



A Phase 2, Randomized, Placebo-controlled Trial to Evaluate the Safety and Efficacy of CD388, a Novel Drug-Fc-Conjugate, for Prevention of Illness due to Influenza A and B in Healthy Unvaccinated Participants (NAVIGATE) (NCT06609460)

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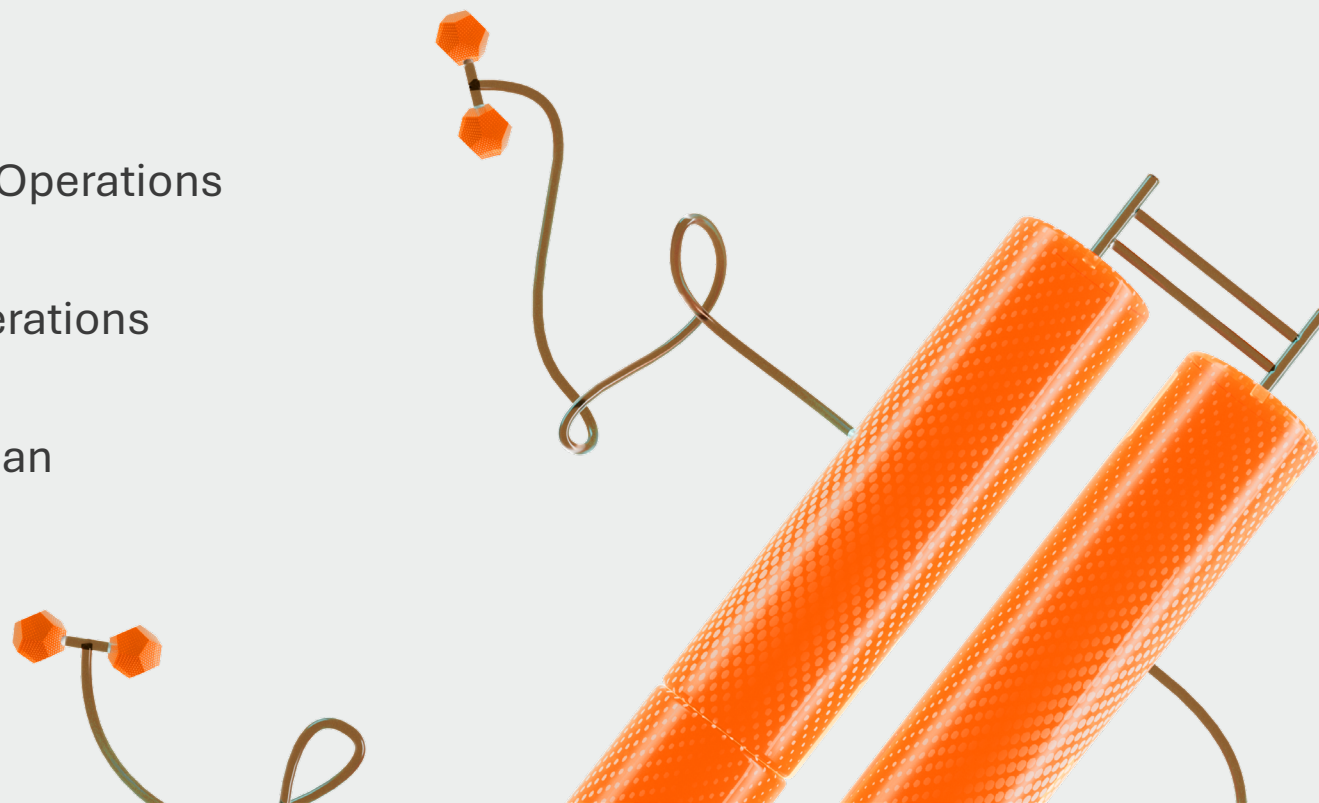
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Forward-looking Statements

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The words “may,” “will,” “estimate,” “plan”, “anticipate,” “expect,” “potential,” “could,” “project,” and similar expressions (including the negative thereof), are intended to identify forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding Cidara’s research and development efforts; preclinical and clinical development activities; plans, projections and expectations for and the potential effectiveness, safety and benefits of, its product candidates, including CD388 and other product candidates from the Cloudbreak platform; whether CD388 may have significant advantages beyond and in addition to flu vaccines; and advancement of its strategic plans.

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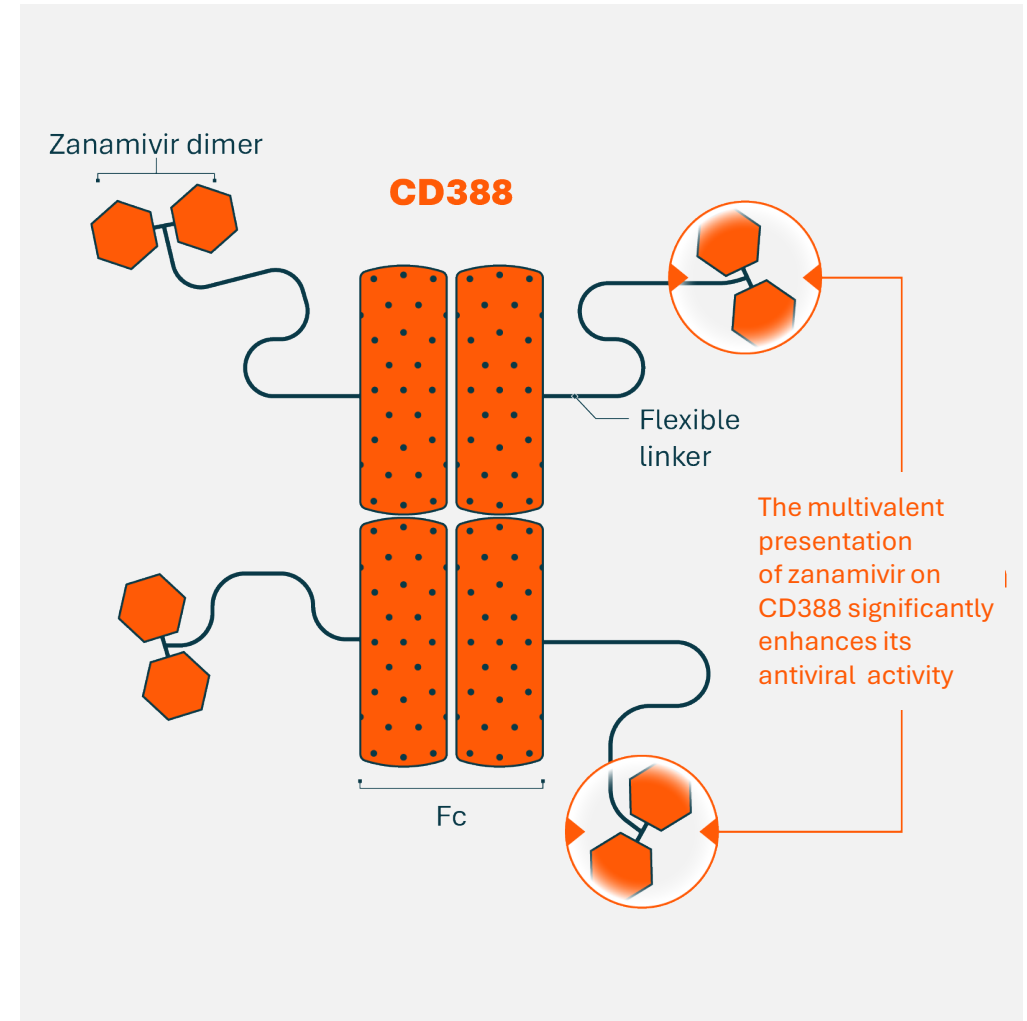
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CD388 : A First-in-Class Drug-Fc Conjugate (DFC)

CD388 contains zanamivir dimers stably conjugated to a N-terminally extended human IgG1 Fc domain containing the M252Y/S254T/T256E (YTE) triple mutation to increase half-life (1)

CD388 has potent activity against influenza A and B, including A/H5N1, A/H7N9, and zanamivir and oseltamivir-resistant strains (1)

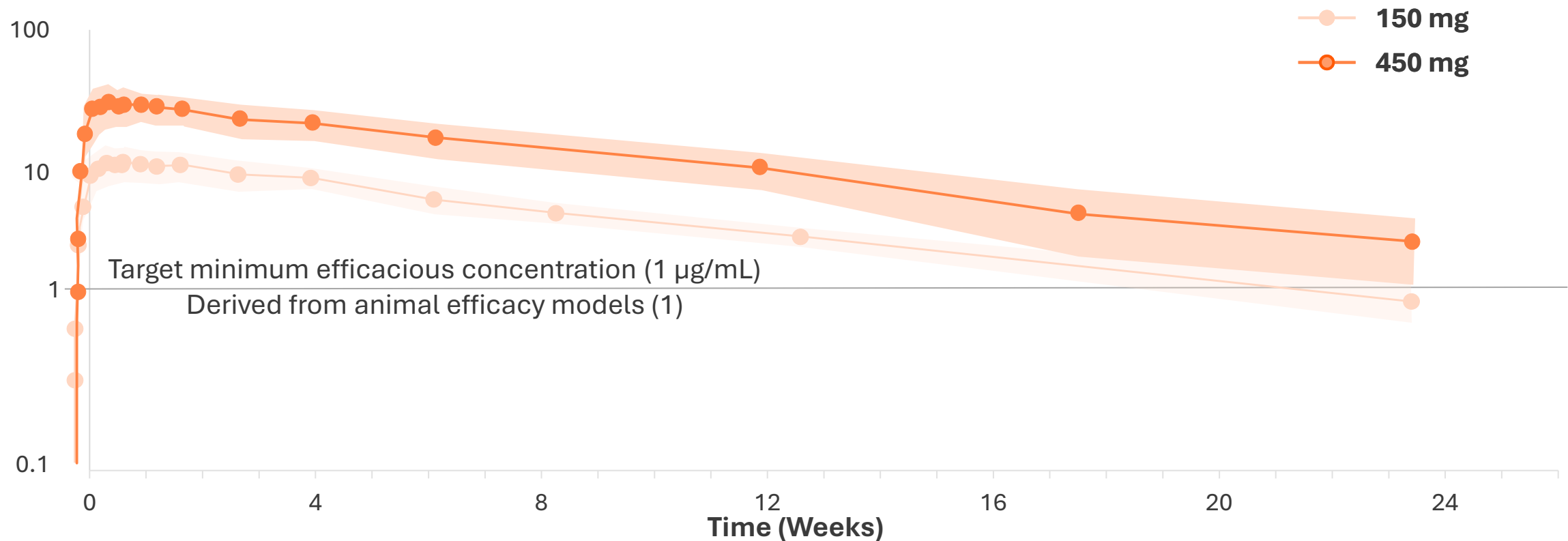
CD388 (150 mg SQ) showed significant reductions in RT-PCR-positive infections and peak viral loads in a controlled human infection model with influenza A/H3N2 challenge (2)



1. <https://doi.org/10.1038/s41564-025-01955-3> ;2. Equils O, et al. <https://doi.org/10.1093/ofid/ofae631.174>

Single SQ Dose of CD388 (150mg or 450mg) May Provide Seasonal Protection Against Symptomatic Influenza Illness

Mean (SD) CD388 Plasma Concentration ($\mu\text{g/ml}$)



Data from CD388.IM.SQ.1.01 - First in Human Study (N=8 per arm)

CD388 NAVIGATE Trial Design*

Novel AntiViral for Long-Acting Influenza Guard Against Transmission Effort

)

Study Population

Generally healthy, unvaccinated adults aged 18-64 not at risk for complications of influenza

Study Size

n=5000 across CD388 and placebo groups

R
1:1:1:1

150 mg

300 mg

450 mg

Placebo

First/Last Participant Dosed

Sep 2024/Dec 2024

Primary Endpoint

Prevention Efficacy (PE) of Influenza-like illness (ILI)

Defined by all 3 criteria present

- ≥7 days to 24 weeks after dosing:
- PCR-confirmed influenza by NP swab
- ≥2 respiratory or 1 respiratory and 1 systemic sign/symptom
- Body temp ≥38° C

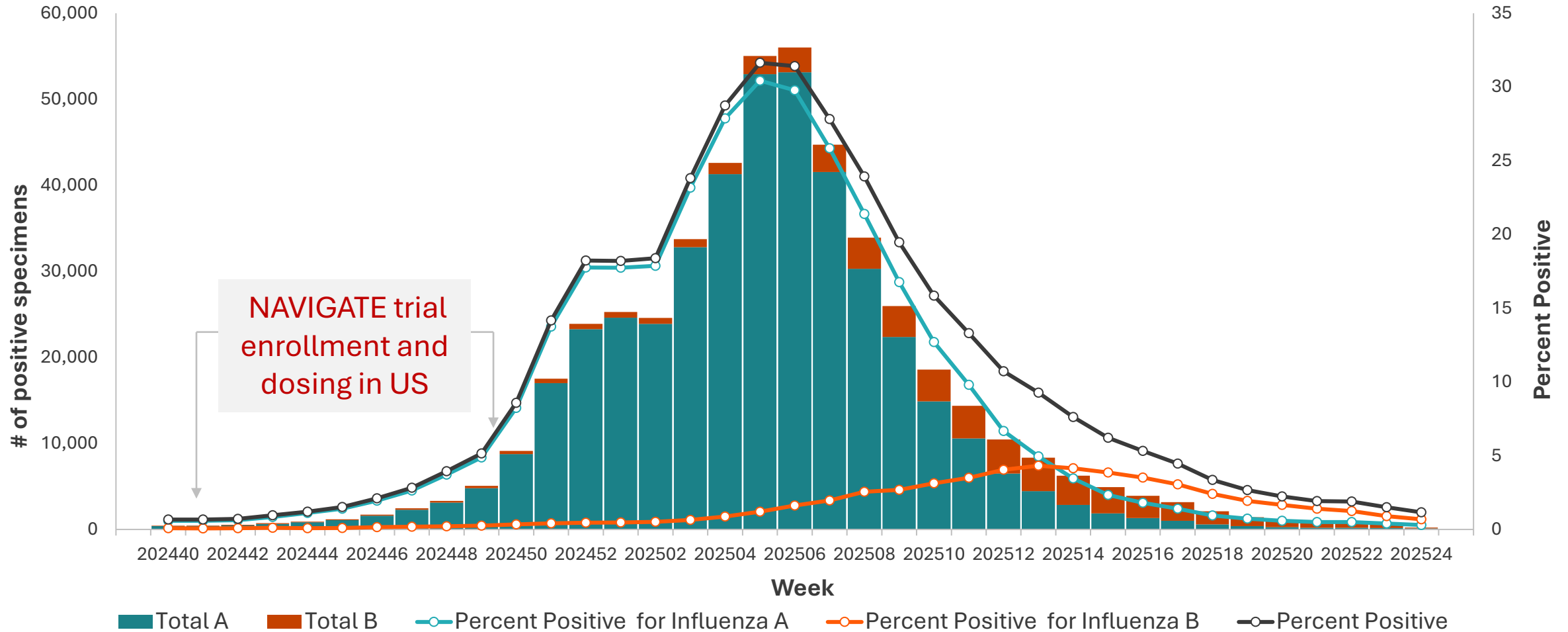
Follow-up After ILI

- Visits on days 3,6,10,15,20,29
- Symptoms assessment and MT swab collection for virology

*Phase 2b trial originally designed as dose-ranging trial without statistical significance testing to select optimal dose to advance to Phase 3.

Abbreviations: PCR=polymerase chain reaction; NP=nasopharyngeal;; MT=mid-turbinate; R=randomization

Influenza Positive Tests Reported to CDC by Clinical Laboratories, National Summary, 2024-25 Season, Week Ending Jun 14, 2025



Demographic Characteristics of Participants at Baseline

Characteristic	CD388 150 mg (N=1268)	CD388 300 mg (N=1268)	CD388 450 mg (N=1268)	Placebo (N=1267)
Age – years (± SD)	39.7 (± 12.67)	39.6 (± 12.91)	39.5 (± 12.94)	39.9 (± 13.19)
Female sex – no. (%)	674 (53.2)	682 (53.8)	697 (55.0)	692 (54.6)
White – no. (%)	930 (73.3)	911 (71.8)	876 (69.1)	885 (69.9)
Black – no. (%)	225 (17.7)	240 (18.9)	246 (19.4)	245 (19.3)
Asian – no. (%)	61 (4.8)	62 (4.9)	74 (5.8)	69 (5.4)
Other races – no. (%)	52 (4.1)	55 (4.3)	72 (5.7)	70 (5.5)
BMI (mean ± SD)	27.0 (± 4.3)	27.2 (± 4.2)	26.9 (± 4.2)	27.0 (± 4.2)
Tobacco usage- no.(%)	209 (16.6)	300 (15.3)	204 (16.2)	201 (16.0)

Primary Endpoint :

**Temp $\geq 38^{\circ}\text{C}$; ≥ 2 Respiratory or 1 Respiratory & 1 Systemic Sign/Symptom;
Positive RT-PCR for Influenza A or B from a Nasopharyngeal Swab**

CD388

	150 mg N=1,175* n (%)	300 mg N=1,192* n (%)	450 mg N=1,187* n (%)	Placebo N=1172* n (%)
Primary Endpoint**				
Number of Participants Protocol-Defined ILI	14 (1.2)	13 (1.1)	8 (0.7)	33 (2.8)
Preventive Efficacy (PE) (%)	57.7	61.3	76.1	–
95% CI (%)	21.1, 78.9	27.0, 81.2	49.3, 89.9	–
p-value	0.0050	0.0024	<0.0001	–

Intercurrent events of death, receipt of anti-influenza therapy, or discontinuation are considered as experiencing ILI.

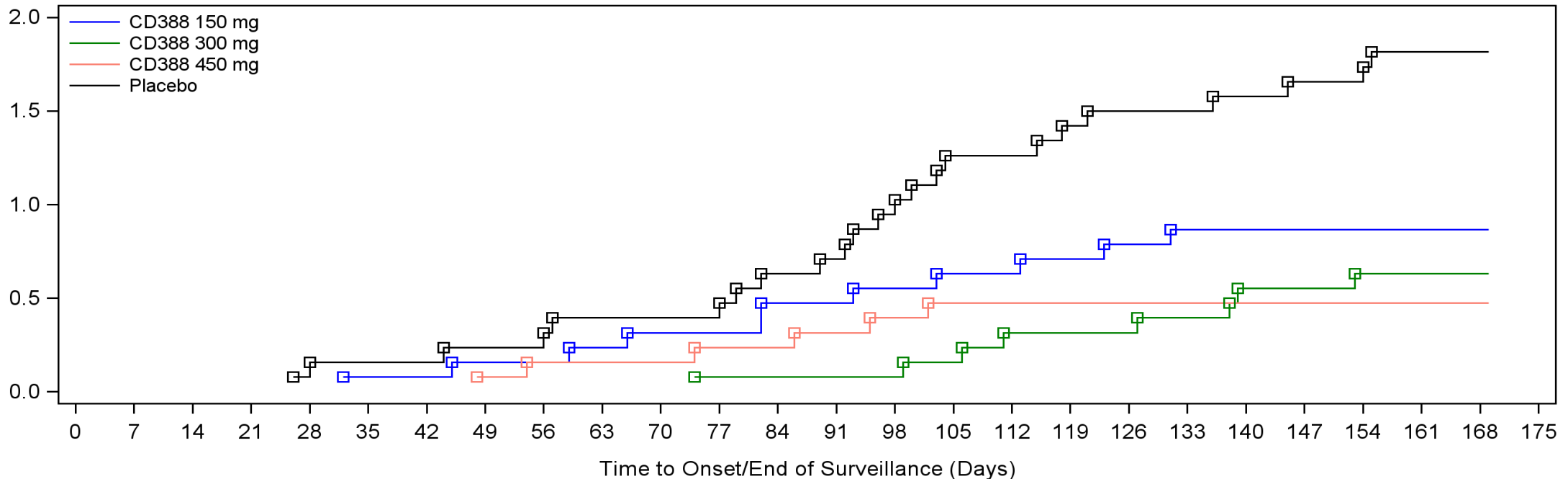
*Sample size (N) indicates participants in ITT population without missing data at time of primary analysis data cut (Apr 30, 2025)

**Statistical significance for grouped 300mg + 450mg dose groups was met (PE=68.6%; $p < 0.0001$), enabling pair-wise testing of individual dose groups v. placebo. P-value based on the Farrington-Manning statistic.

Abbreviations: ILI=influenza-like illness; CI=confidence interval

Primary Endpoint : Temporal Onset of ILI Cases

Cumulative Incidence of Observed Influenza Virus A and B Illness (%)



Cumulative Number of Infections

0	0	0	0	0	1	1	2	2	3	4	4	6	6	7	8	8	9	10	11	11	11	11	11	11	11	11	11
0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2	4	4	4	5	7	7	7	8	8	8	8	8
0	0	0	0	0	0	0	1	2	2	2	3	3	4	5	6	6	6	6	6	6	6	6	6	6	6	6	6
0	0	0	0	2	2	2	3	4	5	5	6	8	9	13	16	16	18	19	19	20	21	22	23	23	23	23	23

Observed Influenza Virus A and B Illness defined as central laboratory-confirmed RT-PCR+ influenza infection (nasopharyngeal swab), new onset of fever (oral temperature $\geq 38.0^{\circ}\text{C}$), and new onset of ≥ 2 respiratory symptoms (nasal congestion, sore throat, cough) or ≥ 1 respiratory symptom and ≥ 1 systemic symptom (headache, feeling feverish, body aches/pains, fatigue). Intercurrent events of death, regardless of cause, receipt of anti-influenza therapy, or discontinuation due to lack of efficacy are ignored. Cumulative percentages are based on the ITT Population (i.e., missing data are included).

Abbreviations: ITT = intention to treat; RT-PCR+ = reverse-transcriptase polymerase chain reaction positive; ILI=influenza-like illness

Secondary Endpoint :

Temp ≥ 37.2°C; ≥2 Respiratory or 1 Respiratory & 1 Systemic Sign/Symptom;
Positive RT-PCR for Influenza A or B from a Nasopharyngeal Swab

Secondary Endpoint	CD388			
	150 mg N=1,175* n (%)	300 mg N=1,192* n (%)	450 mg N=1,187* n (%)	Placebo N=1,172* n (%)
Number of Participants with ≥37.2°C Temp	22 (1.9)	21 (1.8)	12 (1.0)	41 (3.5)
Preventive Efficacy (PE) (%)	46.5	49.6	71.1	–
95% CI (%)	10.2, 69.3	14.8, 71.9	45.8, 86.1	–
P-value	0.0148	0.0083	<0.0001	–

Endpoint defined as central laboratory-confirmed RT-PCR+ influenza infection (nasopharyngeal swab), new onset of fever (oral temperature ≥ 37.2°C), and new onset of ≥2 respiratory symptoms or ≥1 respiratory symptom and ≥1 systemic symptom. Intercurrent events of death, receipt of anti-influenza therapy, or discontinuation are considered as experiencing ILI.

*Sample size (N) indicates participants in ITT population without missing data at time of primary analysis data cut (Apr 30, 2025).

Abbreviations: ITT = intention to treat; RT-PCR+ = reverse-transcriptase polymerase chain reaction ; ILI=influenza-like illness

Participants with ILI due to Influenza A or Influenza B

CD388

	150 mg	300 mg	450 mg	Placebo
ILI - Influenza A/H1N1 or A/H3N2	9	5	5	20
Preventive Efficacy (PE) (%)	55.1	75.4	75.3	
(p-value)	(0.039)	(0.002)	(0.002)	
ILI - Influenza B	2	3	1	4
Preventive Efficacy (PE) (%)	50.1	26.2	75.3	
(p-value)	NS	NS	NS	

ILI event defined as central laboratory-confirmed RT-PCR+ influenza infection (nasopharyngeal swab) , new onset of fever (oral temperature $\geq 38.0^{\circ}\text{C}$), and new onset of ≥ 2 respiratory symptoms or ≥ 1 respiratory symptom and ≥ 1 systemic symptom. Intercurrent events of death, receipt of anti-influenza therapy, or discontinuation from study are ignored in this presentation.

Abbreviations: ILI- influenza-like illness; NS=non-significant

Treatment Emergent Adverse Events (TEAEs)

	CD388 150 mg (N=1257)	CD388 300 mg (N=1263)	CD388 450 mg (N=1261)	Placebo (N=1260)
Any TEAE	521 (41.4%)	515 (40.8%)	524 (41.6%)	2515(40.9%)
TEAEs by maximum toxicity grade				
Grade 1	318 (25.3%)	327 (25.9%)	340 (27.0%)	320 (25.4%)
Grade 2	178 (14.2%)	165 (13.1%)	166 (13.2%)	171 (13.6%)
Grade 3	120 (1.6%)	19 (1.5%)	16 (1.3%)	22 (1.7%)
Grade 4	3 (0.3%)	3 (0.2%)	1 (0.1%)	2 (0.2%)
Treatment-Related TEAEs				
Grade 1	35 (2.8)%	29 (2.3%)	38 (3.0%)	34 (2.7%)
Grade 2	3 (0.2%)	8 (0.6%)	5 (0.4%)	10 (0.8%)
Grade 3	0	1 (<0.1%)	0	1 (<0.1%)
Grade 4	0	0	0	1 (<0.1%)
Serious TEAEs	8 (0.6%)	8 (0.6%)	6 (0.5%)	13 (1.0%)**
Treatment-Related Serious TEAEs	0	0	0	0
Serious TEAEs with Fatal Outcome *	1 (0.1%)	1 (0.1%)	1 (0.1%)	0

*Middle cerebral artery stroke (150 mg); blunt force head injury (300 mg); accidental drug overdose (450 mg)

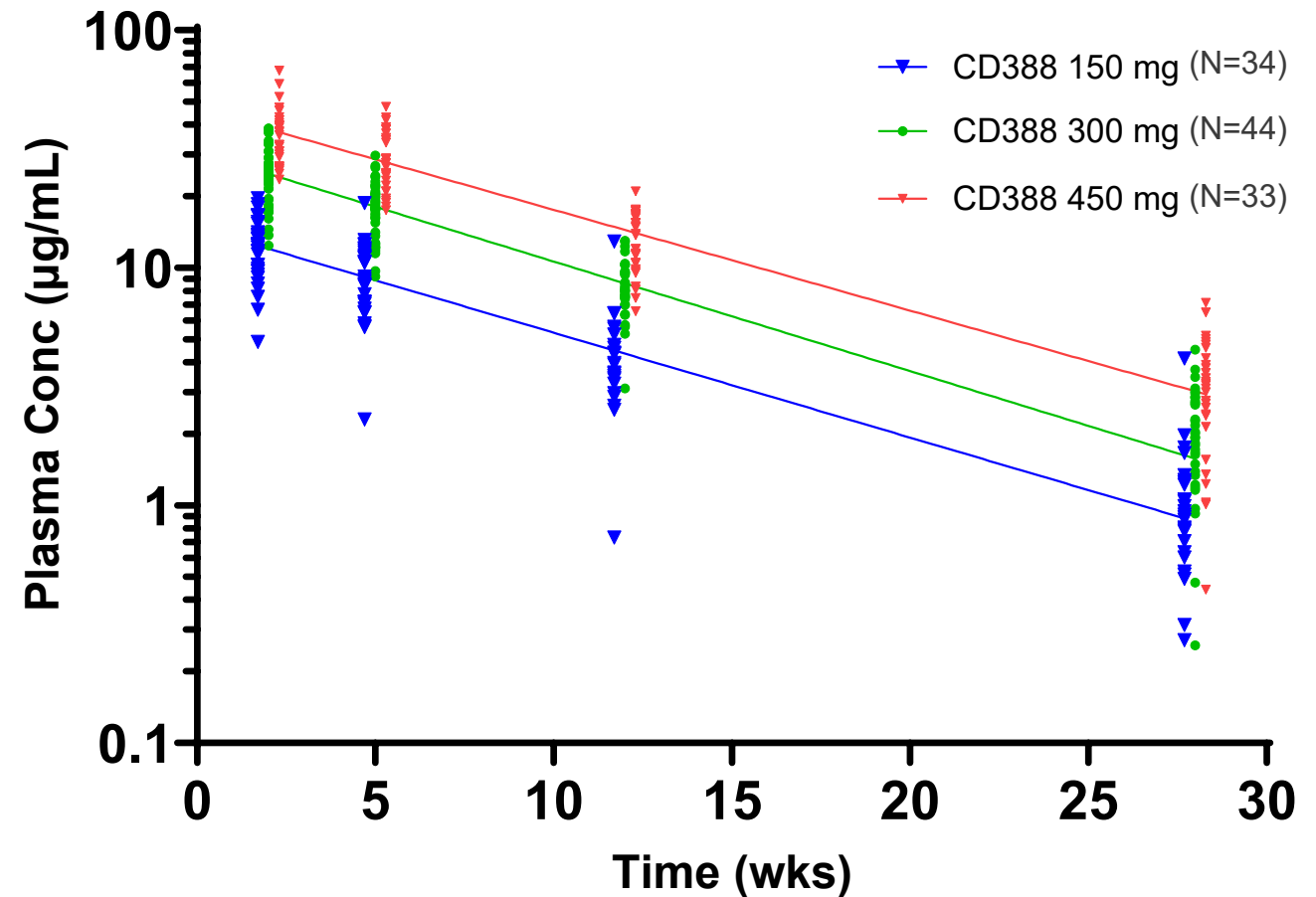
**Hospitalization due to influenza A in 22-year old who received placebo

CD388 Pharmacokinetics (PK)

- Subset of 111 participants
- PK data are consistent with results from first-in-human study
- Dose-linear PK demonstrated

CD388 Concentrations at Day 197

Dose (mg)	150	300	450
Mean Conc. (µg/mL)	0.98	2.07	3.13
Max Conc. (µg/mL)	4.15	4.52	7.13
Min Conc. (µg/mL)	<0.05	0.26	0.44



SUMMARY

Phase 2 NAVIGATE Trial (NCT06609460)

- Preventive efficacy of CD388 450 mg dose was higher than the reported effectiveness of seasonal vaccine during the 2024-2025 season (1)
- Each dose of CD388 evaluated was well-tolerated with a safety profile similar to placebo

Phase 3 ANCHOR Trial (NCT07159763)

Advancing a **N**ovel **C**onjugate for **H**igh-risk **O**utpatients to Prevent **R**espiratory Influenza

- CD388 450 mg (vs. placebo) will be evaluated in participants at higher risk of influenza complications due to comorbid conditions and/or age ≥ 65 years
- First participant was dosed on 25 September 2025
- Study sites are activated in the US and UK for the 2025-2026 Northern Hemisphere influenza season

1. Frutos AM, et al. MMWR 2025; 74: 83-90. DOI: <http://dx.doi.org/10.15585/mmwr7406a2>.



Acknowledgements

- The 5071 persons who volunteered to participate in NAVIGATE
- Investigators, Sub-Investigators, and Staff at 57 clinical study sites
- Parexel Biotech for clinical site management
- PharPoint Research, Inc for biostatistical support
- hVIVO Services Ltd. for virologic assays



Injection Site Reactions (ISRs) – Mild or Moderate Severity

	CD388 150 mg (N=1257)	CD388 300 mg (N=1263)	CD388 450 mg (N=1261)	Placebo (N=1260)
Participants Reporting Any ISR on Days 1-7 post injection	270 (21.5%)	310 (24.5%)	318 (25.2%)	251 (19.9%)
Erythema/Redness	89 (7.1%)	113 (8.9%)	121 (9.6%)	85 (6.7%)
Mild	72 (5.7%)	86 (6.8%)	103 (8.2%)	74 (5.9%)
Moderate	15 (1.2%)	25 (2.0%)	18 (1.4%)	10 (0.8%)
Induration/Swelling	49 (3.9%)	91 (7.2%)	80 (6.3%)	38 (3.0%)
Mild	42 (3.3%)	78 (6.2%)	78 (5.8%)	33 (2.6%)
Moderate	7 (0.6%)	12 (1.0%)	7 (0.6%)	4 (0.3%)
Pain	107 (8.5%)	150 (11.9%)	119 (9.4%)	103 (8.2%)
Mild	95 (7.6%)	133 (10.5%)	108 (8.6%)	97 (7.7%)
Moderate	10 (0.8%)	15 (1.2%)	10 (0.8%)	6 (0.5%)
Tenderness	182 (14.5%)	192 (15.2%)	189 (15.0%)	167 (13.3%)
Mild	156 (12.4%)	155 (12.3%)	171 (13.6%)	143 (11.3%)
Moderate	22 (1.8%)	34 (2.7%)	17 (1.3%)	23 (1.8%)

Injection Site Reactions (ISRs) – By Day Post-Injection

	CD388 150 mg (N=1257)	CD388 300 mg (N=1263)	CD388 450 mg (N=1261)	Placebo (N=1260)
Any ISR (n; %)				
Day 1	139 (11.1)	137 (10.8)	139 (11.0)	123 (9.8)
Day 2	124 (9.9)	177 (14.0)	167 (13.2)	110 (8.7)
Day 3	61 (4.9)	93 (7.4)	95 (7.5)	63 (5.0)
Day 4	42 (3.3)	71 (5.6)	63 (5.0)	38 (3.0)
Day 5	26 (2.1)	40 (3.2)	49 (3.9)	24 (1.9)
Day 6	16 (1.3)	31 (2.5)	34 (2.7)	17 (1.3)
Day 7	12 (1.0)	21 (1.7)	28 (2.2)	17 (1.3)