Don't eat me

ALX Oncology

SABCS Evorpacept + Zanidatamab Breast Cancer Presentation

December 17, 2024

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ALX Oncology SABCS Breast Cancer Data Review



ALX Oncology Introduction



Jason Lettmann CEO, ALX Oncology



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SABCS '24 Clinical Data Review



Dr. Alan Sandler, MD CMO, ALX Oncology



Fireside Chat on SABCS '24



Dr. Alberto Montero, MD Professor, UH Seidman Cancer Center & Case Western Reserve University Medical School



Closing remarks and Q&A



Jason Lettmann CEO, ALX Oncology



ALX Oncology is transforming cancer treatment for patients by developing evorpacept as a firstin-class foundational checkpoint immunotherapy

ALX Oncology is advancing a highly differentiated immuno-oncology pipeline led by evorpacept, a potential best and first-in-class CD47 innate immune system checkpoint inhibitor that has been studied in >700 patients treated to date

Evorpacept is the first and only CD47 agent to demonstrate both durable improvement in overall response rate and a well-tolerated safety profile in a prospective randomized study

Differentiated mechanism of action as evorpacept is the only CD47 in development with a dead Fc with a clear biomarker to target patients (eg, HER2 expression)

Multiple positive clinical studies across bladder, NHL, gastric, and head and neck (HNSCC) and currently pursuing additional studies in combination with 3 therapeutic classes: anti-cancer antibodies, checkpoint inhibitors & ADCs

Expanding evorpacept to new indications supported by multiple pharma partnerships, building a strong pipeline beyond evorpacept, and a strong balance sheet with cash runway through Q1 2026.

New Data at SABCS '24 Demonstrated Evorpacept in Combination with Zanidatamab Generated Promising Antitumor Activity in Advanced Breast Cancer

Evorpacept: A first-in-class approach to targeting CD47



Target cells overexpress CD47 to evade destruction by macrophages



A differentiated CD47 blocker



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Evorpacept has demonstrated robust enhancement of combinations and consistent tolerability



Strong activity observed across 5 different clinical trials to date
Evorpacept is the only CD47 blocker to demonstrate activity across both heme and solid cancers

 Further, evo is the only CD47 to demonstrate positive data in a large randomized trial



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1. AUGMENT study 3. Burtness, Lancet, 2019: 4. Cohen, Lancet, 2018.: 5 EV-301 study Evorpacept's differentiated design results in differentiated safety profile and robust clinical activity



Pursuing a robust development plan

Indication		Evorpacept Combination Agent	Discovery	IND Enabling	Phase 1	Phase 2	Phase 3	Fast Track	Supplier/ Collaborator
orpacept Combination Studies ANTI-CANCER ANTIBODIES AND ADCS	GC Gastric/Gastroesophageal Junction Cancer	Herceptin + Cyramza + Paclitaxel (ASPEN-06)							¹ Lilly
	Urothelial Cancer	Padcev (ASPEN-07)							
	Breast Cancer	Zanidatamab							2 Jazz Pharmaceuticals.
		Enhertu (I-SPY)							3 Quantum Leap Healthcare Collaborative
	MM Multiple Myeloma	Sarclisa + Dexamethasone							sonofi
CHECKPOINT	HNSCC Head And Neck	Keytruda (ASPEN-03)							
	Squamous Cell Carcinoma	Keytruda + 5FU + Platinum (ASPEN-04)							

Jazz Pharmaceuticals conducted and sponsored clinical trial and ALX Oncology supplied evorpacept

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¹ ALX Oncology wonducts and sponsors AS PEN-06, Lilly supplies Cyramza.² Jazz Pharmaæuticals conducts and sponsors dinical trial, ALX Oncology supplies evorpacept.³ Quantum Leap Hedthcare Collaborative conducts and sponsors dinical trial, ALX Oncology supplies evorpacept. ⁵ ALX Oncology supplies evorpacept.⁴ Sanofi wonducts and sponsors conducts and sponsors dinical trial, ALX Oncology supplies evorpacept. ⁵ ALX Oncology supplies evorpacept.⁴ Sanofi wonducts and sponsors conducts and sponsors dinical trial, ALX Oncology supplies evorpacept. ⁵ ALX Oncology supplies evorpacept. ⁴ Sanofi wonducts and SPEN-04, Merck supplies Keytruda

Dr. Alan Sandler



Chief Medical Officer



Chief Medical Officer Head of Global Development Oncology

zailab

Global Head of Product Development, Oncology

Genentech A Member of the Roche Group

OHSU

MIRATI

Acquired by BMS





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Evorpacept HER2 thesis is validated by new data in combination with zanidatamab in breast cancer



Evo + Zani is a chemo-free regimen targeting the unmet need in breast cancer of patients who have progressed on multiple HER2-targeted agents including Enhertu

Evorpacept + Zanidatamab Mechanism of Action



Evorpacept may drive antitumor activity of zanidatamab by targeting HER2expressing cells for phagocytosis



Dr. Alberto Montero



Clinical Director

Breast Cancer Medical Oncology Program

Medical Director

Oncology Clinical Trials Unit

University Hospitals Seidman Cancer Center

Professor of Medicine

Case Western Reserve University School of Medicine



Improvement of clinical outcomes in patients with breast cancer through the development of novel targeted therapies, with a particular interest in immune-based therapies and the mechanism by which tumors evade the immune system.



Prior reviewer and study chair for the Department of Defense **Breast Cancer Research Program** ASCO (sitc)

University Hospitals

UNIVERSITY

The Science of Health. The Art of Compassion.

CASE WESTERN RESERVE



Member of several educational and scientific committees



Financial Relationships/Disclosures

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Consulting:

Paragon Healthcare, Astra Zeneca, Welwaze Medical, Gilead, Scorpion Therapeutics, ALX Oncology

Stock/Equity Ownership:

Celcuity and CareVive (stock options)



Breast Cancer Epidemiology









Metastatic HER-2+ BC patients are in need of novel, chemo-free therapeutics that are efficacious particularly after progressing on several prior lines of HER2-targeted therapy



*NCCN Category 1 preferred regimen for this line of therapy Adapted from NCCN guidelines v6.2024



Abstract #SESS-2007 at SABCS 2024

Zanidatamab in Combination With Evorpacept in HER2-Positive and HER2-Low Metastatic Breast Cancer: Results From a Phase 1b/2 Study

Alberto J. Montero^{1*}, Kari B. Wisinski², Bruno Fang³, Kelly E. McCann⁴, Sara Hurvitz⁵, Kay T. Yeung⁶, Ritesh Parajuli⁷, Jorge Chaves⁸, Adam Brufsky⁹, Peter A. Kaufman¹⁰, Manish R. Patel¹¹, Timothy Pluard¹², Bob Salim¹³, Kavita V. Shah¹³, Shanhong Guan¹⁴, Athanasios C. Tsiatis¹⁴, Sophia Randolph¹⁴, Funda Meric-Bernstam¹⁵

¹UH Cleveland Medical Center/Seidman Cancer Center Case Western Reserve University, Cleveland, OH, USA; ²University of Wisconsin Carbone Cancer Center, Madison, Wisconsin, USA; ³Astera Cancer Care, East Brunswick, NJ, USA; ⁴David Geffen School of Medicine, University of California at Los Angeles, CA, USA; ⁵Fred Hutchinson Cancer Center, University of Washington School of Medicine, Seattle, WA, USA; ⁶University of California at Los Angeles, CA, USA; ⁸Fred Hutchinson Cancer Center, University of Washington School of Medicine, Seattle, WA, USA; ⁶University of California at Los Angeles, CA, USA; ⁸Northwest Medical Specialties, Tacoma, WA, USA; ⁹University of Pittsburgh School of Medicine, Pittsburgh, PA, USA; ¹⁰Larner College of Medicine at the University of Vermont, Burlington, VT, USA; ¹¹Florida Cancer Specialists/Sarah Cannon Research Institute, Sarasota, FL, USA; ¹²Saint Luke's Cancer Institute, Kansas City, MO, USA; ¹³Jazz Pharmaceuticals, Palo Alto, CA, USA; ¹⁴ALX Oncology Inc., South San Francisco, CA, USA; ¹⁵The University of Texas MD Anderson Cancer Center, Huston, TX, USA

Phase 1b/ 2 Study Design: Evorpacept plus zanidatamab in HER2+ and HER2-low in patients who have progressed on prior HER2-directed therapy



This study provides clinical data supporting further development of evorpacept with HER2targeted agents in patients with breast cancer

(1) Prior HER2-targeted therapies were initially excluded; the protocol was amended to allow prior treatment with T-DXd following its approval in this patient population. (2) RP2D Zanidatamab 1200 mg (<70 kg) or 1600 mg (\geq 70kg) and evorpacept 30 mg/kg IV Q2W on days 1 and 15 of each 28-day cycle. (3) Mandatory IRR prophylactic treatment included corticosteroids, antihistamines, and acetaminophen.



17 | Study conducted by Jazz Pharmaceuticals

Patient Demographics and Baseline Disease Characteristics

Characteristic	Cohort 1 HER2-Positive (n=21)	Cohort2 HER2-Low (n=15)	Cohort3 Other HER2- Overexpressing Cancers (n=8) ⁶
Age, median, years (range)	58.0(34.0-81.0)	63.0 (42.0-74.0)	48.5 (36.0-74.0)
Female, n (%)	21 (100)	15 (100)	4 (50.0)
Race, n (%)			
White	14 (66.7)	9 (60.0)	6 (75.0)
Asian	0 (0)	2 (13.3)	0 (0)
Black or African American	4 (19.0)	3 (20.0)	0 (0)
Multiple/Other	1 (4.8)	0 (0)	2 (25.0)
Unknown/Not reported	2 (9.5)	1 (6.7)	0 (0)
Baseline ECOG PS, n (%) 0 1	9 (42.9) 12 (57.1)	8 (53.3) 7 (46.7)	4 (50.0) 4 (50.0)
HER2 status per central assessment, n (%)			
IHC 0	2 (9.5)	0 (0)	1 (12.5)
IHC 1+ or IHC 2+/FISH-	10 (47.6)	14 (93.3)	3 (37.5)
IHC 2+/FISH+ or IHC 3+	9 (42.9)	0 (0)	4 (50.0)
Unknown	0 (0)	1 (6.7)	0 (0)
Median number of prior systemic cancer therapy regimens in the metastatic setting (range)	6 (2.0-10.0)	5 (2.0-9.0)	3.5 (2.0-11.0)
Prior HER2-targeted the rapies, n_(%)			
<u>T-DXd</u>	21 (100)	5 (33.3)	5 (62.5)
Trastuzumab	21 (100)	0 (0)	8 (100)
Pertuzumab	20 (95.2)	0 (0)	3 (37.5)
T-DM1	14 (66.7)	0 (0)	1 (12.5)
Tucatinib	12 (57.1)	0 (0)	0 (0)
Neratinib	5 (23.8)	0 (0)	0 (0)
Margetuximab	4 (19.0)	0 (0)	0 (0)
Lapatinib	3 (14.3)	0 (0)	0 (0)
Prior brain metastases, n (%)	9 (42.9)	4 (26.7)	1 (12.5)
De novo metastatic disease, n (%)	7 (33.3)	4 (26.7)	3 (37.5)

Data cut off date 1 August 2024 Montero. et. Al. SABCS 2024, Poster Spotlight Presentation. Abstr #SESS-2007

Population represented heavily pretreated R/R population

- Median of 6 prior therapies in Cohort 1 and 5 prior therapies in Cohort 2, including multiple HER2-targeted therapies
- Notably, 100% of patients in cohort 1 and 33% of patients in cohort 2 had received prior Enhertu

Local assessment of HER2 in archived tumor samples was used for enrollment; when unavailable, patients could be enrolled based on central assessment

- Data were analyzed for all patients enrolled and based on central assessment
- Of the 20/21 patients with local HER2 assessment in cohort 1, 8 (40%) were confirmed HER2-positive by central assessment (1 centrally HER2-positive patient did not have local assessment).
 - For cohort 2, 14/15 (93%) patients were confirmed HER2-low by central assessment

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The combination of evorpacept and zanidatamab was well-tolerated with a manageable safety profile that is consistent with prior experience with each agent

	Al	l Patients (N=52)		
Any TRAE, n (%)		45 (86.5)		
Grade 1-2		38 (73.1)		
Grade 3		7 (13.5)		
Grade 4-5	0 (0)			
Serious TRAEs, n (%)	3 (5.8)b			
TRAEs leading to treatment discontinuation, n (%)	2 (3.8)c			
TRAEs leading to dose reductions, n (%)	0 (0)			
Treatment-related AESI, n (%)				
Left ventricular dysfunctional	1 (1.9)			
IRR	12 (23.1)			
Non-infectious pulmonary toxicities		0 (0)		
Most common TRAEs* n (%)	Grade 1	Grade 2	Grade 3	
Diarrhea	20 (38.5)	9 (17.3)	3 (5.8)	
Fatigue	9 (17.3)	7 (13.5)	1 (1.9)	
Nausea	11 (21.2)	3 (5.8)	0 (0)	
IRR	3 (5.8)	7 (13.5)	2 (3.8)	

a. TRAEs defined as events with an onset during or after receiptof the first dose of study treatment within 30 days after the last dose and were determined as related to zanidatamb and/or evonparejet by the investigators. D. Ywo additional events (darinet and UVEF decreased) occurred outside the 30-day window for TRAEs. c. Both events were grade 3 IRRs that resolved following treatment discontinuation. Defined as LVEF

AESI, adverse event of special interest; RR, infusion-related reaction; LVEF, left ventricular ejection fraction; TRAE, treatment-related adverse event.

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Data cut off date 1 August 2024

- Most treatment-related adverse events were grade 1 or 2 (related to zanidatamab and/or evorpacept)
 - The most common grade 3 TRAEs were diarrhea (5.8%) and IRRs (3.8%); there were no grade 4 TRAEs
 - Serious TRAEs included dyspnea, gamma-glutamyltransferase increased, and IRR (occurring in 1 patient each)
 - TRAEs of special interest included:
 1 (1.9%) patient with grade 3 ejection fraction decreased and 12 (23.1%)
 patients with IRRs – All IRRs resolved; 1
 (%) patient had an IRR event after the dosing order was reversed to zanidatamab followed by evorpacept
- No non-infectious pulmonary toxicities occurred

There were no treatment-related deaths



Breast cancer patients with confirmed HER2-positivity by central assessment had the greatest benefit from evorpacept + zanidatamab

	Coh	Cohort 2	
	HER2-Positive by Central (n=9)	HER2- Low/Ultralow* by Central (n=12)	HER2-Low mBC (n=15)
cORR, n (%)	5 (55.6)	2 (16.7)	3 (20.0)
[95% Cl]	[21.2, 86.3]	[2.1, 48.4]	[4.3, 48.1]
CR, n (%) ^a	0 (0)	0 (0)	0 (0)
PR, n (%)	5 (55.6)	2 (16.7)	3 (20.0)
SD, n (%)	2 (22.2)	6 (50.0)	3 (20.0)
PD, n (%)	1 (11.1)	4 (33.3)	7 (46.7)
NE, n (%)	1 (11.1)	0 (0)	2 (13.3)
DCR. n (%)	7 (77.8)	8 (66.7)	6 (40.0)
[95% CI]	[40.0, 97.2]	[34.9, 90.1]	[16.3, 67.7]
Median DOR, months	NE	NE	5.5
(range) ^c	(5.6-25.9)	(3.6-15.0)	(3.6-11.0)
Median PFS, months	7.4	3.5	1.9
(95% CI)	(0.6, NE)	(1.6, 14.6)	(1.6, 3.9)

- Chemo-free regimen of evo+ zani post-Enhertu compares favorably with chemo regimen with no prior Enhertu
 - SOPHIA study (n=536) of margetuximab + chemo vs. trastuzumab + chemo 22% vs. 16% cORR¹
- Highest responses observed in patients with confirmed HER2postivity

Encouraging activity of a chemo free regimen in an R/R and T-DXd (Enhertu) experienced population

Median follow-up (range) was 9.6 (0.6, 29.7) months, with 6 patients on treatment at data cutoff as of August 1, 2024

*HER2-Low/Ultralow = IHC1+, IHC2+ / ISH-, IHC 0

^aThere was one HER2-positive mBC patient treated at the lower dose of evorpacept in Part 1 that achieved a complete response (med ian DOR: 20.2 months) cORR, confirmed objective response rate; CR, complete response; DCR, disease control rate; DOR, duration of response; HER2, human epidermal growth factor receptor 2; mBC, metastatic breast cancer; NE, not evaluable; PD, progressive disease; PFS, median progression-free survival; PR, partial response; SD, stable disease. Data cutoff August 1, 2024.



20 1) JAMA Oncol. 2021;7(4):573-584. doi:10.1001/jamaoncol.2020.7932

71% of patients (15/21) in cohort 1 (HER2+ BC) had a reduction in target lesion size from baseline



Dotted lines indicate 20% increase and 30% decrease in sum of diameters of target tumors. Treated patients without a post-baseline assessment are not shown in either panel (1/21 patient in cohort 1 and 2/15 patients in cohort 2).

*Boxed, bolded text indicate patients who are HER2-positive by central assessment. *Four patients in cohort 1, 1 patient in cohort 2, and 1 patient in cohort 3 (not shown) remained on treatment as of data cutoff.

BOR, best overall response; cPR, confirmed partial response; FISH, fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; HC, immunohistochemistry; PD, progressive disease; PR, partial response; SD, stable disease; T-DXd, trastuzumab deruxtecan.

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Encouraging durability with evorpacept and zanidatamab in breast cancer patients



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Dotted lines indicate 20% increase and 30% decrease in sum of diameters of target tumors. Treated patients without a post-baseline assessment are not shown in either panel (1/21 patient in cohort 1 and 2/15 patients in cohort 2).

*Boxed, bolded text indicate patients who are HER2-positive by central assessment. Four patients in cohort 1, 1 patient in cohort 2, and 1 patient in cohort 3 (not shown) remained on treatment as of data cutoff.

BOR, best overall response; cPR, confirmed partial response; FISH, fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; PD, progressive disease; PR, partial response; SD, stable disease; T-DXd, trastuzumab deruxtecan.

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SABCS Conclusions

- This is the **first study reporting data on the safety and efficacy of evorpacept, a CD47 blocker in combination with zanidatamab, a dual HER2-targeted bispecific antibody**, in previously treated patients with HER2-expressing cancers
- Evorpacept + zanidatamab showed promising antitumor activity in patients with heavily pretreated HER2-positive mBC including after progression on prior T-DXd (cORR: 55.6%; mPFS: 7.4 months in patients with centrally confirmed HER2-positive mBC)
- Antitumor activity was also observed in patients with heavily pretreated HER2-low mBC (cORR: 20.0%)
- Among all patients, the combination therapy was well tolerated with a manageable safety profile that is consistent with prior experience with each agent
- Based on the results presented here, further development of this novel chemotherapy-free regimen is warranted

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Fireside Chat



Dr. Alberto Montero, MD Professor

Case Western Reserve University School of Medicine



Dr. Alan Sandler, MD Chief Medical Officer ALX Oncology



This study again demonstrates the power of evorpacept engaging the innate immune response and further validates its mechanism with anti-cancer antibodies particularly in HER2+ tumors

Robust and Durable Clinical Activity in HER2+ Cancers		Validated Mechanism of Action with a Clear Biomarker	Consistently Well-Tolerated with HER2-targeted agents	Active in patients that have progressed on conventional HER2-directed therapy		
HER2+ Gastric/ GEJ Cancer						
• In de cc Ol cc	n ASPEN-06, evorpacept + TRP emonstrated an ORR of 40.3% ompared to the TRP control IRR of 26.6% and 15.7 months ompared to 7.6 months mDOR	 In ASPEN-06, evorpacept + TRP demonstrated an ORR of 59.1% in patients with fresh HER2+ biopsies vs. 23.1% in control 	 Evorpacept + TRP was well- tolerated with a safety profile consistent with that of the backbone TRP therapy 	 Efficacy demonstrated in patients that had all progressed on prior trastuzumab 		
HER2+ Breast Cancer						
• Ev he th	vo+ zani had an ORR of 33% in eavily pre-treated HER2+ BC in ne ITT population	 Evo+ zani had an ORR of 55% in heavily pre-treated HER2+ BC patients confirmed via central lab 	 Evorpacept + zanidatamab was well-tolerated with a manageable safety profile consistent with zanidatamab alone 	 Efficacy demonstrated in patients who had all progressed on several HER2-targeted agents and Enhertu 		

Evorpacept has now delivered consistent data in two different HER2+ tumor types with two different Fc-active antibodies de-risking the program significantly

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ALX Conclusions and Next Steps

- This study adds to the growing body of evidence suggesting that evorpacept can combine with various therapies to treat HER2-positive cancers in patients that have already received multiple HER2-targeted agents
- This data demonstrates that patients with heavily pre-treated HER2-positive breast cancer, who have seen a median of 5 to 6 prior lines of treatment, including multiple HER2-targeted agents and Enhertu had benefit from the combination of evorpacept and zanidatamab, a novel, chemo-free regimen
- Validation of biomarker strategy as patients with confirmed HER2-positivity had the greatest benefit, across both studies
- These findings provide us with the POC necessary to accelerate clinical development plans in HER2+ BC

Next Data Update: ASPEN-06 HER2+ Gastric Cancer Study Update: Medical Meeting in Q1 '25



HER2+ by central assessment



