BDTX-189 Phase 1 Clinical Data Presentation

May 19, 2021



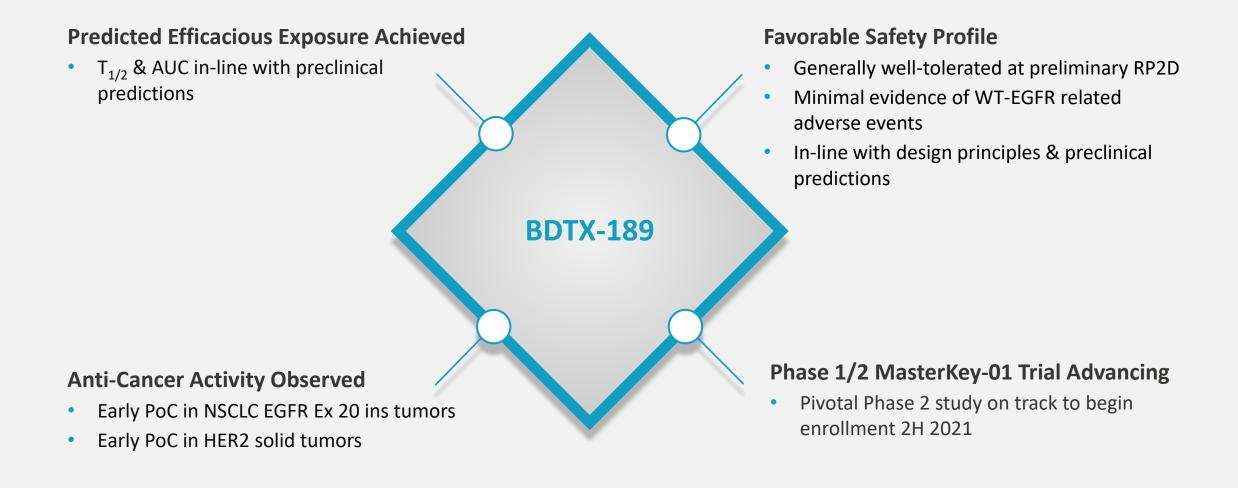
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Early Proof-of-Concept Demonstrated for BDTX-189, a MasterKey EGFR/HER2 Inhibitor





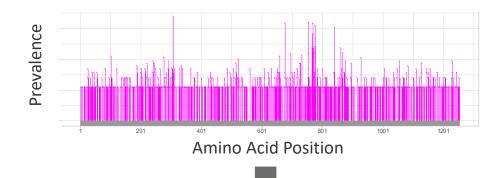
AUC = area under the curve; EGFR = epidermal growth factor receptor; Ex 20 ins = Exon 20 insertion; HER2 = human epidermal growth factor receptor 2; NSCLC = non-small cell lung cancer; PoC = proof of concept; RP2D = recommended Phase 2 dose; T_{1/2} = half-life; WT-EGFR = wild-type EGFR

BDTX-189 Designed to Address Unmet Medical Need in Patients Harboring EGFR/HER2 Alterations



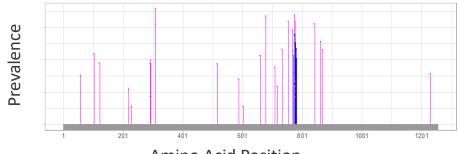
Black Diamond's Proprietary MAP Platform Elucidates Undrugged Allosteric EGFR/HER2 Mutations, Enabling the Development of a MasterKey Inhibitor

NGS reveals thousands of undrugged EGFR/HER2 mutations

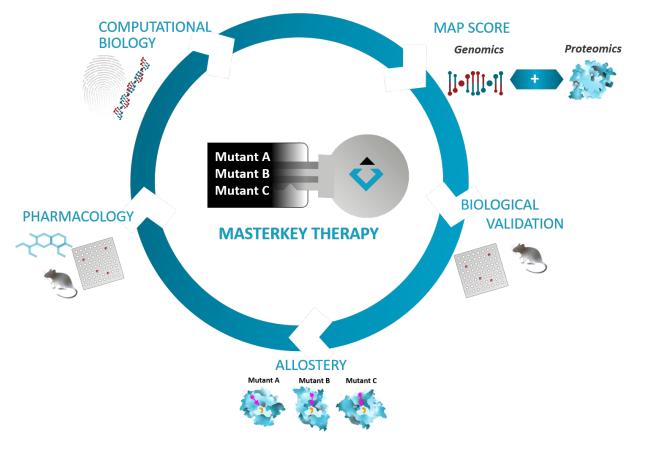


47 allosteric oncogenic mutations in EGFR and HER2

(includes EGFR/HER2 Ex 20 ins mutants)

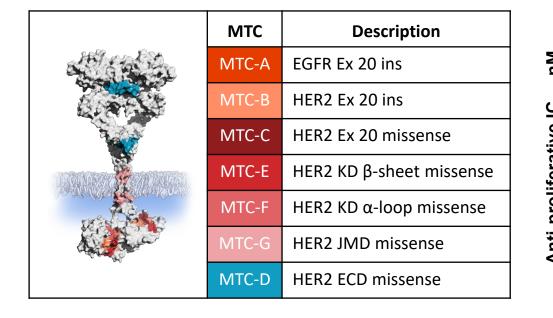


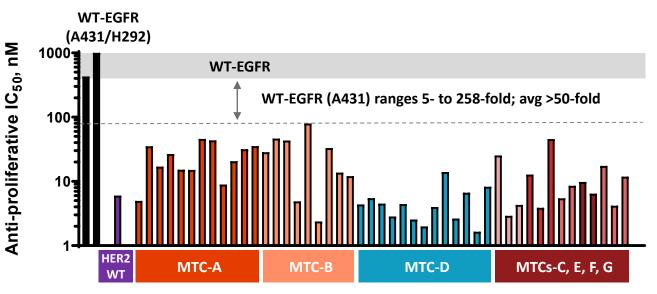
Amino Acid Position



BDTX-189 Is a Potent and Selective MasterKey Inhibitor of a Broad Range of Allosteric EGFR/HER2 Mutational Clusters

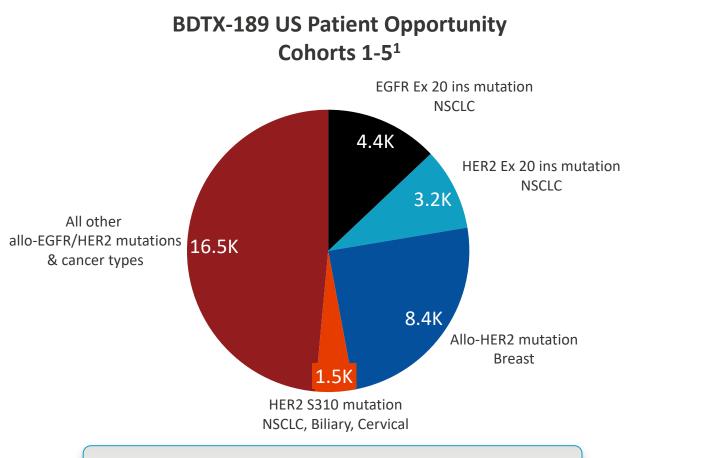
Oncogenic MTCs for EGFR and HER2 Oncogenes Phenotypic Activity and Selectivity v. WT-EGFR for BDTX-189 Across Targeted MTCs







Significant Unmet Medical Need for Patients Across Solid Tumors Harboring EGFR/HER2 Mutations



Clear Unmet Medical Need No approved targeted therapies Poor prognostic indicators In-clinic EGFR/HER2 agents have significant WT-EGFR toxicities that drive dose interruptions/reductions 10-90% diarrhea²⁻⁷ 12-86% rash²⁻⁷

~34K Newly Diagnosed US Patients

BLACK DIAMOND THERAPEUTICS 1. Based on 2020 solid tumor incidence data from SEER (seer.cancer.gov/) and prevalence of genetic alterations from Foundation Medicine, GENIE8.0/TCGA, and publications 2. Mobocertinib: WCLC 2020 for N=114 PPP (post-platinum patients) EGFR Ex 20 ins mut. NSCLC; 3. CLN-081: Dec 2020 S-1 for N=37 EGFR Ex 20 ins mut. NSCLC in Dose Escalation; 4. Amivantamab: WCLC 2020 for N=114 pre-treated EGFR Ex 20 ins. mut. NSCLC; 5. Poziotinib: ESMO 2020 for N=90 pre-treated HER2 Ex 20 ins mut. NSCLC in ZENITH20 Cohort 2; 6. DS-8201: 2020 ASCO for N=42 HER2mut. NSCLC in DESTINY-Lung01; 7. Neratinib: Smyth 2020 for N=81 HER2mut. Breast Cancer treated as monotherapy (N=34) or in combo with fulvestrant (N=47). Note: These tolerability data are derived from different clinical trials at different points in time, with differences in trial design and patient population. No headto-head clinical trials have been conducted.

BDTX-189 Phase 1 Clinical Data



Phase 1 Portion of Masterkey-01 Study Evaluates BDTX-189 in Solid Tumors Driven by Broad Range of EGFR and HER2 Genomic Alterations

MasterKey-01 Study Schema^a

Part A (Phase 1)



- RP2D and schedule
- BID schedule also under evaluation

Key Eligibility Criteria

Part A: Phase 1 Dose

- Relapsed/refractory solid tumor, no available SOC
- Treated, asymptomatic CNS malignancy allowed
- Prior EGFR/HER2-targeted therapy allowed

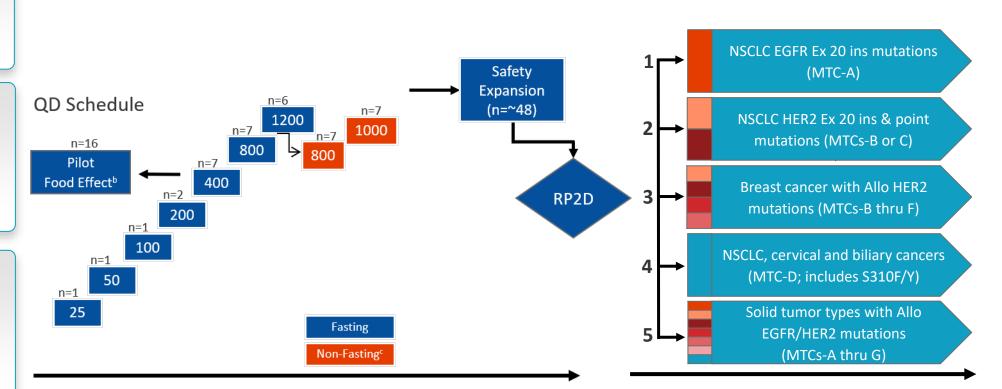
Genomic Alterations

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- Allosteric HER2 or HER3 mutation
- EGFR/HER2 Ex 20 ins mutation
- HER2 amplification/overexpression
- EGFR Ex 19 or L858R mutation



BID, twice daily; BOIN, Bayesian Optimal Interval Design; CNS, central nervous system; QD, once daily; SOC, standard of care. ¹Yuan Y, et al. *Clin Cancer Res.* 2016;22(17):4291-4301.

^aFigure summarizes number of patients in Full Analysis Set (i.e., those who received at least 1 dose of study drug).

^bSingle dose crossover study at 400 mg. On day 5, patients begin dosing with 800 mg QD.

^cAdministered with meal of patient's preference.

Data presented is as of April 2, 2021, unless otherwise noted. This is an ongoing study and is undergoing active data entry and cleaning.

Part B (Phase 2)

Phase 1 Dose Escalation was Conducted in Heavily Pre-Treated Patients with a Diverse Array of Cancer Types and MTCs

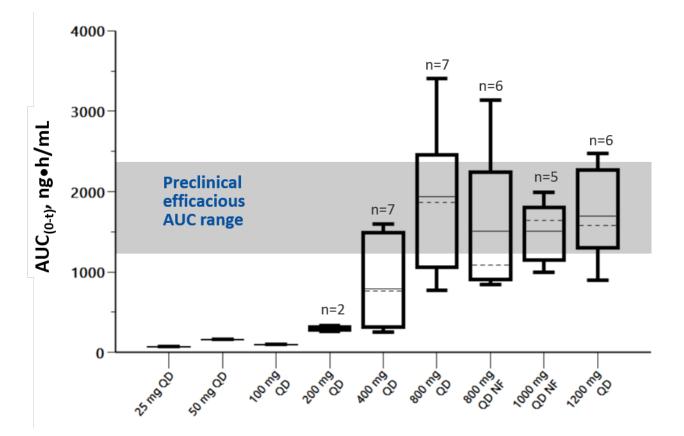
	25–400 mg QD Fasting	800 mg QD (+ FE) Fasting	800 mg QD (+ FE) Non-Fasting	1000 mg QD Non-Fasting	1200 mg QD Fasting
Characteristics	n = 12	n = 21	n = 9	n = 7	n = 6
Age, median (range)	64 (45-75)	65 (39-83)	59 (45-70)	63 (40-80)	57 (47-64)
ECOG PS, 0/1	4/8	3/18	7/2	4/3	1/5
Race (White/Asian/Black/Other)	9/0/1/2	13/2/1/5	7/1/0/1	4/2/0/1	4/2/0/0
# of prior lines of therapy					
1 line	3	4	0	1	0
2 lines	2	3	6	2	2
≥3 lines	7	14	3	4	4
Tumor types					
Lung	4	9	5	0	2
Breast	1	2	0	1	2
CRC (colon, rectal)	3	0	1	1	0
Cholangiocarcinoma (bile, gall bladder)	1	2	0	0	0
Esophageal	1	1	0	0	0
Other ^a	2	7	3	5	2
Mutations					
EGFR Ex 20 ins mutations (MTC-A)	2	3	3	0	0
HER2 Ex 20 alterations (MTCs-B & C)	4	4	1	1	1
Extracellular Allo HER2 mutations (MTCs-D thru G)	5	4	2	2	0
Canonical ErbB mutations (Ex 19 del, L858R) or HER3	0	3	0	0	1
HER2 amplified	1	5	3	2	4
Other mutations	0	2	0	0	0
Missing	0	0	0	2	0



CRC, colorectal cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; FE, food effect.

^aIncludes cervical, cancer of unknown primary (CUP), endometrial, kidney, liver, ovarian, prostate, pancreas, salivary, signet ring cell, urothelial, and uterine.

BDTX-189 Achieved the Predicted Efficacious Exposure at 800 mg QD, the Preliminary RP2D for the QD Regimen



Exposure for Dose Escalating Cohorts in QD Schedule

- Rapidly absorbed, with a short elimination t_{1/2} of 1.3 - 4.4 h, consistent with preclinical projections
- No apparent accumulation or change in exposure at steadystate
- Minimal effect of food on exposure



AUC_(0-t), area under the plasma concentration-time curve; NF, non-fasting. Shaded grey box represents interquartile range, arithmetic mean (solid line), median (dotted line), tails (min/max)

Safety Profile Supports Selection of 800 mg QD as Preliminary RP2D

- No DLTs observed at doses of ≤800 mg QD fasting and non-fasting in the dose escalation cohorts
- 1000 mg QD non-fasting did not exceed MTD (BOIN), but won't be explored further due to toxicity profile
- 1200 mg QD fasting exceeded the MTD

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DLTs and Adverse Events Requiring Dose Reductions in QD Schedule

	25-400 mg QD Fasting	800 mg QD (Fasting and <i>Non-Fasting</i>)	1000 mg QD Non-Fasting	1200 mg QD Fasting						
Patients with DLTs/DLT-evaluable ^a patients (during dose escalation)	0/12	0/12	2/6°	2/5						
DLT adverse events	NA	NA	 Diarrhea (2 G3) Nausea (G1) Increased creatinine (G3) Bilirubin increased (G2) 	•Diarrhea (1 G2; 1 G3) •Vomiting (G2)						
Patients with AEs requiring dose reduction/total patients ^b	0/12	6/30	1/7	2/6						
Dose reduction adverse events	NA	•Diarrhea (1 G2; 1 G3) •Nausea (1 G2; 1 G3) •Fatigue (G2) •ALT increased (G2)	•Diarrhea (G2) •Back pain (G3)	•Diarrhea (1 G2; 1 G3) •Vomiting (G2)						

AE, adverse event; DLT, dose-limiting toxicity; G, grade; MTD, maximum tolerated dose; NA, not applicable.

^aDLT evaluable: patients in dose-escalation phase (excluding food effect) who receive at least 75% of the planned doses during cycle 1 and complete all required safety

evaluations or who have a DLT in cycle 1. ^bIncludes full analysis group, including patients enrolled to food effect lead-in cohort. ^cAs of April 23, 2021.

BDTX-189 is Well Tolerated at Preliminary RP2D of 800 mg QD Gastrointestinal Events Predominate, Skin Disorders are Infrequent

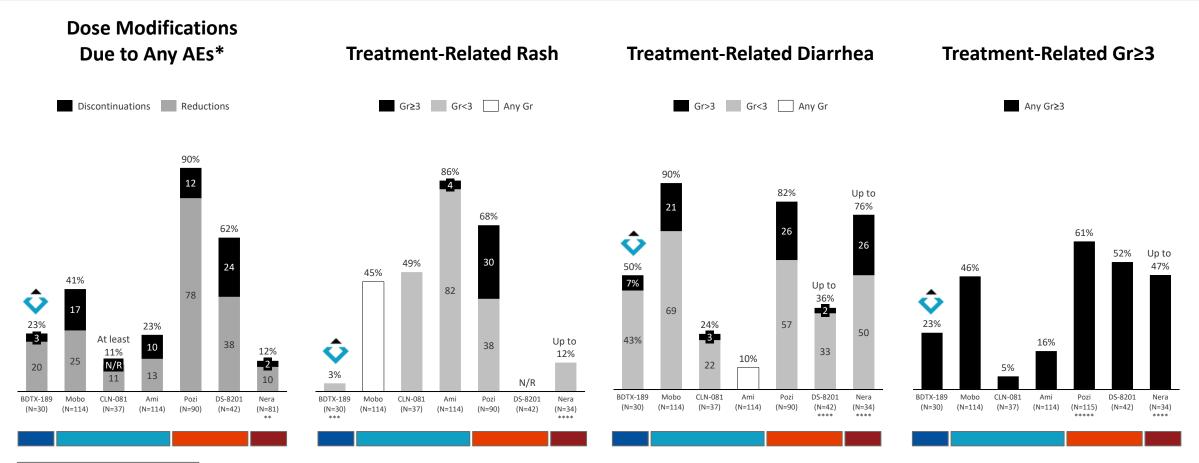
									<u> </u>			
Related Adverse Event (reported in ≥3 patients in any cohort)	25-400 mg QD Fasting n=12		800 mg QD + food-effect Fasting n=21		800 mg QD + food-effect <i>Non-Fasting</i> n=9		800 mg QD + food-effect Fasting & <i>Non-Fasting</i> n=30		1000 mg QD <i>Non-Fasting</i> n=7 ^b		1200 mg QD Fasting n=6	
	Any Grade %	Grade 3 %	Any Grade %	Grade 3 %	Any Grade %	Grade 3 %	Any Grade %	Grade 3 %	Any Grade %	Grade 3 %	Any Grade %	Grade 3 %
Any Related AE	50	0	95	24	89	22	93	23	100	43	83	50
Diarrhea	25	0	52	10	44	0	50	7	86	29	50	33
Nausea	17	0	48	5	56	11	50	7	43	0	33	0
Vomiting	8	0	29	5	33	0	30	3	29	0	67	0
ALT increased	8	0	24	10	11	11	20	10	29	0	17	0
AST increased	8	0	14	5	11	0	13	3	14	0	17	0
Blood bilirubin increased	0	0	0	0	0	0	0	0	43	0	0	0
Fatigue	8	0	19	0	22	0	20	0	57	14	17	0
Skin disorders ^a	8	0	14	0	11	0	13	0	0	0	17	0
Decreased appetite	8	0	14	0	0	0	10	0	14	0	0	0

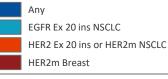
Most Common Treatment-Related Adverse Events

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^aInclude following AE terms: rash, dermatitis acneiform, rash morbilliform, dry skin, urticaria. ^bData incomplete as of cutoff date. Note: No grade 4 or 5 events reported.

Favorable Safety Profile for BDTX-189 Among EGFR/HER2 Agents





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x 20 ins or HER2m NSCLC Breast Sources: BDTX-189: ASCO 2021 for N=30 in MasterKey-01 Do

design and patient population. No head-to-head clinical trials have been conducted. * "Dose reductions" and "discontinuations" not always mutually exclusive, may be double-counted; **Dose modification data for N=34 monotherapy patients not reported; ***4/30 = 13% patients with any "skin disorder" ("rash", "dry skin", and/or "dermatitis acneiform") for BDTX-189, all Gr<3; ***TRAEs not reported, only TEAEs reported; ****Data for "any treatment-related Gr>3 AEs" not reported

ami, amivantamab; NR, not reported; mobo, mobocertinib; pozi, poziotinib; nera, neratinib. Note: These data are derived from different clinical trials at different points in time, with differences in trial

for poziotinib's HE20 NSCLC Cohort; as a proxy, data taken from EGFR Ex 20 ins NSCLC Cohort of ZENITH20 (AACR 2020)

Sources: BDTX-189: ASCO 2021 for N=30 in MasterKey-01 Dose Escalation treated at 800mg QD; mobocertinib: WCLC 2020 for N=114 PPP (post-platinum patients) EGFR Ex 20 ins mut. NSCLC; CLN-081: Dec 2020 S-1 for N=37 EGFR Ex 20 ins mut. NSCLC in Dose Escalation; amivantamab: WCLC 2020 for N=114 pre-treated EGFR Ex 20 ins. mut. NSCLC; poziotinib: ESMO 2020 for N=90 pre-treated HER2 Ex 20 ins mut. NSCLC in ZENITH20 Cohort 2, unless otherwise noted; DS-8201: 2020 ASCO for N=42 HER2mut. NSCLC in DESTINY-Lung01; neratinib: Smyth 2020 for N=81 HER2mut. Breast Cancer treated as monotherapy (N=34) or in combo with fulvestrant (N=47)

MasterKey-01 Dose Escalation in Diverse Array of Solid Tumors & MTCs: Evidence of Anti-Cancer Activity, Including Confirmed PRs

	Matrix to Describe Anti-Cancer Activity for Tumor Types v. Mutation Types												
	Cluster Type	Lung	Breast	Ovary	CRC	Uterine/ Cervical	Biliary Tract	Esopha- geal	Salivary Gland	Other	МТС	Description	
PR	MTC-A			\diamond							MTC-A	EGFR Ex 20 ins	
				·	•						MTC-B	HER2 Ex 20 ins	
SD	MTC-B				0						MTC-C	HER2 Ex 20 missense	
	MTC-C				\bigtriangleup			ightarrow			MTC-E	HER2 KD β-sheet missense	
PD	MTC-D				Δ	\diamond	0				MTC-F	HER2 KD α -loop missense	
						•	•				MTC-G	HER2 JMD missense	
	MTC-E										MTC-D	HER2 ECD missense	
NE	MTC-F									(1)			
🔿 400 mg QD	MTC-G	\diamond											
☐ 800 mg QD ♦ 800 mg QD NF	HER2-Amp	V (1)	▽ (1)	$\mathbf{\nabla}$	\diamond	(2)			•				
	L858R												
	HER3 Mut												
	Other												

AMP, amplified; NE, nonevaluable; PD, progressive disease; PR, partial response; and SD, stable disease.

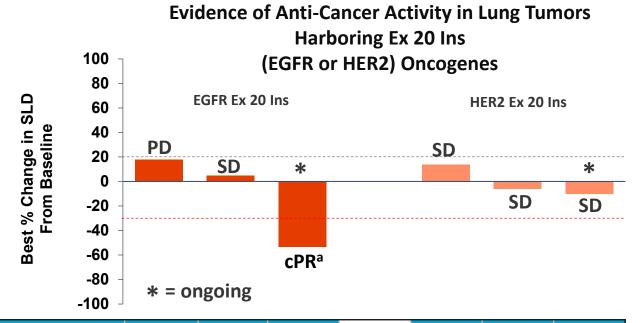
Responses are not necessarily confirmed. SD observed at least 30 days after first dose of study drug and includes 2 patients with non-measurable disease at baseline with non-CR/non-PD assessment. Number in parentheses represent number of patients on treatment, but yet to have a post-baseline assessment.

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NE = patients who discontinued treatment prior to first post-baseline assessment or who are otherwise not evaluable per RECIST criteria.

Two patients excluded due to missing mutation information. Tumor category of "other" includes kidney (n=1), pancreas (n=1), prostate (n=1), CUP (n=1), and urinary bladder (n=1).

Early PoC Achieved for BDTX-189 in NSCLC EGFR Ex 20 Ins Population Despite Prior Anti-EGFR/HER2 Therapy



Cluster Type	MTC-A	MTC-A	MTC-A		MTC-B	MTC-B	MTC-B
Dosing	800 mg QD	800 mg QD	800 mg QD NF		800 mg QD	800 mg QD	800 mg QD NF
Prior lines of therapy	1	2	2		7	1	2
Prior EGFR/HER2 TKI therapy	Osi		Pozi		Nera		Afa
Prior EGFR/HER2 mAb therapy		Ami					
Platinum-based therapy		Carbo	Carbo		Carbo	Carbo	Carbo
I/O therapy		Pembro			Pembro	Pembro	Pembro
Waterfall plot reflects data for	or a subset of p	atients from th	ne overall wate	rfall plot, repre	senting patien	ts with NSCLC e	expressing

EGFR or HER2 Ex 20 ins mutations and treated at doses of ≥800 mg QD.

Anti-cancer activity observed at ≥800mg QD among lung cancer patients expressing EGFR/HER2 Ex 20 ins mutations

• EGFR Ex 20 ins

- 3 evaluable by RECIST (1 cPR, 1 SD, 1 PD)
- All patients received prior ErbB targeted therapy

• HER2 Ex 20 ins

- 3 evaluable by RECIST (3 SD)
- 2/3 received prior ErbB targeted therapy

afa, afatinib; ami, amivantamab; carbo, carboplatin; cPR, confirmed partial response; I/O, immuno-oncology; mAb, monoclonal antibody; nera, neratinib; NF, non-fasting; osi, osimertinib; PD, progressive disease; pembro, pembrolizumab; pozi, poziotinib; SD, stable disease; SLD, sum of longest diameters. Three patients without SLD data excluded from plot.

^aConfirmed after the data cut-off.

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NSCLC EGFR Ex 20 Ins: 51-year-old Woman with 53% Tumor Reduction and Improved Diffuse Lung Disease (Confirmed PR^a, on study 13+ wks)

Genomic alteration: EGFR Ex 20 ins (SVD)

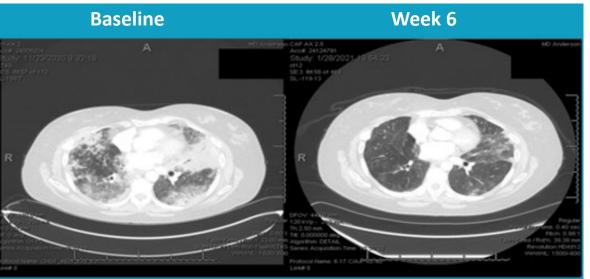
Prior therapy:

- Poziotinib with PR and toxicity followed by PD
- Carboplatin and pemetrexed

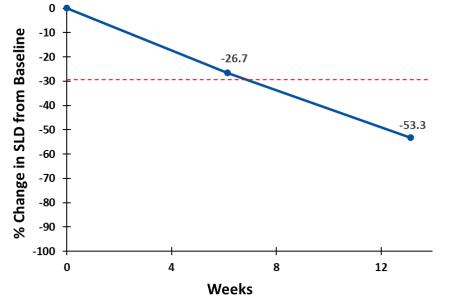
Treatment regimen: on study

- BDTX-189, 800 mg QD NF
- Controlled, low-grade diarrhea
- Off oxygen starting at ~9 weeks

Radiologic Scans

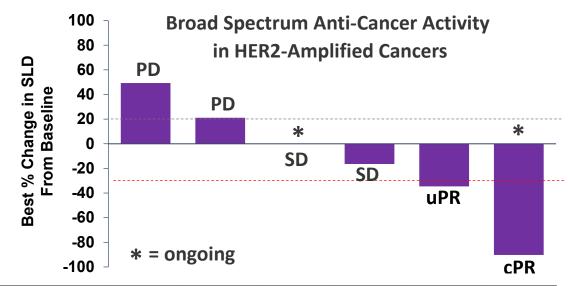


Target Lesions Over Time





Early PoC Achieved for BDTX-189 in Solid Tumors with HER2-Amp



800 mg	1200 mg	000 mg	4000	1000	
QD	QD	800 mg QD	1200 mg QD	1200 mg QD	800 mg QD
1	3	3	3	6	4
				Afa, Osi	
Tras	Tras Pertuz		Marget		
Oxali		Oxali	Carbo	Cis Carbo	Carbo, Oxali
	1 Tras Oxali	1 3 Tras Tras Pertuz Oxali	1 3 3 Tras Tras Image: Constraint of the second seco	133133Tras PertuzMargetOxaliOxaliCarbo	1 3 3 3 1 3 3 6 Image: Second stress of the sec

Clinical activity observed at ≥800mg QD among broad group of HER2-Amp expressing patients

- 6 evaluable patients by RECIST (1 cPR / 1 uPR / 2 SD / 2 PD)
- 4/6 patients received prior EGFR/HER2-directed therapy



cis, cisplatin; marget, margetuximab; oxali, oxaliplatin; pertuz, pertuzumab; tras, trastuzumab; uPR, unconfirmed partial response. Eight patients without SLD data excluded from plot. Cancer of Unknown Primary^a (HER2 Amplification): 73-year-old Woman with Deep and Durable Confirmed PR (on study 7+ mos)

Genomic alteration: HER2-amplification

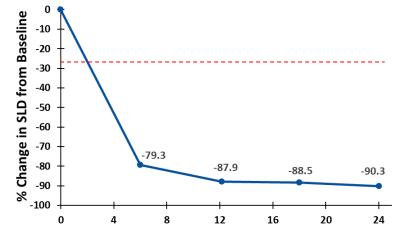
Prior therapy:

Carbo/taxol, FOLFIRINOX, Everolimus

Treatment regimen: on study

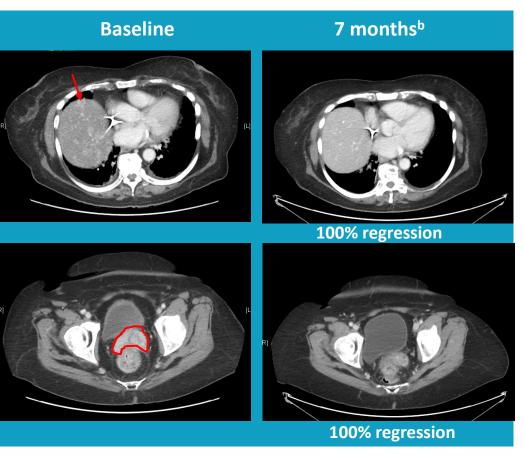
- BDTX-189 800 mg daily (fasting)
- No ongoing related toxicity, had brief episodes of G1 diarrhea

Target Lesions Over Time



Weeks

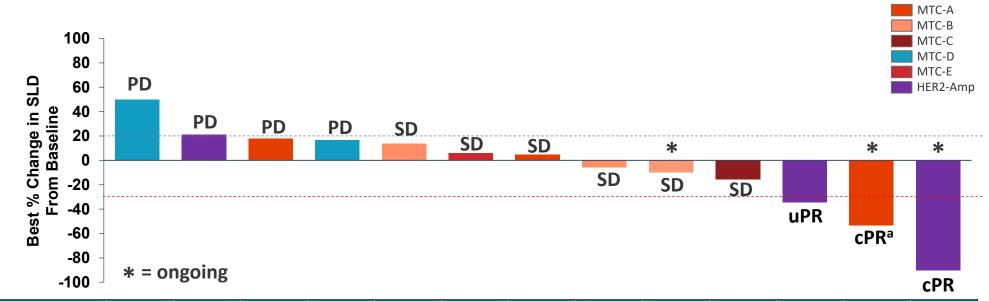
Radiologic Scans





^aCUP presumed by the investigator of this patient to be of breast cancer, pancreato-biliary or upper gastrointestinal origin. ^bScans from April 23, 2021.

Anti-Cancer Activity in Phase 1 in Tumor/Mutation Pairs Slated for Phase 2



Dose, mg QD	800 NF	1200	800	800	800	800	800	800	800 NF	800	1200	800 NF	800
Tumor Origin	Cervix	Breast	Lung	Lung	Lung	Breast	Lung	Lung	Lung	Breast	Lung ^b	Lung	CUP
Prior Lines of Therapy	2	3	1	11	7	4	2	1	2	6	6	2	4
Prior EGFR/HER2 TKI Therapy	Nera		Osi	Pyro, Nera	Nera				Afa	Nera	Afa, Osi	Pozi	
Prior EGFR/HER2 mAb Therapy		Tras Pertuz		Tras ADC-ZW49 Fam-tras			Ami						
Prior Platinum-based Therapy	Carbo			Carbo, Cis	Carbo		Carbo	Carbo	Carbo		Cis, Carbo	Carbo	Carbo, Oxali
Prior I/O Therapy				lpi, Niv, Atezo	Pembro		Pembro	Pembro	Pembro				

Waterfall plot includes patients treated at 800 mg QD and above whose tumor/mutation pairs are slated for Cohorts 1-4 in MasterKey-01 Phase 2, together with those patients with HER2 amplification in select tumor types demonstrated to be sensitive to other HER2 inhibitors (e.g., NSCLC, breast cancer, gastric cancer, endometrial [where HER2-P95 is expressed], CRC, and biliary). Breast, gastric, CRC, NSCLC, biliary, and endometrial tumor types were chosen based on analysis of reported clinical data across multiple TKIs, mAbs, and ADCs in *HER2^{amp}/HER2+* solid tumors; 3 representative sources.¹⁻⁵

BLACK DIAMOND THERAPEUTICS atezo, atezolizumab; fam-tras, fam-trastuzumab; ipi, ipilimumab; niv, nivolumab; pyro, pyrotinib.

12 patients without SLD data excluded from plot. ^aConfirmed after the data cut-off. ^bCo-occurring EGFR Ex 19 del mutation.

1. Waters N, et al. ASCO 2021, Poster #3097. 2. Yuan Y, et al. Clin Cancer Res. 2016;22(17):4291-4301. 3. Meric-Bernstam F, et al. ASCO GI 2021, Abstract #299. 4. Tsurutani J, et

al. Cancer Discov. 2020;10(5):688-701. 5. Iqbal S, et al. Ann Oncol. 2011;22(12):2610-2615.



Summary



Emerging Clinical Data Support Ongoing Development of BDTX-189 as an Active and Differentiated EGFR/HER2 Inhibitor

РК

Clinical exposure in line with preclinical predictions

• 800 mg QD non-fasting selected as preliminary RP2D for QD regimen

Favorable safety profile

- Lower rates of rash, diarrhea, Grade 3 toxicities versus other EGFR/HER2 TKIs
- Adverse events were gastrointestinal in nature and generally medically manageable; skin disorders were infrequent



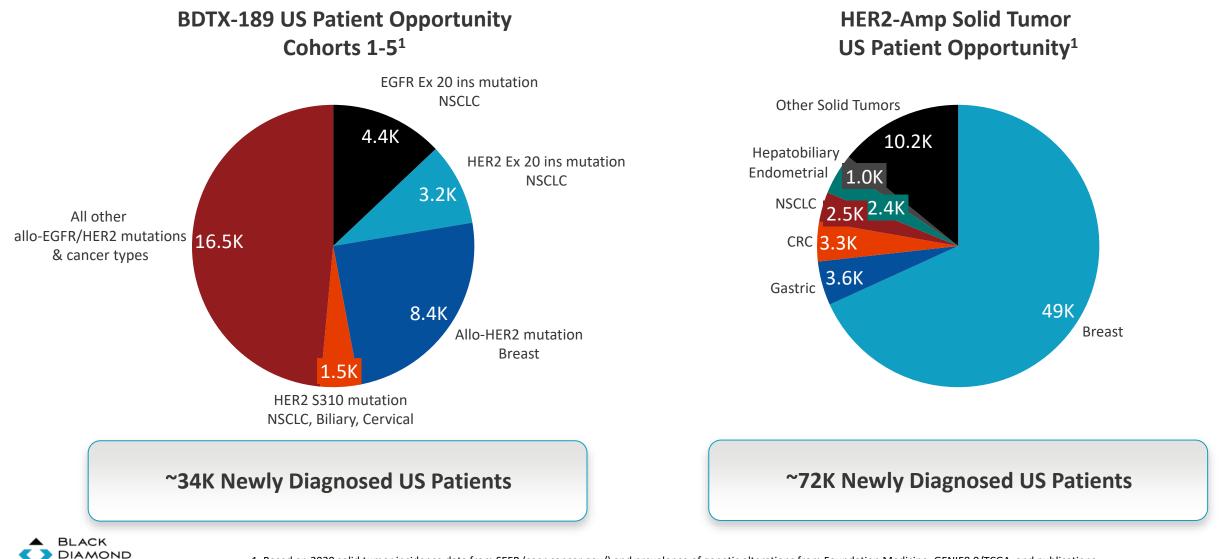
Safety Profile

Anti-cancer activity observed

- PR/SDs among EGFR/HER2 Ex 20 ins in patients pre-treated with EGFR/HER2-directed TKIs
- Deep and durable confirmed response in setting of HER2-Amp



BDTX-189 Has a Significant Market Opportunity as an Allosteric EGFR/HER2 Inhibitor as Well as in HER2-Amp Patients



1. Based on 2020 solid tumor incidence data from SEER (seer.cancer.gov/) and prevalence of genetic alterations from Foundation Medicine, GENIE8.0/TCGA, and publications

HERAPEUTICS

Pivotal Phase 2 MasterKey-01 Study in Patients with EGFR/HER2 Mutations On Track to Begin Enrollment in 2H 2021

Next steps in advancing BDTX-189 through the clinic

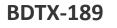
- Complete evaluation of BID dosing regimen
- Enroll and dose patients in Phase 1 safety expansion cohort
- Initiate Phase 2 portion of MasterKey-01 study in 2H 2021

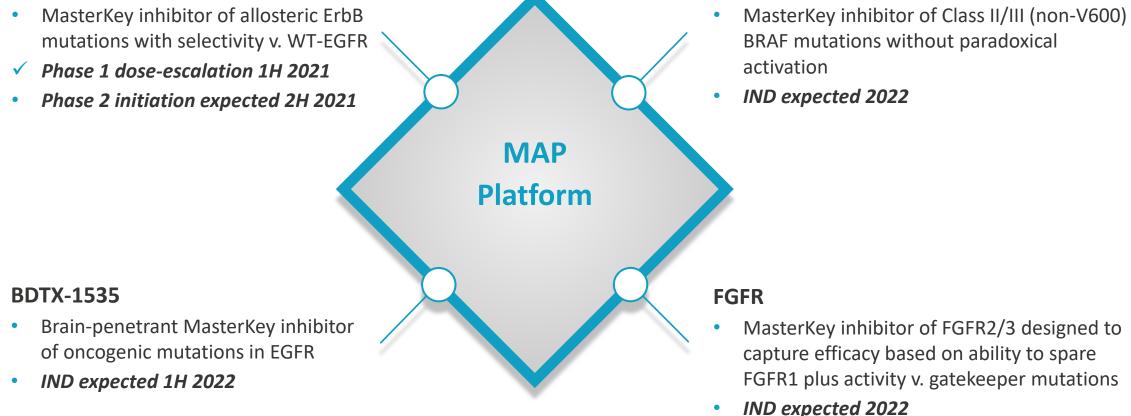
Learnings from on-going Phase 1 study inform our adaptation of pivotal Phase 2 study

- Focus on TKI naïve patients and patients without resistance mutations
- Focus on select tumor type/MTC pairs in pivotal Phase 2 study
- Explore opportunity in solid tumors with HER2-Amp



Initial BDTX-189 Clinical Data Provides Validation for Black Diamond's Proprietary MAP Platform and MasterKey Approach





BRAF



Thank You

