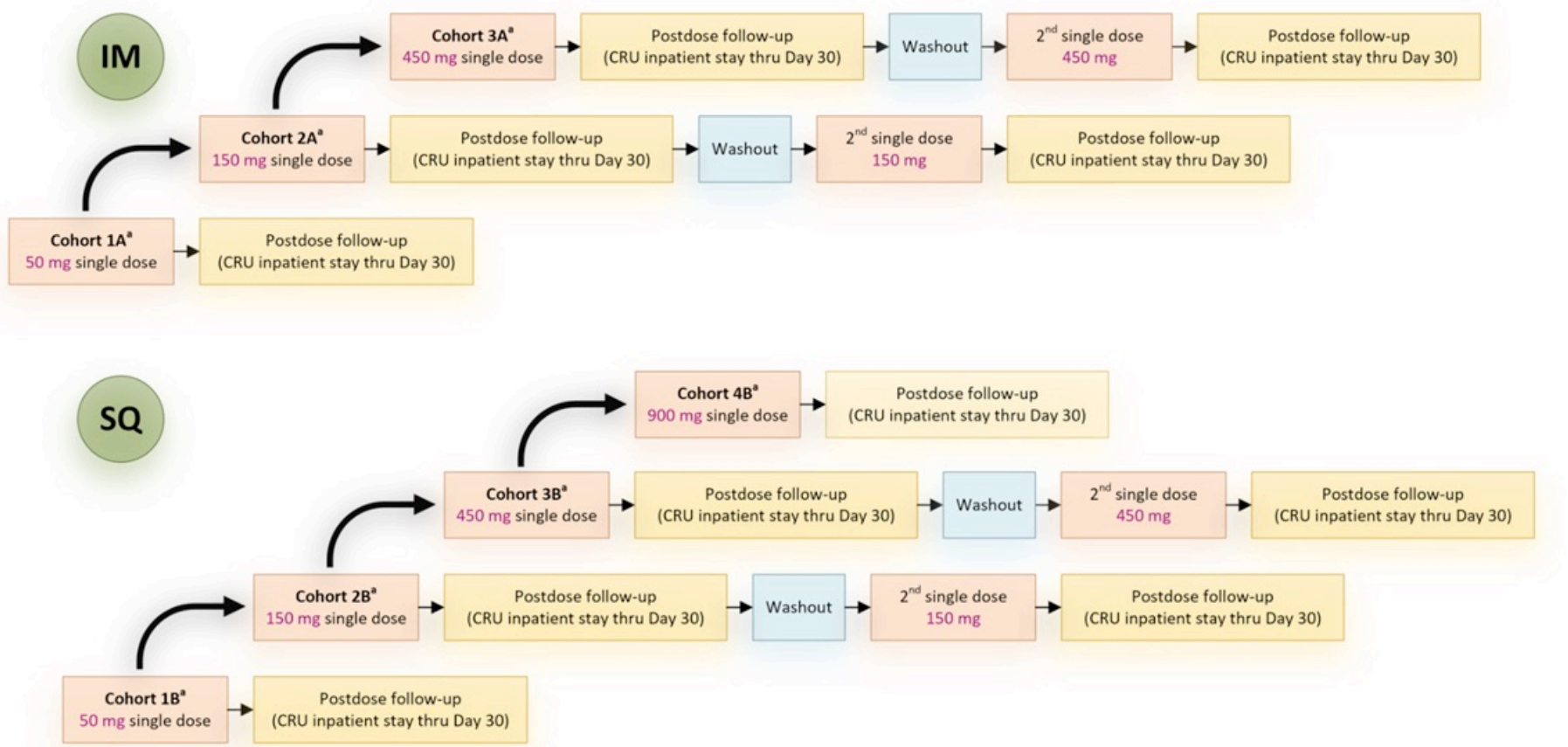
- Universal protection
- Protection for immune-compromised individuals and other high-risk groups
- Dual prevention and treatment

DFC=drug-Fc conjugate.

1. Döhrmann S, et al. bioRxiv 2024.06.04.597465; doi: https://doi.org/10.1101/2024.06.04.597465.

CIDARA THERAPEUTICS

CD388 FIRST IN HUMAN STUDY SCHEMA



N = 77 total – N = 11 per Cohort (8 CD388 Injection : 3 Placebo)

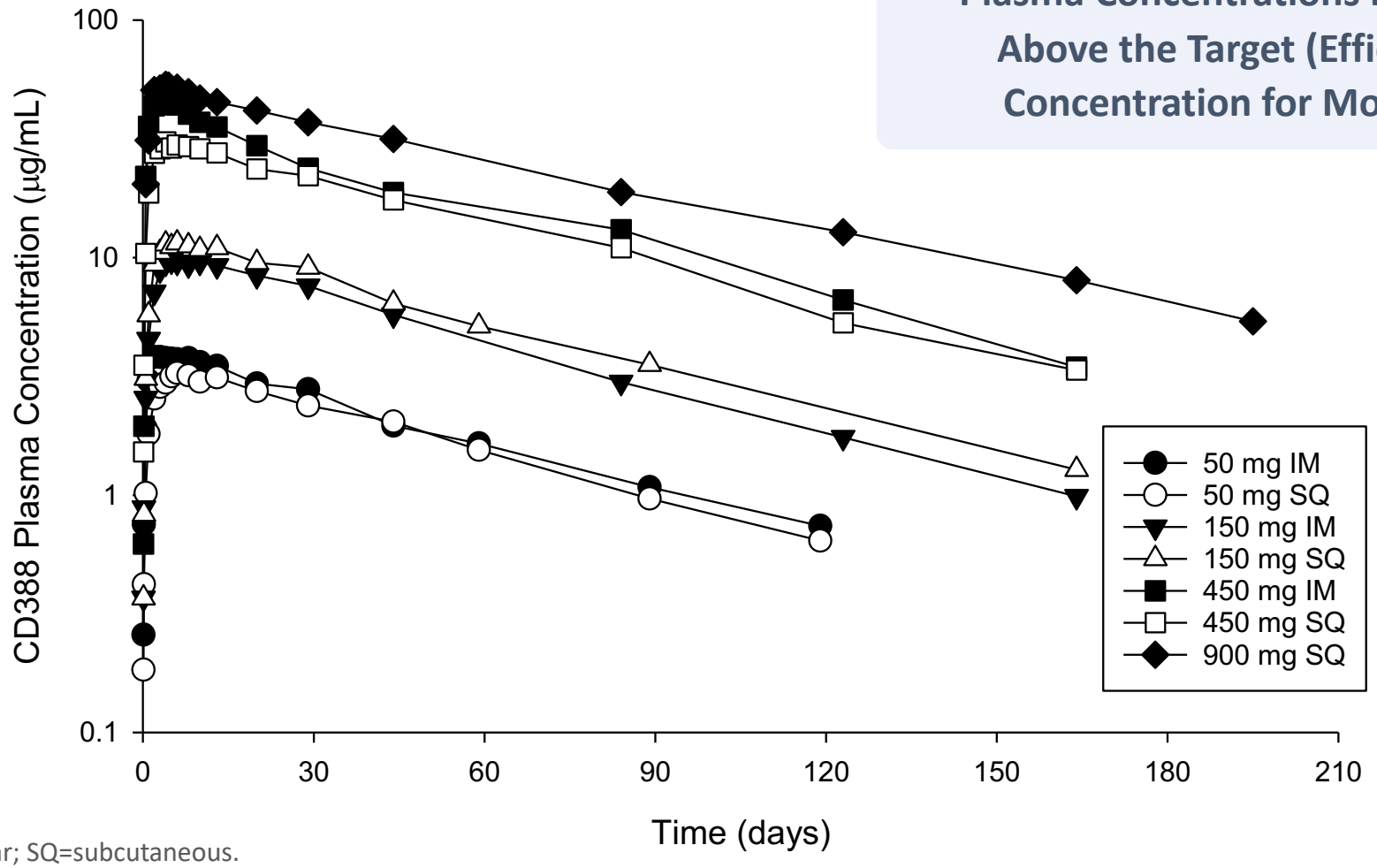
a Dose the 2 subjects in the sentinel group. After ≥7 days, if no drug-related SAEs or drug-related Grade ≥3 AEs have occurred, the 9 subjects in the corresponding main group may be dosed within 24 hours. Cohorts 1A, 1B, 2A, 2B, 3B: if the dose/route of administration is determined to be safe and well tolerated ≥14 days after dosing, the next cohort of subjects will be enrolled and randomized to receive the next higher dose level of CD388 Injection or placebo.

CIDARA THERAPEUTICS

CD388 MEAN PLASMA CONCENTRATIONS

PLASMA CONCENTRATIONS SIMILAR FOLLOWING SINGLE IM OR SQ DOSE

Plasma Concentrations Remain Above the Target (Efficacy) Concentration for Months

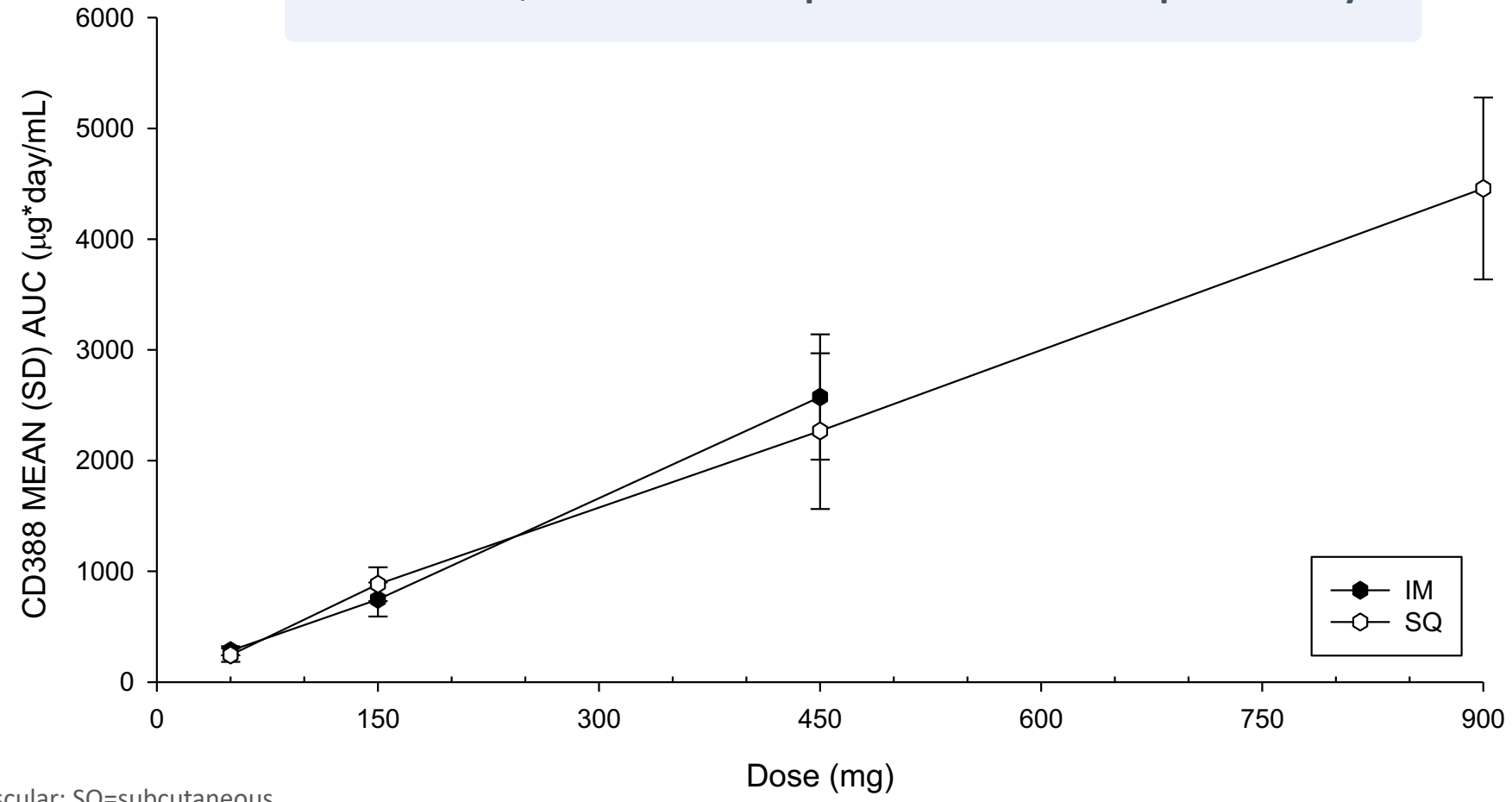


IM=intramuscular; SQ=subcutaneous.

CD388 MEAN (SD) AUC

FOLLOWING IM OR SQ ADMINISTRATION

IM and SQ Show Similar Exposure and Dose Proportionality



IM=intramuscular; SQ=subcutaneous.