CD388: A Novel Long-Acting Antiviral for the Prevention of Seasonal Influenza NAVIGATE Phase 2b Clinical Trial Results

- Presented by: Rick A. Bright, PhD, on behalf of the Cidara CD388 NAVIGATE Study Team

- 8th ISIRV Antiviral Group (AVG) Meeting
- Singapore | September 17, 2025

Forward-looking Statements

These slides contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

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Executive Summary

The CD388 NAVIGATE Study for Prevention of Influenza Met Primary and All Secondary Endpoints

- **The primary endpoint of Preventive Efficacy (PE) of protocol-defined ILI events at 24 weeks was met with statistical significance at each dose group**
- **All secondary endpoints also met statistical significance in each dose group**

- Placebo attack rate was 2.8% for primary endpoint
- There is a clear dose response relationship
- 76% PE at the high (450 mg) dose
- Safety profile and tolerability were similar to placebo at all doses
- PE was maintained to 28 weeks with statistical significance at all doses
- Loss to follow up rates were low and similar in all arms

- Abbreviations: ILI, influenza-like illness; Ph, phase.

Influenza Disease Burden

Influenza continues to drive significant morbidity and mortality despite available vaccines and antivirals

In the United States (Each Season)[1]

CDC estimates 2024-2025 Flu Season

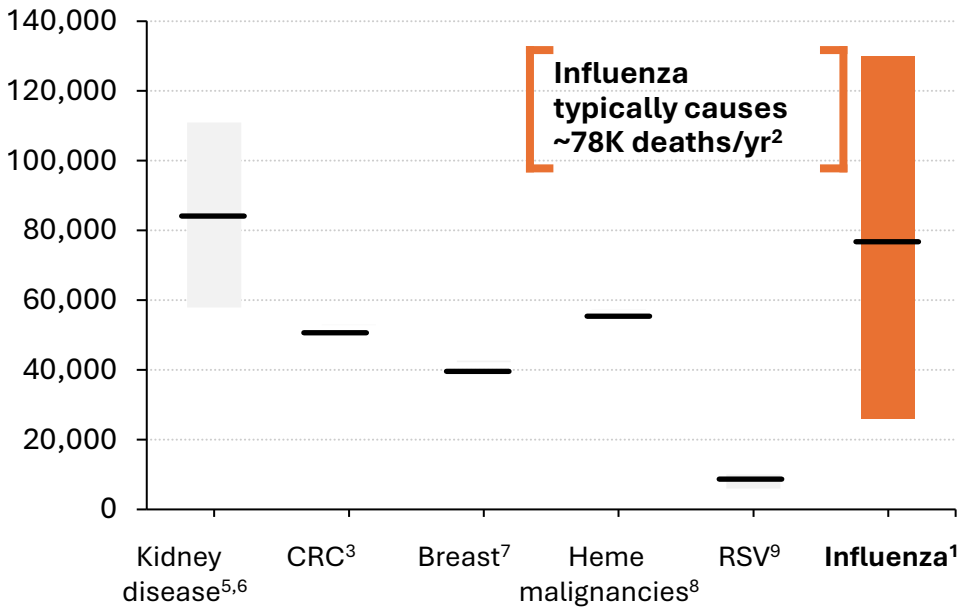
47M – 82M
Influenza illnesses

21M – 37M
Influenza medical visits

610K – 1.3M
Influenza hospitalizations

27K – 130K
Influenza deaths

Influenza Mortality in the US is Similar to Breast Cancer, CRC, & All Blood Cancers[3,4]



[1]CDC: Preliminary Estimated Flu Disease Burden 2024-2025 Flu Season; [2]CDC: WONDER; [3]National Cancer Institute Cancer Stat Facts; [4]American Cancer Society. [5]CDC: Kidney Disease Mortality by State; [6]CDC: Mortality in the United States, 2023; [7]CDC: U.S. Cancer Statistics Breast Cancer Stat Bite; [8]Leukemia & Lymphoma Society: Facts and Statistics Overview; [9]CDC: Preliminary Estimates of RSV Burden for 2024-2025.
Abbreviations: CRC, colorectal cancer; RSV, respiratory syncytial virus.

No Existing Solution Offers Adequate Protection for At-Risk Subjects

Treatment Interventions	Influenza Therapeutics and Vaccines	Limitations
Traditional Flu Vaccines	Fluzone® Influenza Vaccine; afluria® INFLUENZA VACCINE	• Widely available but low efficacy (~30-50% in healthy subjects) • Lower efficacy with strain mismatches and/or reduced health status or immune compromised
Enhanced Vaccines	Fluzone® High-Dose Quadrivalent Influenza Vaccine; FLUAD™ influenza vaccine, adjuvanted	• Modest efficacy improvements (~20% relative increase) • At-risk groups remain exposed to flu infections and burden
Antivirals	Tamiflu® oseltamivir phosphate; xofluza® (baloxavir marboxil) tablets	• Most effective when initiated <48 hrs of symptom onset • Short half-life limits use for pre-exposure prophylaxis (PrEP)

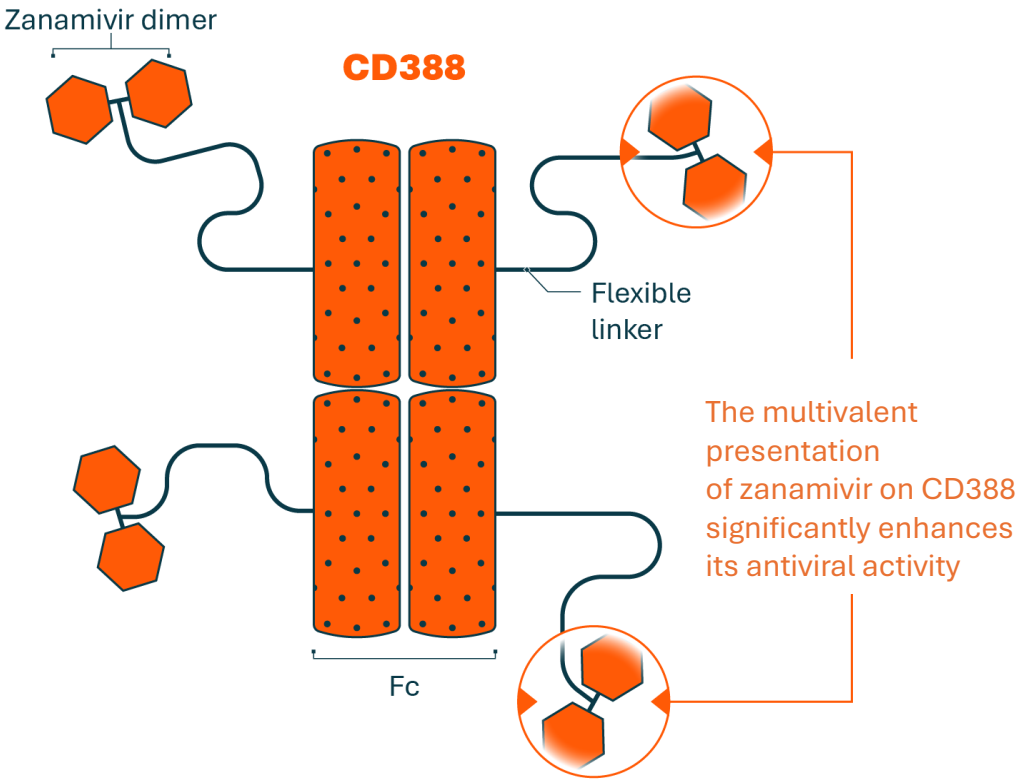
Existing vaccines and antivirals have significant limitations

Note: https://www.cdc.gov/flu-vaccines-work/php/effectiveness-studies/index.html. Accessed 21OCT2024; https://tinyurl.com/9y3bh9f6; (last 3-years flu season average for any influenza infection in adults over 18); Hughes K, Middleton DB, Nowalk MP, et al. Effectiveness of Influenza Vaccine for Preventing Laboratory-Confirmed Influenza Hospitalizations in Immunocompromised Adults. Clin Infect Dis. 2021;73(11): e4353-e4360; Influenza VE in Elderly over 65 (https://tinyurl.com/2xt89p4c).

Revolutionizing influenza protection

CD388, A Drug-Fc-Conjugate, is Part of a Novel Drug Class

CD388 is a Drug-Fc-Conjugate (DFC) that arrays multiple copies of zanamivir, the active ingredient of FDA-approved influenza drug Relenza®, on a clinically validated human antibody fragment engineered for extended half-life.



See Nature Microbiology manuscript for more details: *https://doi.org/10.1038/s41564-025-01955-3*

CD388 can complement seasonal influenza vaccines

CD388 has the Potential to Overcome the Limitations of Vaccines

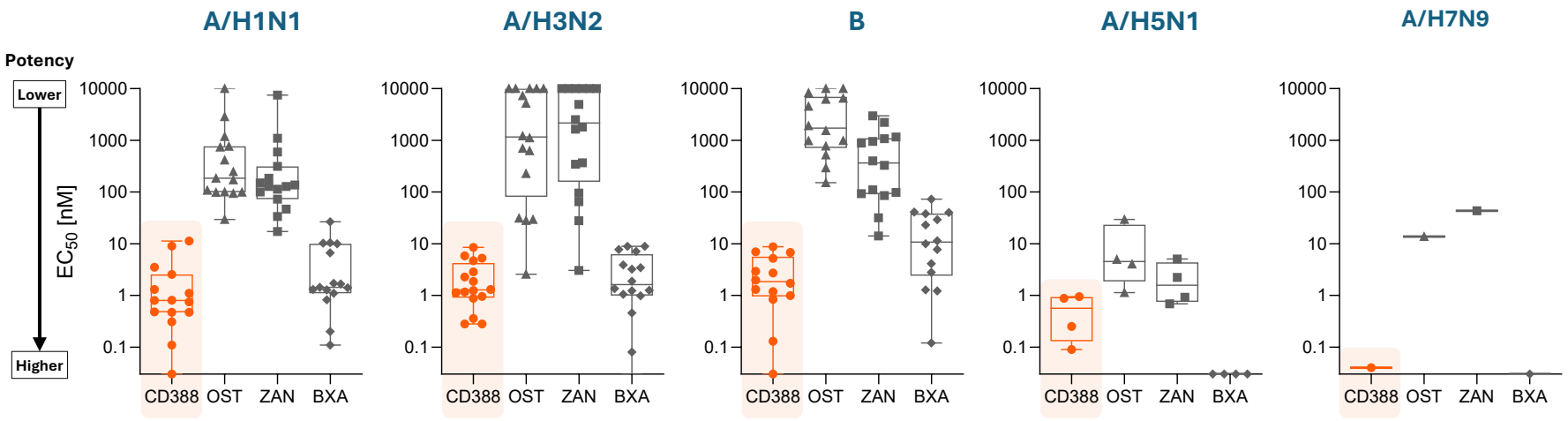
Attribute	CD388 Target Product Profile	Seasonal Flu Vaccines
Spectrum	Universal against all flu strains and in all people	Variable coverage of seasonal strains YoY and substantially less effective in high-risk populations
Administration	Once per season	Once or twice per season
Safety	No expected immune mediated safety issues. No hypersensitivity reactions in Ph 1, Ph 2a[1], or Ph 2b	Potential for immune mediated safety concerns
Manufacturing	Consistent year-round manufacturing with no change based on influenza strain	Must be manufactured anew every flu season (NH & SH)

1. https://www.cidara.com/wp-content/uploads/2024/10/Sandison_Options-XII-Oral-Presentation_FINAL_updated.pdf

Abbreviations: YoY, year over year.

Broad Influenza Prophylaxis

Cytopathic Effect Activity Versus Influenza Subtype Panels[1]



CD388 demonstrated antiviral activity across diverse seasonal and high pathogenicity strains, including H5N1 & H7N9

A/Vietnam/1194/2004 – clade 1
A/Indonesia/05/2005 – clade 2.1.3.2
A/Turkey/2005 – clade 2.2.1
A/Hong Kong/156/97 – clade 0

1. https://doi.org/10.1038/s41564-025-01955-3

Abbreviations: BXA, baloxavir acid; OST, oseltamivir carboxylate; ZAN, zanamivir.

CD388 Activity Observed Against Resistant Strains[1]

In Vitro Activity of CD388 and NAI Comparators vs NAI Resistant Strains

Influenza Strain	NA Genotype	CD388 IC_{50} [nM]	Oseltasmivir IC_{50} [nM]	Zanamivir IC_{50} [nM]
A/Illinois/45/2019 (H1N1)pdm09	H275	1.30	0.3	0.19
A/Alabama/03/2020 (H1N1)pdm09	H275Y	0.98	**426.8**	0.16
B/Laos/0080/2016	H134	7.44	33.35	2.61
B/Laos/0654/2016	H134N	4.66	**171.8**	**310.8**

>5X Shifts in NA inhibition IC_{50} or protective dose are highlighted in orange

In Vivo Activity of CD388 vs Zanamivir

Influenza Strain	Protective Dose (mg/kg), Lethal Challenge Model[2]	
	CD388 IC_{50} [nM]	Zanamivir IC_{50} [nM]
B/Laos/0080/2016 H134 (NAI-S)	0.3	1
B/Laos/0654/2016 H134N (NAI-R)	0.3	**10**

1. https://doi.org/10.1038/s41564-025-01955-3
2. 5 mice/group treated a single IM dose of CD388 2-hours after viral challenge. Zanamivir dosed IN once daily for 5-days starting 2-hours after infection. Survival monitored for 21 days.

Abbreviations: IM, intramuscular; IN, intranasal; NA, neuraminidase; NAI, neuraminidase inhibitor.

CD388 NAVIGATE Phase 2b Trial

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CD388 NAVIGATE Trial Design*

(NCT06609460)

Blinded, randomized, controlled trial of CD388 in 3 doses vs placebo as a single SQ administration to assess efficacy and safety of CD388 in prevention of influenza in subjects not at risk for influenza complications

A Double-blind RCT of CD388 for Influenza Prophylaxis

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

Sites, N=58

- US, n=57
- UK, n=1

R 1:1:1:1

- 150 mg
- 300 mg
- 450 mg
- Placebo

First/Last Dosed

Sep 2024/Dec 2024

Primary Endpoint

Preventive Efficacy (PE) = defined by all 3 criteria:

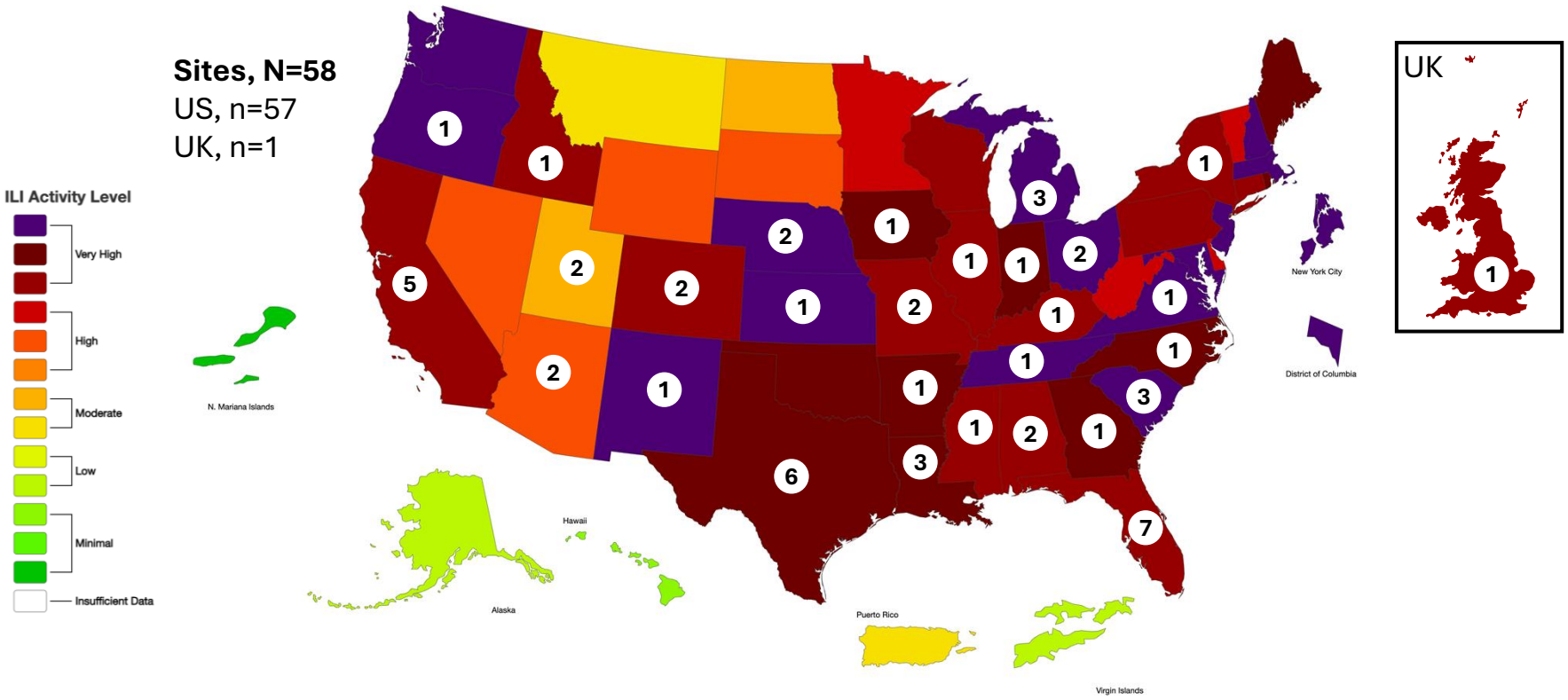
- PCR-confirmed influenza
- ≥2 respiratory or 1 respiratory and 1 systemic sign/symptom
- Body temp ≥38° C

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

Abbreviations: PCR, polymerase chain reaction; RCT, randomized controlled trial; SQ, subcutaneous.

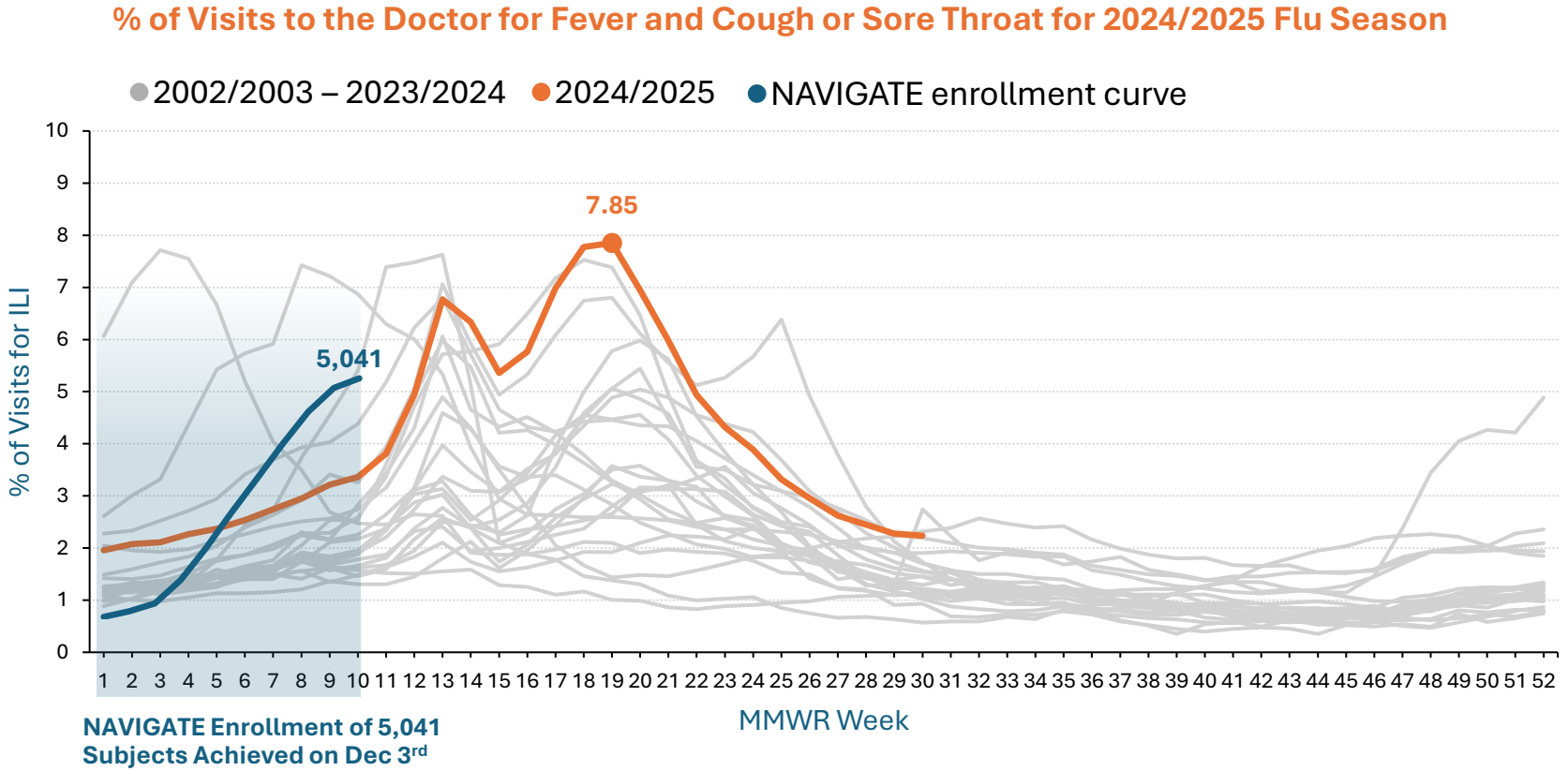
NAVIGATE Enrollment Site Map

Overlay of Heat Map Demonstrating Influenza Activity at Peak of 2024-25 NH Season (Week of Feb 9)



Source: https://gis.cdc.gov/grasp/fluview/main.html

NAVIGATE Enrollment Curve Relative to NH Influenza Activity



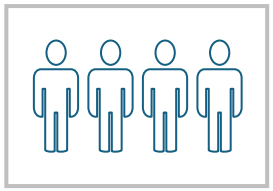
Flu season runs from early October (shown as week 1, corresponding to epi week 40) to the end of May. Data Sources: CDC and Datawrapper.

Abbreviations: ILI, influenza-like illness; MMWR, Morbidity and Mortality Week Report.

CD388 NAVIGATE Study Design Overview

Primary measure between 7 days and 24 weeks, secondary measures out to 28 weeks

Screening



Healthy unvaccinated subjects – 5000 randomized

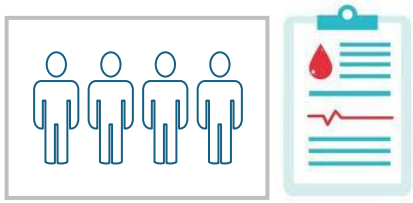
Day 1

– Study drug dosing
– ePRO training
– Baseline safety labs
– Baseline PK/ADA
– Baseline flu serology

Day 7 to 28 weeks

ARI surveillance and monitoring:
– Nasal swab for influenza infection
– ePRO symptom monitoring
– PK/ADA/Flu serology

Final visit (Week 28):



– Final safety labs
– Final PK/ADA
– Final flu serology

Abbreviations: ARI = acute respiratory illness; ePRO, electronic patient-reported outcomes.

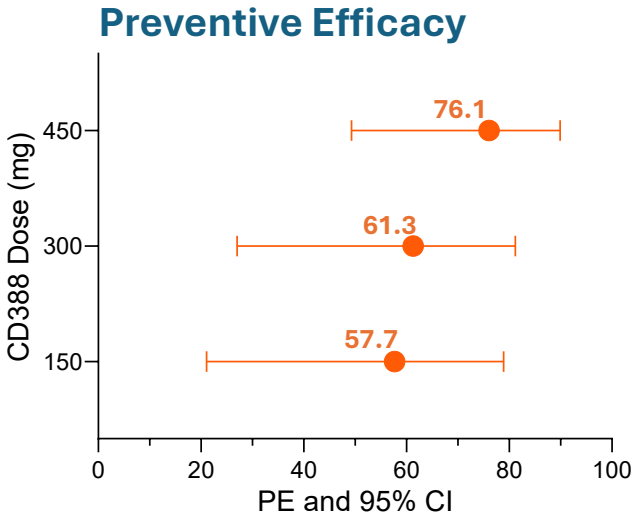
CD388 NAVIGATE Participant Demographics: Balanced Across All Arms

	CD388			
	150 mg N=1,268	300 mg N=1,268	450 mg N=1,268	Placebo N=1,267
Age				
18 - <40 yrs (%)	649 (51.2)	640 (50.5)	646 (50.9)	620 (48.9)
40 - <64 yrs (%)	619 (48.8)	628 (49.5)	622 (49.1)	647 (51.1)
Mean (SD)	39.7 (12.67)	39.6 (12.91)	39.5 (12.94)	39.9 (13.19)
Median	39	39	39	40
Sex				
Male (%)	594 (46.8)	586 (46.2)	571 (45.0)	575 (45.4)
Female (%)	674 (53.2)	682 (53.8)	697 (55.0)	692 (54.6)
Race				
White (%)	930 (73.3)	911 (71.8)	876 (69.1)	885 (69.9)
African American (%)	225 (17.7)	240 (18.9)	246 (19.4)	245 (19.3)
Asian (%)	61 (4.8)	62 (4.9)	74 (5.8)	69 (5.4)
Other (%)	52 (4.1)	55 (4.3)	72 (5.7)	48 (5.4)

Primary Endpoint Met With Statistical Significance in Each Dose Group

	CD388			
	150 mg	300 mg	450 mg	Placebo
Primary Endpoint*	N=1,268 n (%)	N=1,268 n (%)	N=1,268 n (%)	N=1,267 n (%)
Number of Participants Protocol-Defined ILI[1]	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	–

*Statistical significance for grouped 300mg + 450mg dose groups was met (PE=68.6%, p<0.0001), allowing progression down hierarchy for testing of individual dose groups.



Primary Endpoint

Preventive Efficacy (PE) = defined by all 3 criteria:

- PCR-confirmed influenza
- ≥2 respiratory or 1 respiratory and 1 systemic sign/symptom
- Body temp ≥38° C

1. ILI event defined as central laboratory-confirmed RT-PCR+ influenza infection (nasopharyngeal swab), new onset of fever (oral temperature ≥38.0°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)

Abbreviations: ILI, influenza like illness; CI, confidence interval

Primary Endpoint Met With Statistical Significance in Each Dose Group

Primary Endpoint*	CD388 150 mg N=1,268 n (%)	CD388 300 mg N=1,268 n (%)	CD388 450 mg N=1,268 n (%)	Placebo N=1,267 n (%)
Number of Participants Protocol-Defined ILI[1]	14 (1.2)	13 (1.1)	8 (0.7)	33 (2.8)
Preventive Efficacy (PE) (%)	57.7	61.3	76.1	–
95% CI (%)				
p-value				

*Statistical sign
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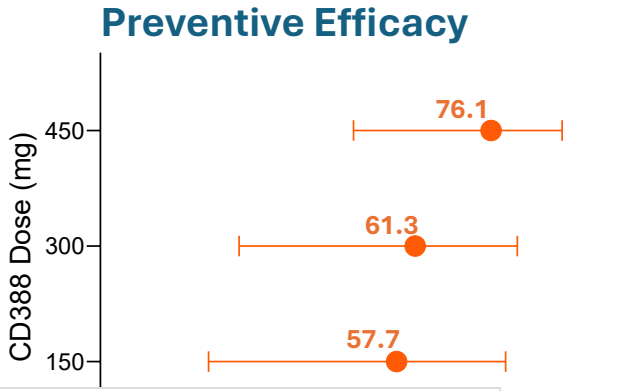
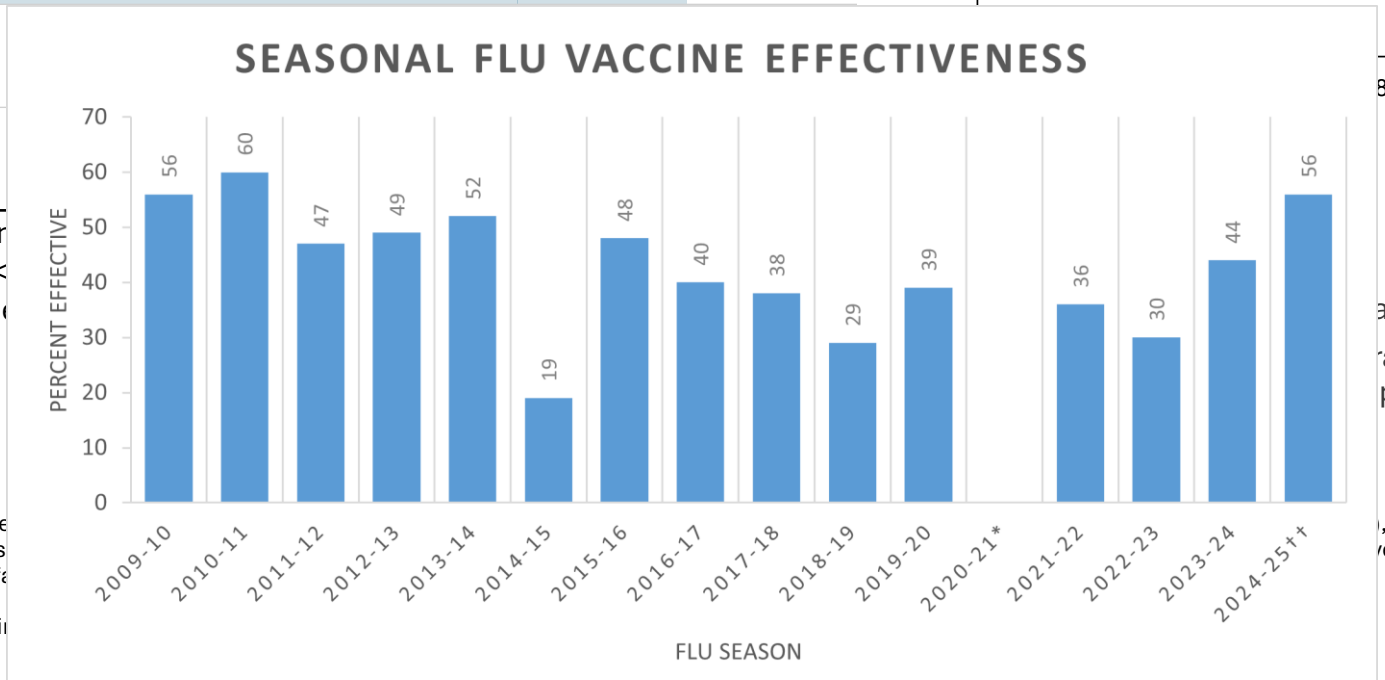
Abbreviations: ILI, i





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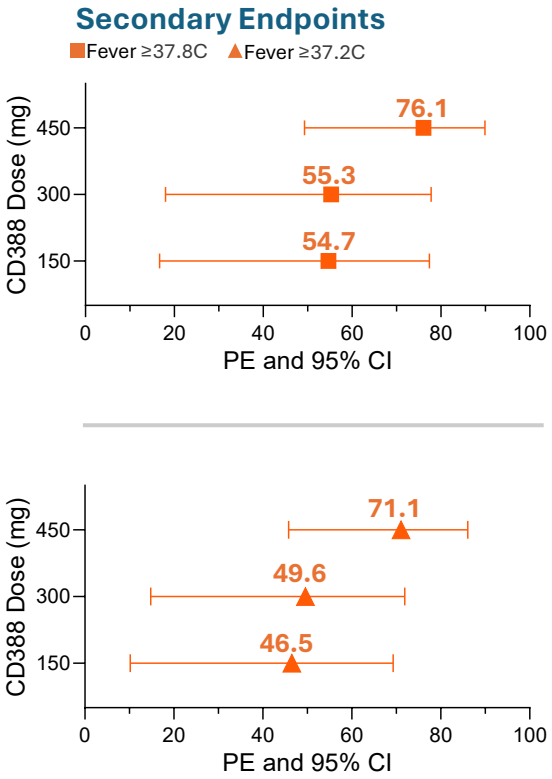
Secondary Endpoints Demonstrate Statistical Significance at All Temperatures

CD388

Secondary Endpoints	150 mg N=1,268 n (%)	300 mg N=1,268 n (%)	450 mg N=1,268 n (%)	Placebo N=1,267 n (%)
Number of Participants with ≥37.8 Temp[1]	15 (1.3)	15 (1.3)	8 (0.7)	33 (2.8)
Preventive Efficacy (PE) (%)	**54.7**	**55.3**	**76.1**	–
95% CI (%)	16.7, 77.4	18.0, 77.8	49.3, 89.9	–
P-value	0.0084	0.0073	<0.0001	-
Number of Participants with ≥37.2 Temp[2]	22 (1.9)	21 (1.8)	12 (1.0)	41 (3.5)
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	-



1. CDC definition: ILI event defined as central laboratory-confirmed RT-PCR+ influenza infection (nasopharyngeal swab), new onset of fever (oral temperature ≥37.8°C), and new onset of ≥2 respiratory symptoms (nasal congestion, sore throat, cough).
2. ILI event 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 (nasal congestion, sore throat, cough) or ≥1 respiratory symptom and ≥1 systemic symptom (headache, feeling feverish, body aches/pains, fatigue).

Abbreviations: ILI, influenza like illness; CI, confidence interval: PCR, polymerase chain reaction.

Safety Summary: No Safety Signals

- **Safety profile and tolerability were similar in all arms with no safety signals observed**
- **There were no drug-related SAEs**
- **Treatment-emergent adverse events (TEAEs) showed no dose-dependent pattern between CD388 and placebo groups**
- **Majority of TEAEs were unrelated to study drug and Grade1/ Grade 2**
- **Injection site reaction rates were subject-reported and similar across CD388 doses and placebo**

	CD388			
	150 mg N=1,257 n (%)	**300 mg** N=1,263 n (%)	**450 mg** N=1,261 n (%)	**Placebo** N=1,260 n (%)
Any TEAE	521 (41.4)	515 (40.8)	524 (41.6)	515 (40.9)
Any SAE	8 (0.6)	8 (0.6)	6 (0.5)	13 (1.0)
Any drug-related SAE	0	0	0	0
Any ISR	270 (21.5)	310 (24.5)	318 (25.2)	251 (19.9)
Erythema	89 (7.1)	113 (8.9)	121 (9.6)	85 (6.7)
Induration	49 (3.9)	91 (7.2)	80 (6.3)	38 (3.0)
Pain	107 (8.5)	150 (11.9)	119 (9.4)	103 (8.2)
Tenderness	182 (14.5)	192 (15.2)	189 (15.0)	167 (13.3)

Abbreviations: ISR, injection site reaction; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

Summary and Next Steps

NAVIGATE Study Highlights the Potential of CD388 for Broad, Seasonal Influenza Prevention

- CD388 met all primary and secondary endpoints for prevention of influenza with statistical significance following a single subcutaneous administration
- CD388 demonstrated a benign safety profile at all tested doses
- NAVIGATE trial supports advancement of the 450 mg dose to Phase 3
- Pharmacokinetic and virology data to be presented at future conferences

For More Information

- Please visit our luncheon “CD388: A New Modality for Broad Influenza Protection in Healthy and High-Risk Populations” (Drs. Fred Hayden and Rick Bright co-chairing)
  - **Friday, Sept 19th, 13:00-13:45, Grand Ballroom 1, Level 4,**
  - **Waterfront Conference Center**

- Andreev Konstantin (St. Jude): “A Single Prophylactic dose of CD388 Provides Protection Against highly Pathogenic Bovine-Origin Influenza A(H5N1) Virus in the Ferret Model”
  - **Friday, Set 19th, 12:30-12:45**

Available for Q&A

Les Tari, Ph.D.
CSO

Corrina Pavetto
SVP, Clinical Operations