

JUNE 2025 NASDAQ: CDTX

NAVIGATE Ph 2B

June 23, 2025



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Торіс	Discussant
Introduction	Jeff Stein, PhD
NAVIGATE Phase 2b Trial Data Cut	Nicole Davarpanah, MD, JD
Q&A Discussion	Cidara Management

DFCs: 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





Executive Summary

The NAVIGATE Study Met Primary and All Secondary Endpoints

- The primary endpoint of Prevention Efficacy (PE) of protocol-defined Influenza-like illness (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

- Single doses of 450mg, 300mg and 150mg of CD388 conferred 76, 61 and 58% protection, respectively, from symptomatic influenza over 24 weeks compared to placebo
- Placebo attack rate was 2.8% for primary endpoint
- Safety and tolerability data were similar in all arms with no dose/safety relationship observed
- Meeting request with the FDA has been submitted

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



Prevention Efficacy tells us the percentage by which a prevention method reduced the chance of getting sick compared to not using it

*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.

First/Last Dosed

Sep 2024/Dec 2024

Primary Endpoint

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

defined by all 3 criteria up to 24 weeks:

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



Primary Endpoint Met With Statistical Significance in Each Dose Group



testing of individual dose groups versus placebo.

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

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).

Key Secondary Endpoints Demonstrated Statistical Significance at All Specified Temperatures

	CD388			
Secondary Endpoints	150 mg N=1,175* n (%)	300 mg N=1,192* n (%)	450 mg N=1,1187* n (%)	Placebo N=1,172* n (%)
Number of Participants with ≥37.8 Temp ¹	15 (1.3)	15 (1.3)	8 (0.7)	33 (2.8)
Prevention 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 \ge 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	_

*sample size (N) indicates evaluable population at time of primary analysis data cut-off (Apr 30, 2025).

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

- 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. ILl 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).

Safety Summary: No Safety Signals

- Safety and tolerability data were similar in all arms with no safety signals observed
- Treatment-emergent adverse events (TEAEs) showed no dose-dependent pattern between CD388 and placebo groups
- Majority of TEAEs were unrelated to study drug and Grade 1/Grade 2 (mild to moderate)
- There were no drug-related SAEs
- 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)



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)	68 (5.4)

*15 participants (0.3%) were ≥64 yrs: 6 in 150mg arm, 5 in 300mg arm, 2 in 450mg arm, 2 in placebo arm

Next Steps

- Full primary analysis details will be submitted to upcoming scientific conferences in 2025
- Dose for Phase 3 will be selected after full PK data is assessed
- Drug supply for any dose is available to begin Phase 3
- End of Phase 2 FDA meeting request has been submitted to continue discussion on Phase 3 study design and start time



Thank You

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