The UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 4, 2024

BLACK DIAMOND THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39200**	**81-4254660**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

One Main Street, 14th Floor **Cambridge, Massachusetts** (Address of Principal Executive Offices)	**02141** (Zip Code)

(617) 252-0848
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	BDTX	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On January 4, 2024, Black Diamond Therapeutics, Inc. (the "Company") issued a press release titled, "*Black Diamond Therapeutics Announces Corporate Update and Expected 2024 Milestones*" and updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the press release and a copy of the corporate presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on the Form 8-K.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Black Diamond Therapeutics, Inc., dated January 4, 2024.
99.2	Corporate Presentation of Black Diamond Therapeutics, Inc. as of January 4, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BLACK DIAMOND THERAPEUTICS, INC.

Date: January 4, 2024

By: /s/ Brent Hatzis-Schoch
Name: Brent Hatzis-Schoch
Title: Chief Operating Officer and General Counsel

Exhibit 99.1

Black Diamond Therapeutics Announces Corporate Update and Expected 2024 Milestones

FDA feedback on BDTX-1535 enables initiation of Phase 2 cohort in first-line treatment of non-classical EGFR mutant NSCLC

Fast Track Designation granted for BDTX-1535 as second-line treatment for EGFR mutant/C797S NSCLC

BDTX-1535 Phase 2 results for 2L/3L patients with EGFR mutant NSCLC expected Q3 2024

BDTX-1535 Phase 1 clinical trial results and "window of opportunity" data in patients with EGFR mutant GBM expected to be presented at a medical meeting in Q2 2024

BDTX-4933 Phase 1 results in patients with KRAS mutant NSCLC expected Q4 2024

Existing cash, cash equivalents and investments expected to be sufficient to fund milestone achievements and operations into Q2 2025

CAMBRIDGE, Mass., January 4, 2024 (GLOBE NEWSWIRE) – Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a clinical-stage oncology company developing MasterKey therapies that target families of oncogenic mutations in patients with genetically defined cancers, today provided a corporate update outlining clinical development plans and anticipated corporate milestones for 2024.

"We made significant progress in 2023 and sharpened our focus on our clinical programs: BDTX-1535 in both EGFR mutant NSCLC and GBM, and BDTX-4933 in KRAS mutant NSCLC," said Mark Velleca, M.D., Ph.D., Chief Executive Officer of Black Diamond Therapeutics. "In 2024, we anticipate key readouts from each of these programs, including Phase 2 data from BDTX-1535 in NSCLC. Moreover, recent FDA feedback enables the enrollment of first-line NSCLC patients into the Phase 2 trial, reflecting the potential of BDTX-1535 to benefit patients in earlier lines of therapy. Due to disciplined spend, we expect our cash to be sufficient for this year's milestones and to extend into the second quarter of 2025."

Clinical Program Updates/Anticipated 2024 Milestones

BDTX-1535 in patients with Epidermal Growth Factor Receptor (EGFR) mutant Non-Small Cell Lung Cancer (NSCLC)

- Dose escalation results were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2023. Phase 2 data in second/third-line patients with EFGR mutant NSCLC are expected in the third quarter of 2024. The Company intends to discuss Phase 2 results with the U.S. Food and Drug Administration (FDA) to finalize a pivotal clinical trial design.
- BDTX-1535 received Fast Track Designation for the treatment of patients with EGFR mutant C797S-positive NSCLC whose disease has progressed on/after a third-generation EGFR tyrosine kinase inhibitor (TKI).
- Following End of Phase 1 feedback received from the FDA in the fourth quarter of 2023, a Phase 2 cohort in first-line patients with non-classical EGFR mutant NSCLC is being initiated.
- The Company is also exploring the potential development of BDTX-1535 in first-line patients who are post-osimertinib adjuvant treatment.

BDTX-1535 in patients with EGFR mutant Glioblastoma (GBM)

- Following release of top-line Phase 1 data in December 2023, presentation of Phase 1 trial results is anticipated at a medical meeting in the second quarter of 2024.
- Enrollment is ongoing in a "window of opportunity" trial sponsored by the Ivy Brain Tumor Center in patients with recurrent glioma who are undergoing a planned resection. Results from this trial are expected to be presented at a medical meeting in the second quarter of 2024.
- The Company expects that results from the dose escalation and "window of opportunity" trials will inform the next steps in the GBM development program, including a potential randomized trial in the first-line setting.

BDTX-4933 in patients with KRAS mutant NSCLC

- BDTX-4933 was designed as a "RAF/RAS clamp" to target the activated RAF conformation in the context of either RAF or RAS mutations, a mechanism distinct from earlier generation RAF inhibitors.
- Enrollment in a Phase 1 trial began in September 2023 in patients with KRAS mutant NSCLC. Results from this trial are anticipated in the fourth quarter of 2024.

About BDTX-1535

BDTX-1535 is an oral, brain-penetrant MasterKey inhibitor of oncogenic epidermal growth factor receptor (EGFR) mutations in non-small cell lung cancer (NSCLC), including classical driver mutations, families of non-classical driver mutations (e.g., L747P, L718Q), acquired resistance C797S mutation, and complex mutations. BDTX-1535 is a fourth-generation tyrosine kinase inhibitor (TKI) that potently inhibits, based on preclinical data, more than 50 oncogenic EGFR mutations expressed across a diverse group of patients with NSCLC in multiple lines of therapy. Based on preclinical data, BDTX-1535 also inhibits EGFR extracellular domain mutations and alterations commonly expressed in glioblastoma (GBM) and avoids paradoxical activation observed with earlier generation reversible TKIs. A "window of opportunity" trial of BDTX-1535 in patients with GBM is ongoing (NCT06072586) and a Phase 2 trial is currently ongoing in patients with NSCLC (NCT05256290).

About BDTX-4933

BDTX-4933 is an oral, brain-penetrant RAF MasterKey inhibitor designed to target oncogenic alterations in KRAS, NRAS and BRAF, while also avoiding paradoxical activation. In preclinical studies, BDTX-4933 has demonstrated a potential best-in-class profile, showing potent target engagement, inhibition of MAPK signaling and strong anti-tumor activity/tumor regression across tumor models driven by either KRAS, NRAS or BRAF mutations. BDTX-4933 also exhibits high central nervous system (CNS) exposure leading to dose-dependent tumor growth inhibition and a survival benefit in an intracranial tumor model harboring oncogenic BRAF mutation. The ongoing BDTX-4933 Phase 1 clinical trial is currently in dose escalation with emphasis on KRAS mutant NSCLC patients (NCT05786924).

About Black Diamond Therapeutics

Black Diamond Therapeutics is a clinical-stage oncology company focused on the development of MasterKey therapies that address families of oncogenic mutations in clinically validated targets. The Company's MasterKey therapies are designed to address broad genetically defined patient populations, overcome resistance, minimize wild-type mediated toxicities, and be brain penetrant to treat CNS disease. The Company is advancing two clinical-stage programs: BDTX-1535, a brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR mutant NSCLC and GBM, and BDTX-4933, a brain-penetrant RAF MasterKey inhibitor targeting KRAS, NRAS and BRAF alterations in solid tumors. For more information, please visit www.blackdiamondtherapeutics.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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: the continued development and advancement of BDTX-1535 and BDTX-4933, including the ongoing clinical trials and the timing of clinical updates for BDTX-1535 in patients with NSCLC and in patients with recurrent GBM, and for Phase 1 clinical trial results for BDTX-4933, the potential of BDTX-1535 to benefit patients with NSCLC in earlier lines of therapy, potential future development plans for BDTX-1535 in NSCLC and GBM, including in first-line settings, and the Company's expected cash runway. Any forward-looking statements in this statement are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include those risks and uncertainties set forth in its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the United States Securities and Exchange Commission and in its subsequent filings filed with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contacts

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For Media:
media@bdtx.com

Exhibit 99.2


Black Diamond Therapeutics, Inc.
Developing MasterKey Therapies to Defeat Cancer Resistance
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Forward-Looking Statements

Statements contained in this presentation regarding matters that are not historical facts are "fo
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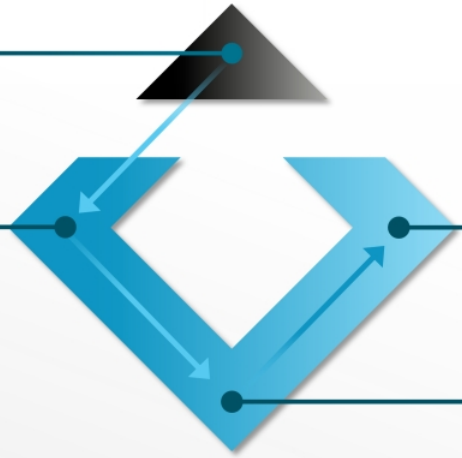
Company undertakes no obligation to update such statements to reflect events that occur or circumstan
after the date on which they were made.

Cancer is a Complex and Ever-Evolving Disease

Current targeted therapies were designed against a **limited subset of oncogenic mutations**

Increasing adoption of liquid biopsies reveals a **broader set of oncogenic mutations**



We are Developing Master Therapies to Defeat Cance

Our oral therapies are designed so that **patie have the opportunity longer, healthier, activ**

MasterKey approach a **provide one solution f mutations and expand addressable patient p**

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Black Diamond Therapeutics At-a-Glance

Clinical-stage company **advancing MasterKey therapies** designed to expand the addressable patient population

Experienced team with deep understanding of cancer biology and oncology drug development

Pipeline
penetrar
candidat
targetin
oncogen

Lead asset BDTX-1535 shows **durable clinical responses in NSCLC**, with additional opportunity in GBM

Multiple clinical catalysts across the pipeline in 2024

Strong bal
with runw
2025; end
with $144.

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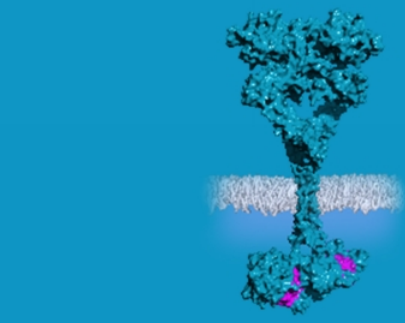
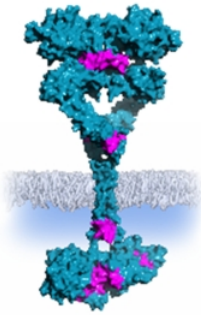
MasterKey: One Solution for Many Mutations

Traditional Approach:
Targeting single mutations in individual tumor types



Limited addressable patient population

Black Diamond Approach:
Targeting families of oncogenic mut



Expanded addressable patient popula

Potent against broad mutation families (including drug resistance mutations)

Brain penetrant to treat CNS disease

Selec we

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Advancing Wholly Owned Pipeline Across Multiple Oncology Indica

Target	Drug Candidate	Indication	Pre-clinical	Phase 1	Phase 2
EGFR	BDTX-1535	NSCLC	Phase 2 enrolling with data expected Q3 2024		
		GBM	Phase 1 and "window of opportunity" data expected Q2 2024		
RAF	BDTX-4933	KRAS mutant NSCLC RAF/RAS mutant solid tumors	Phase 1 enrolling data expected Q4 2024		
FGFR2/3	BDTX-4876	Achondroplasia or solid tumors	Partnering candidate		
Undisclosed	Undisclosed	Multiple Solid tumors	Partnering candidate		

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BDTX-1535: EGFR MasterKey Inhibitor with Clinical Proof-of-Concep

- **MasterKey** — Targets EGFR classical drivers, non-classical and resistance mutations
- **Spares WT-EGFR** — Selective for mutations versus WT-EGFR to deliver favorable safety profile
- **Covalent** — Oral small molecule with covalent MOA for and durability
- **Brain Penetrant** — Designed to treat CNS tumors and brain metastases
- **Clinical PoC** — Clinical proof-of-concept in NSCLC achieved promising activity demonstrated in GBM

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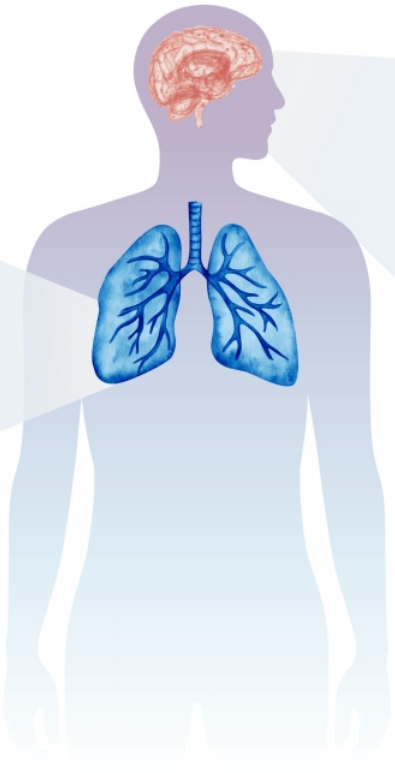
WT=Wild-Type; MOA=mechanism of action; CNS=Central Nervous System; NSCLC=Non-Small Cell Lung Cancer

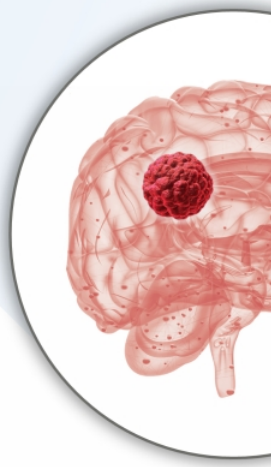
BDTX-1535: Clinical Proof-of-Concept Achieved in NSCLC, Promising

EGFR Mutant Non-Small Cell Lung Cancer (NSCLC)

Clinical proof-of-concept achieved



EGFR Alt Glioblastom



Phase 1 topline data promising a

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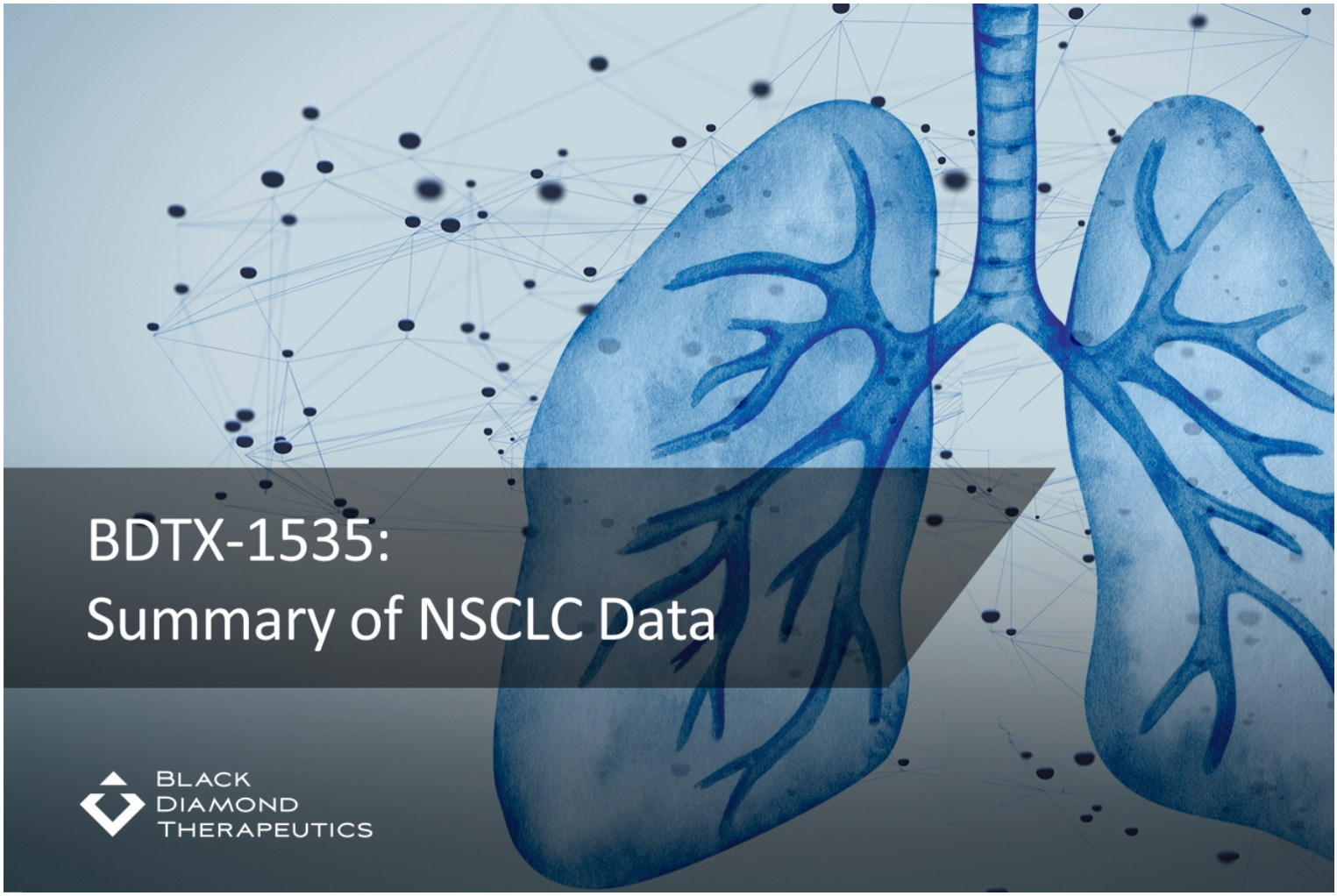
BDTX-1535:
Summary of NSCLC Data
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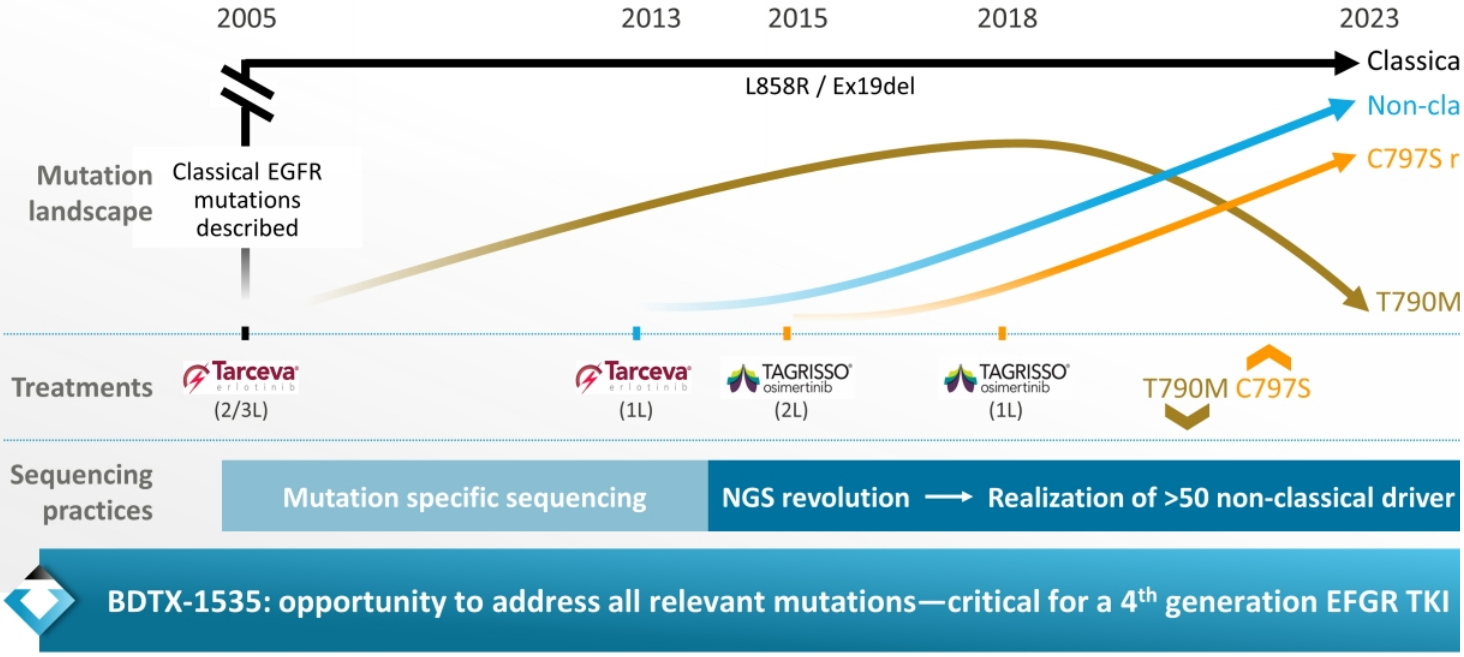
BDTX-1535 Addresses the Most Clinically Relevant EGFR Mutations in NSCLC: Classical / Non-Classical Drivers and C797S Resistance

Evolution of the EGFR mutation landscape over the past 20 years



BDTX-1535: opportunity to address all relevant mutations—critical for a 4th generation EFGR TKI

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Real-World Data Confirms ~90% of Patients Receive 1L Osimertinib Emerging Resistance Mutations Consistent with BDTX Phase 1 Expe

AACR

Real-world treatment patterns and outcomes in patients with advanced non-small cell lung cancer (NSCLC) post-EGFR tyrosine kinase inhibitor (TKI) therapy

Results shared at AACR 2023 revealed the ***1L EGFR TKI treatment*** **that** *428 patients received*[1]

90%	7%	3%
Osimertinib	Afatinib	Erlotinib

Distribution of mutations in NSCLC patients reflects mu BDTX Phase 1

Liquid Biopsies[2]

BDTX-1535 has potential to address emerging resistance mutations that are supported by real-wo

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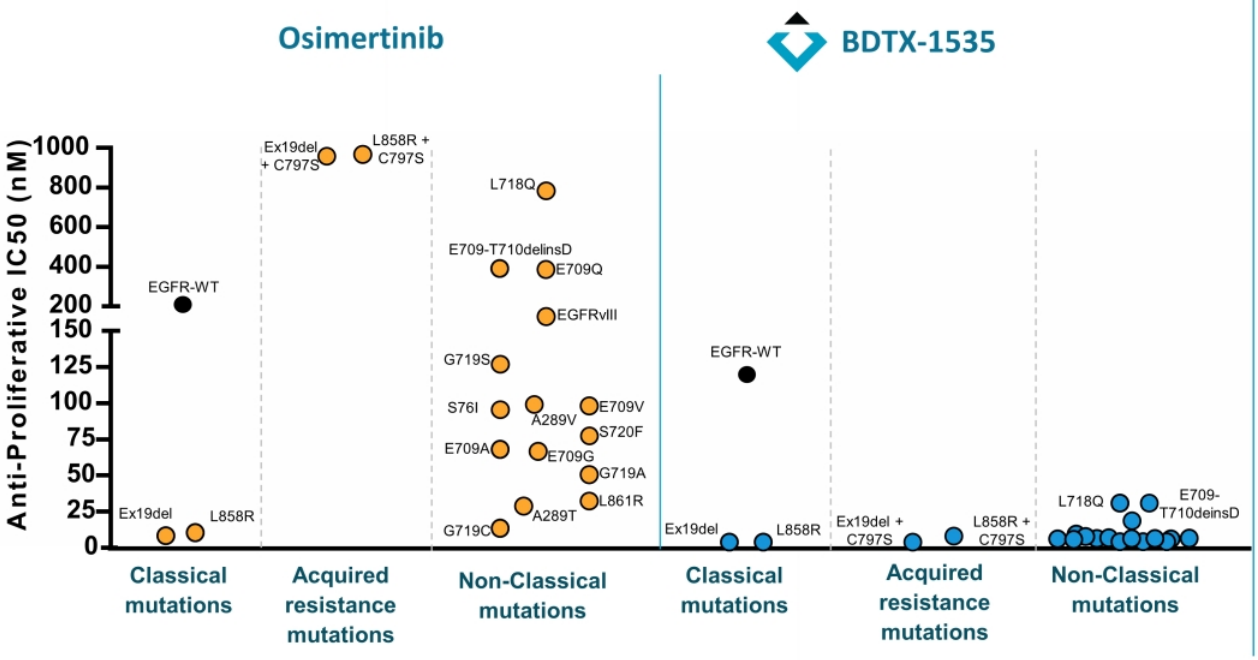
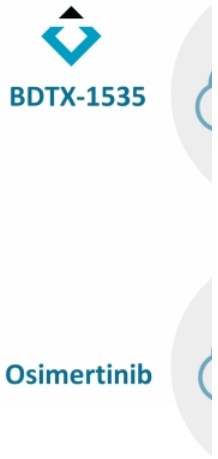
1. Real world treatment patterns and outcomes in patients with advanced non-small cell lung cancer (NSCLC) post-EGFR tyrosine kinase inhibitor (TKI) therapy Source: AACR 2023 Poster
2. Adapted from Rotow, JK., et al., Journal of Thoracic Oncology, 2023.

BDTX-1535: Potent Preclinical Inhibition of Classical and Non-Classi
Mutations and C797S Resistance vs Osimertinib; Superior Brain Exp

BDTX-1535 potently targets >50 EGFR oncogenic mutations



BDTX-1535 Exh
Brain Exposu



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Data adapted from AACR 2023 Poster; non-classical driver formerly referred to as intrinsic driver
EGFR-WT reflects anti-proliferative activity in H292 WT-EGFR expressing cell line. Data for all mutations derived from Ba/F3 transformants.
Kp_{uu} Partition Coefficient Calculation: $AUC_{brain:blood}$ x plasma Fu/brain Fu

BDTX-1535 Phase 1 Dose Escalation: Summary

Mutation Matched Phase 1 Study Inclusion Criteria

Recurrent NSCLC Cohort			Recurrent GBM Cohort	
EGFR mutations at the time of progression: – Non-classical driver, OR – Acquired resistance C797S	Progression after EGFR TKI	Exclusion of EGFR T790M, Ex20ins, KRAS mutations, cMET amplification	EGFR alterations at resection/diagnosis	Wild-type isocitrate dehydrogenase (IDH)

Dose Escalation Completed: 15 mg QD to 400 mg QD

- **Primary objective:** PK and safety
- **Secondary objective:** Anti-tumor activity

- Target coverage and clinical activity at ≥ 100 mg, MTD at 300 mg
- Phase 2 in 2L/3L NSCLC enrolling at 100 mg QD and 200 mg QD

NSCLC Key Data

- Once-daily dosi… sufficient exposu… EGFR mutations
- Manageable EGF… profile at 200 m… osimertinib)
- Radiographic res… durable anti-tum… across multiple … families
- ctDNA reduction… of mutant alleles… predictive of clin…
- Phase 2 data exp…

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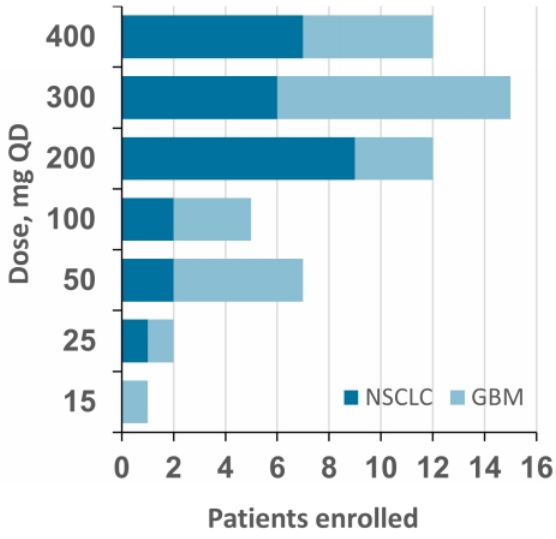
1. Thompson, JC., et al., British Journal of Cancer, 2023.

BDTX-1535-101 Phase 1 Dose Escalation Patient Characteristics

Patient Enrollment



NSCLC	
Patient Characteristics	**All Treated**
Age, mean (range)	64 (46, 81)
Female	18 (67%)
ECOG PS	
0	7 (26%)
1	20 (74%)
Prior lines of therapies	
median (min, max)	2 (1, 9)
Prior anti-cancer agents	
EGFR TKI	27 (100%)
Chemo	19 (70%)
Anti-angiogenic or CPIs	11 (41%)
HER3-ADC	2 (7%)
Prior EGFR TKIs	
Osimertinib	23 (85%)
1st line treatment	17 (74%)
Erlotinib or gefitinib	9 (33%)
Afatinib	3 (11%)
Dacomitinib	1 (4%)
BLU-701	1 (4%)

GBM[1]
Age, mean (range)
Female
Karnofsky PS
90
80
70
60
Prior lines of therapies
median (min, max)
Prior anti-cancer agents
TMZ
Anti-angiogenic or CPIs
Chemo

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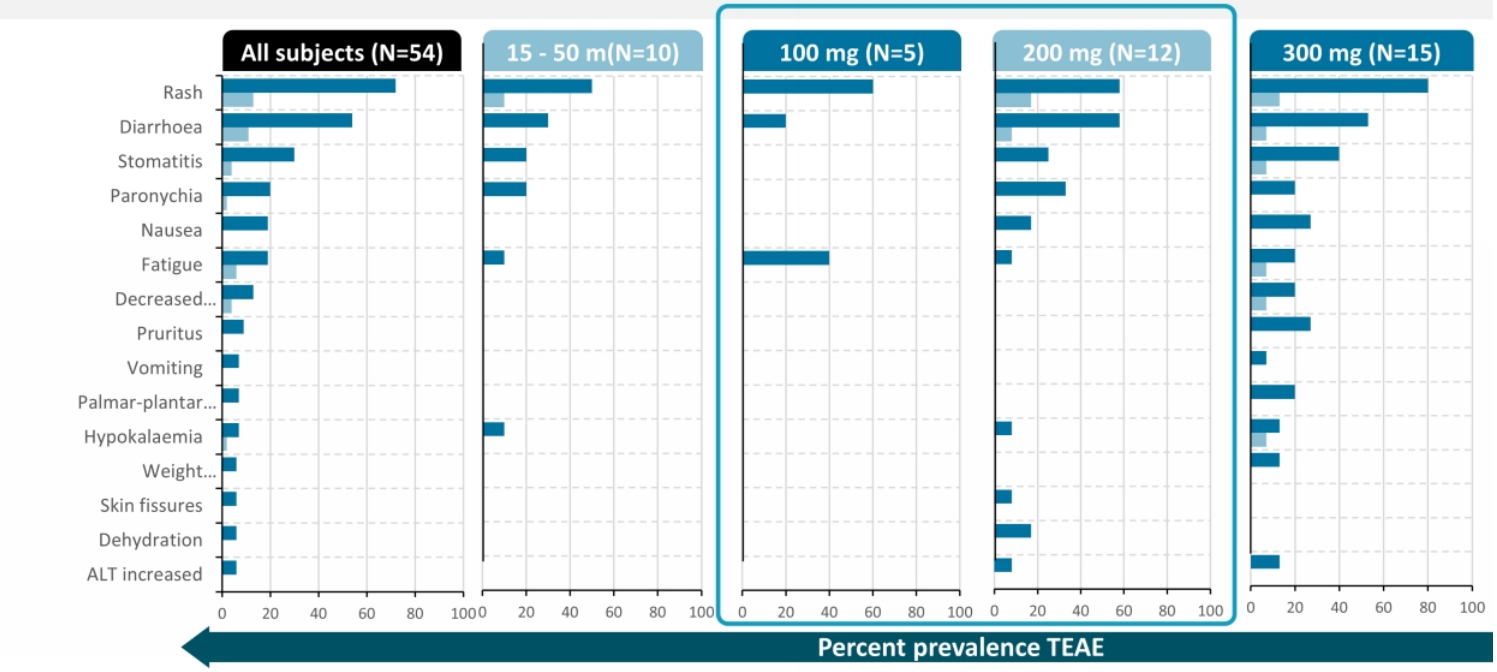
Data from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023; [1]GBM updated November 2023

Dose Escalation Treatment Emergent Adverse Events Related to BDTX-1535: Well-Tolerated Profile



All grade events
Grade 3 events

No Grade 4 AEs were reported	• No dose limiting toxicity (DLTs) were observed at ≤200 mg • Maximum tolerated dose is 300mg QD	Dose reductions: 1 (8%) pt at 200 mg QD; 5 (33%) pts at 300 mg QD

Treatment occurring
All patient prophylaxi
Rash grou dermatitis

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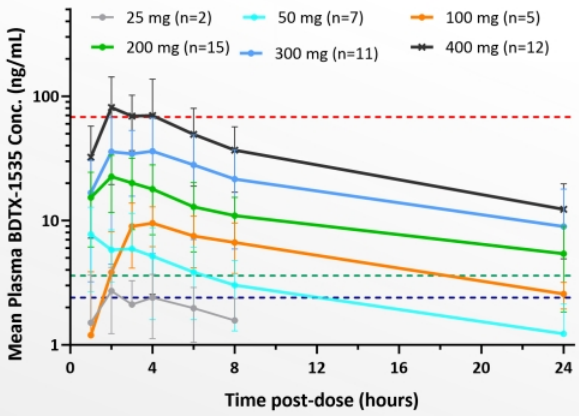
Data from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

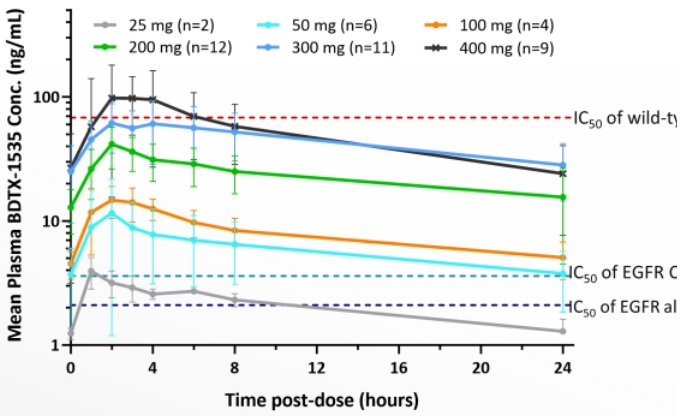
BDTX-1535 Linear Plasma PK Profile Supports Daily Dosing To Achieve 24-Hour Target Coverage

Mean plasma concentration-time profile of BDTX-1535

Day 1
C1D1 mean (±SD)



Steady State
C1D15 mean (±SD)



- Target blockade based on preclinical IC50 was achieved at BDTX-1535 ≥ 100 mg QD
- Exposure was dose proportional with half-life ~15 hours to support daily dosing
- Clinical anti-tumor activity observed at ≥ 100 mg QD

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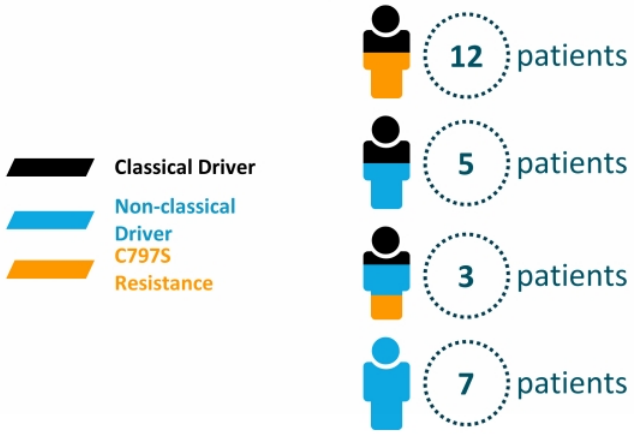
Data from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

**IC_{50} of EGFR alterations in GBM is average IC_{50} of most prevalent EGFR mutations tested in BaF3 cells

*IC_{50} of EGFR C797S is average of IC_{50} of Exon19del/C797S and L858R/C797S mutations tested in Ba/F3 cells

NSCLC Dose Escalation Patients Reflect Real World EGFR Mutation Landscape Post Osimertinib

20 of 27 patients with 2 or more mutations



Classical driver mutations	Non-classical driver mutations	Acquired r muta
Exon 19del L858R	E709A/V L718Q G724S L833V G719A L861Q L747P S768I T751K K754E L747_E759del E746_T751delinsA L747_T751delInsP	C79

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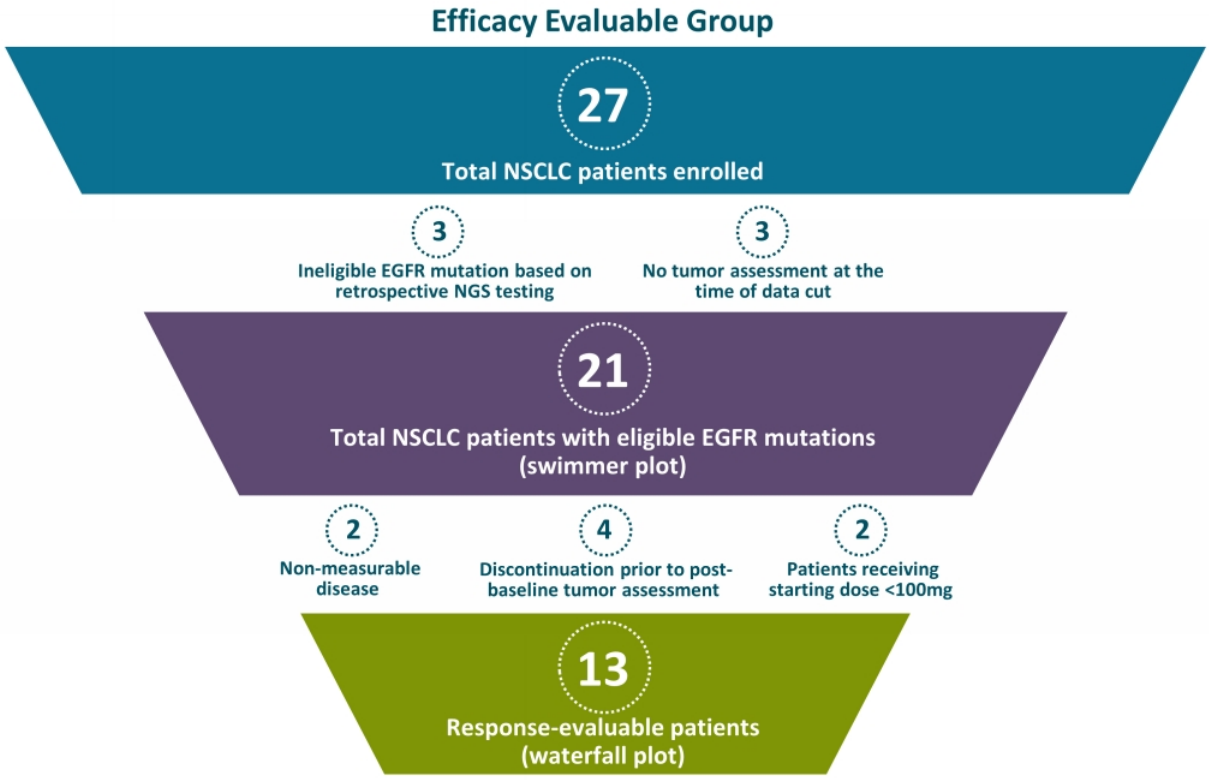
Data from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

BDTX-1535 Phase 1 Dose Escalation: 13 Response-Evaluable NSCLC



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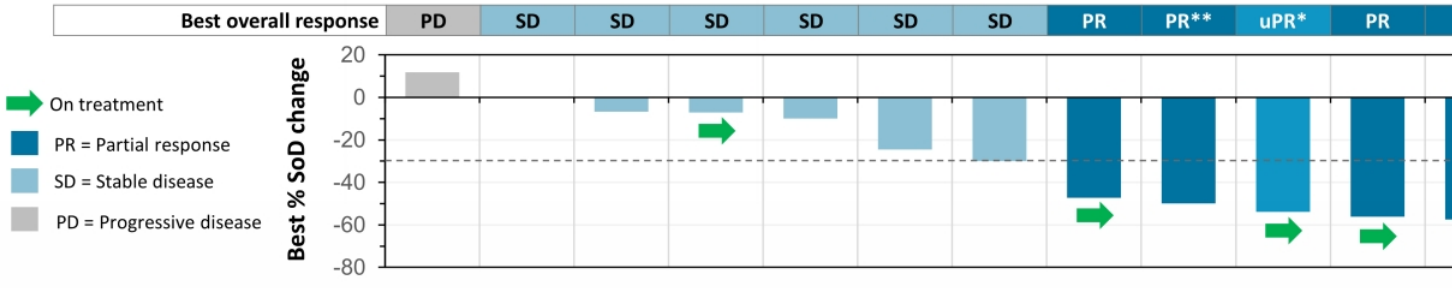
Adapted from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

Radiographical Responses in Efficacy-Evaluable NSCLC Patients Across All Relevant Mutations



Assigned dose level, mg QD		300	400	200	200	200	200	400	400	300	200	200
EGFR mutation (retrospective central testing)	Classical	L858R		Ex19del	L858R#	Ex19del	Ex19del		Ex19del	Ex19del	L858R	
	Non-classical	L833V	G719A		E709V#		G724S	S768I			E709V	L747P
	Acquired	C797S		C797S		C797S	C797S		C797S	C797S		
Prior lines of therapy	1st line	Osi	Osi	Osi	Gefi	Osi	Osi	Erlo	CPI	Osi	Osi	Osi
	2nd line	Daco, Osi	C		C	CPI, C		C	Osi	Osi+Gefi	C	CPI/C
	>2 line	CPI, C	Afa						C	BLU-701		C

Osi = Osimertinib; Afa = Afatinib; Gefi = Gefitinib; Daco = Dacomitinib; Erlo = Erlotinib; CPI = Checkpoint inhibitor, C = Chemotherapy; # - mutations were absent on confirmatory test; * uPR=unconfirmed partial response-patient had baseline scan, but a radiologist was unable to confirm a response on a subsequent scan; this patient remains on study treatment without evidence of PD. **%SoD was updated to -50% from prior data release
24July2023 BDTX-1535-101 clinical data extract
Data from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

Efficacy-Evaluable Patients
5 cPR, 1 uPR of 13 by RECIST

Post-Osimertinib Patients
5 cPR, 1 uPR of 11 by RECIST

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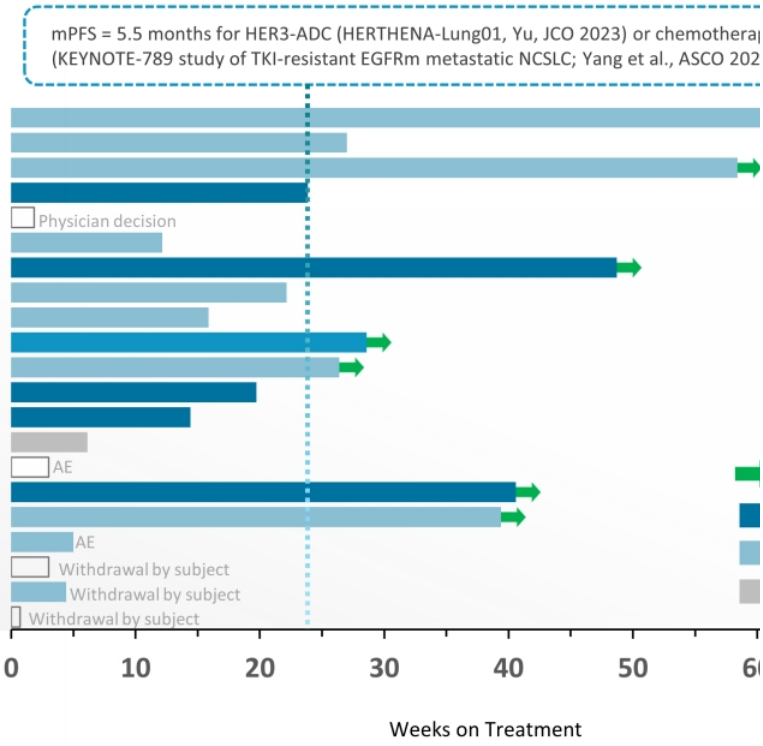
BDTX-1535: Emerging Evidence of Durable Tumor Response in NSC

Assigned Dose (QD)	Baseline EGFR Mutation			Prior Therapy			Response Evaluable
	Classical	Non-classical	Acquired	1st	2nd	>2 line	
25 mg	Exon 19del		C797S	Osi			SD[a]
50 mg	Exon 19del		C797S	Osi			SD[b]
		G719A, L861Q		CPI, Afa	Osi	HER3-ADC	NM[a, c]
100 mg	L858R	L718Q,	C797S	Osi			PR[d]
	L858R			Osi	C	C	No[b]
200 mg	Exon 19del		C797S	Osi	CPI, C		SD
		L747P		Osi	CPI, C	C	PR[c, f]
	Exon 19del		C797S	Osi			SD
	Exon 19del	G724S	C797S	Osi			SD
	L858R	E709V		Osi	C		uPR[e]
	L858R	E709V		Gefi	C		SD
300 mg	Exon 19del		C797S	Osi	Osi + Gefi	BLU-701	PR[c]
	L858R		C797S	C	Osi	C	PR[c]
	L858R,	L833V	C797S	Osi	Daco, Osi	CPI, C	PD[c]
400 mg	Exon 19del		C797S	Osi	C		No
	Exon 19del		C797S	CPI	Osi	C	PR[d]
		E746_T751del insA		Osi	C		NM[d]
		G719A		Osi	C	Afa	SD[c]
	L858R	E709A, L718Q		Osi			No
		S768I		Erlo	C		SD
		G719A		C	Afa		No

[a] Dose was increased incrementally to 100 mg QD
[b] Dose was increased incrementally to 200 mg QD
[c] Received more than two prior lines of therapy
[d] Dose was reduced to 300 mg QD
[e] patient had a PR on a post-baseline scan, but a radiologist was unable to confirm a response on a subsequent scan; this patient remains on study treatment without PD
[f] Patient had >20% increase in target lesions at cycle 11, however, continues the study treatment



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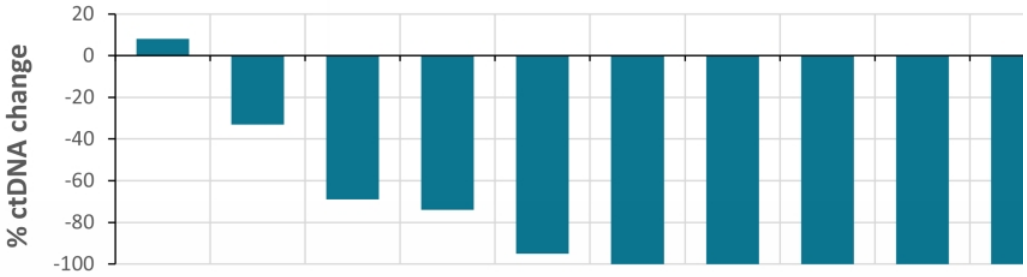
Data from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

BDTX-1535 Drives Clearance of Mutant EGFR VAF and Plasma ctDNA



Assigned Dose, mg QD		200	400	50	100	200	200	200	200	200	40
Retrospective EGFR mutation testing at baseline		EGFRm not detected	Ex19Del, C797S	Ex19Del, C797S	L858R L748Q C797S	E746_S752 delinsV, C797S	Ex19Del, C797S	L747P	Ex19Del, C797S	L858R, E709V	EG E746_ deli
Status of EGFR mutant VAF at C3D1 (central testing)	Classical	EGFRm not detected	Absent	Absent @C5D1	-58%	-96%	Absent		Absent	Absent	
	C797S		Absent	Absent @C5D1	Absent	Absent	Absent		Absent		
	Non-Classical				Absent			Absent		Absent	Abs

ctDNA – circulating tumor DNA; VAF – variant allele frequency; measurable in 10 pa

Eradication of targeted variant alleles and reduction of ctDNA are early predictors of ORR

1. Thompson, JC., et al., British Journal of Cancer, 2023

ctDNA = circulating tumor DNA
VAF = variant allelic fraction.

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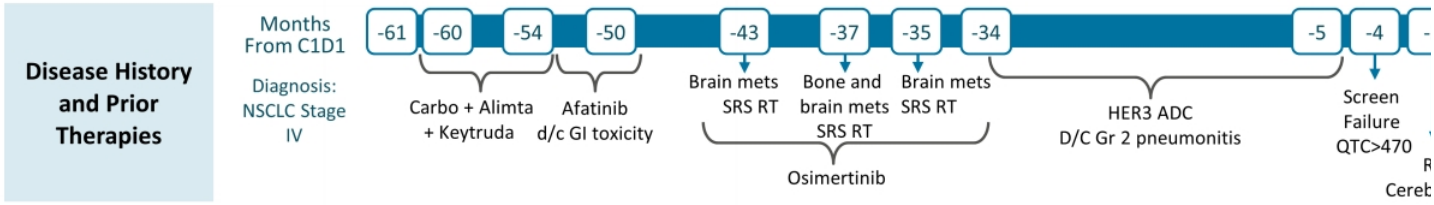
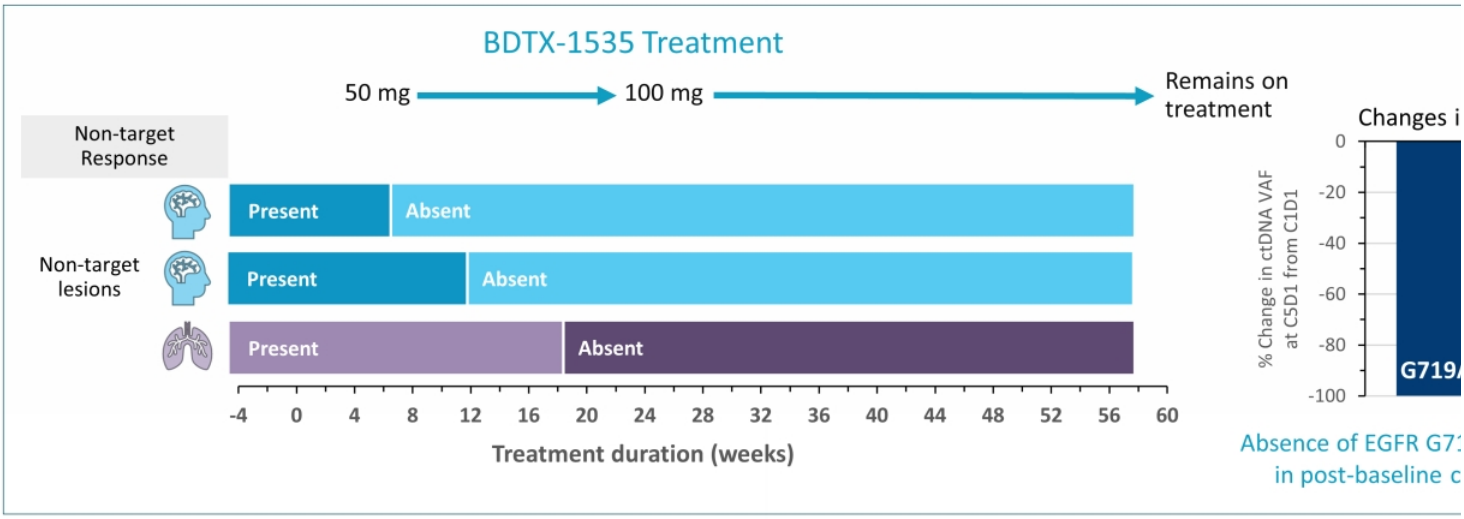
Clinical Benefit in a Non-Response Evaluable Patient With CNS Disease: Remains on Therapy for > 1 year





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1. L861Q was reported by local testing at screening, but not detected in baseline and post-dose samples by central testing

Data from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023; VAF – variant allelic fraction

BDTX-1535: Phase 2 Trial Enrolling in 1L and 2L/3L NSCLC

2L/3L

Cohort 1
n=20

Patients with acquired resistance C797S after ≤2 prior lines of therapy with osimertinib as the only prior EGFR TKI

Cohort 2
n=20

Patients with non-classical driver mutations after ≤2 prior lines of therapy with osimertinib as the preferred prior EGFR TKI

1L

Cohort 3
n=20

Patients with non-classical driver mutations and no prior treatment

- 2L/3L patier
  100 mg QD
- ORR primary
- Phase 2 data
  patients exp
- FDA Fast Tra
  granted for
- End of Phase
  received, 1L

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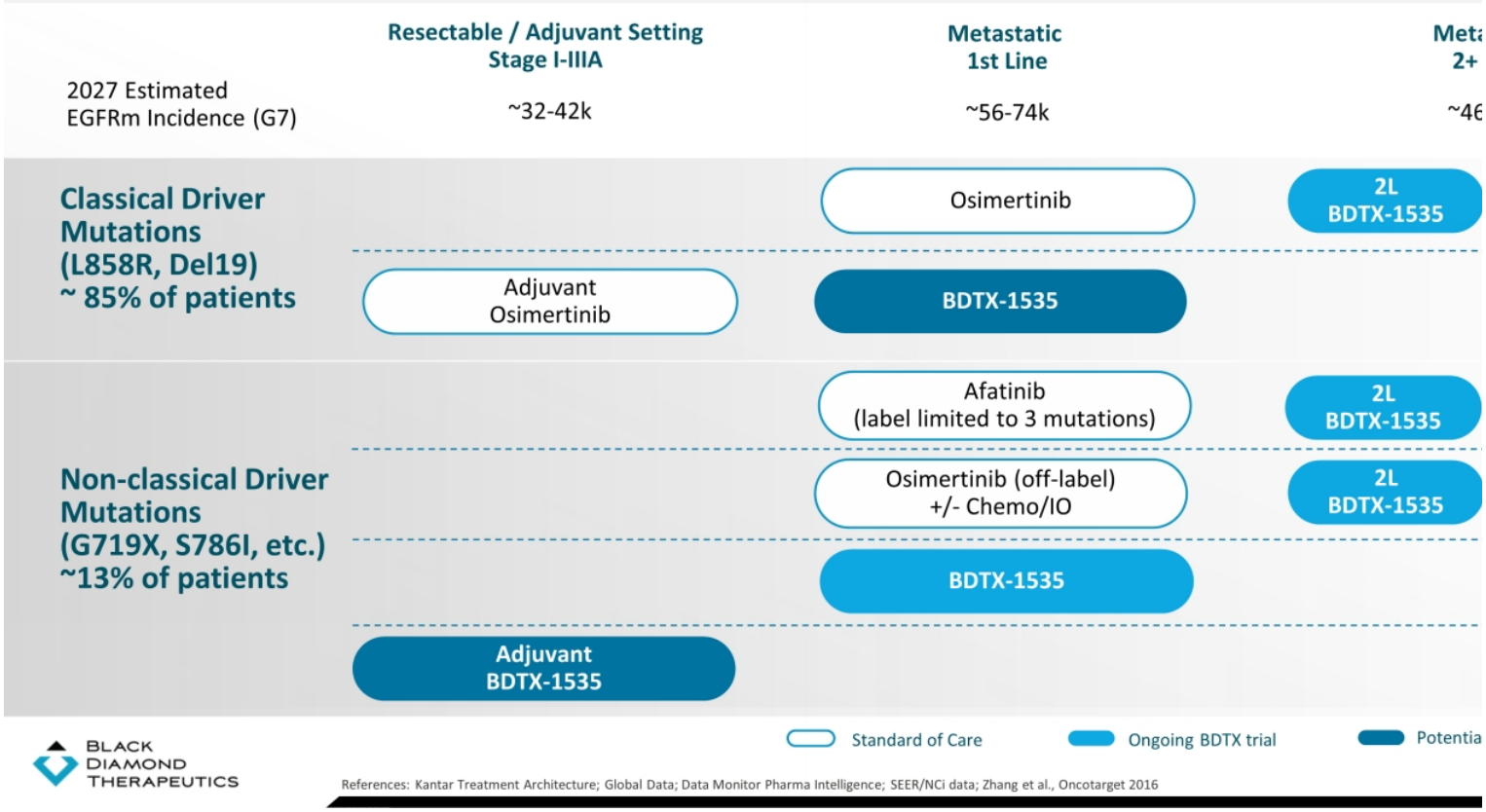
BDTX-1535 Well Positioned Across All Lines of Therapy for EGFRm I



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References: Kantar Treatment Architecture; Global Data; Data Monitor Pharma Intelligence; SEER/NCi data; Zhang et al., Oncotarget 2016


BDTX-1535:
Opportunity in Glioblastoma
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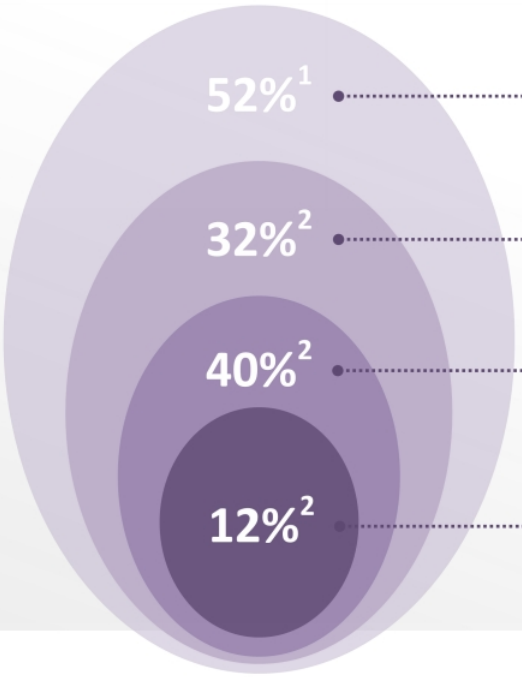
Treatment of EGFR-Driven GBM Requires Inhibition of Complex EG Mutations: Potent Preclinical Inhibition by BDTX-1535



Of all GBM samples carry oncogenic EGFR alterations

Of all GBM samples had EGFR extracellular-domain (ECD) mutations, according to real-world evidence

Of all ECD-driven tumors were complex, containing 2 or more ECD mutations

Of complex ECD-driven tumors were highly heterogeneous, with 3 or more ECD mutations

~7,00

GBM patient the US ar diagnosed e year with EC mutations t have been sh in preclinic studies to inhibited b BDTX-153

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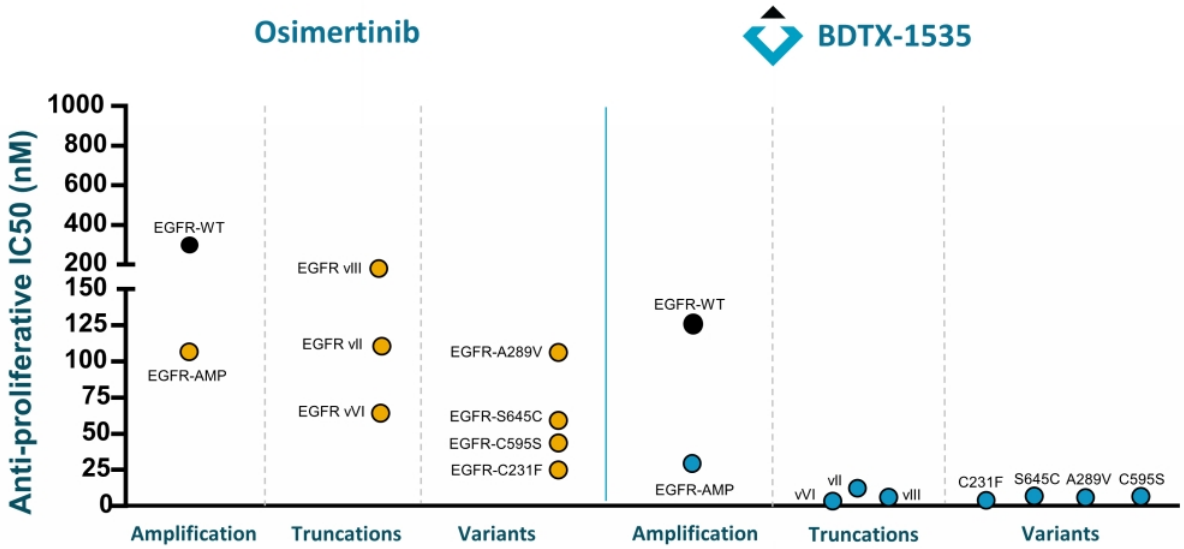
1. Saadeh, F., et al., The International Journal of Biological Markers, 2018 . 2. Real world evidence data from Tempus Labs analysis of 2,540 GBM patient samples

BDTX-1535 Demonstrates Potent Preclinical Inhibition of Oncogeni
GBM EGFR Alterations vs. Osimertinib and Superior Brain Exposure



BDTX-1535 Ex
Brain Exposu

BDTX-1535

Osimertinib

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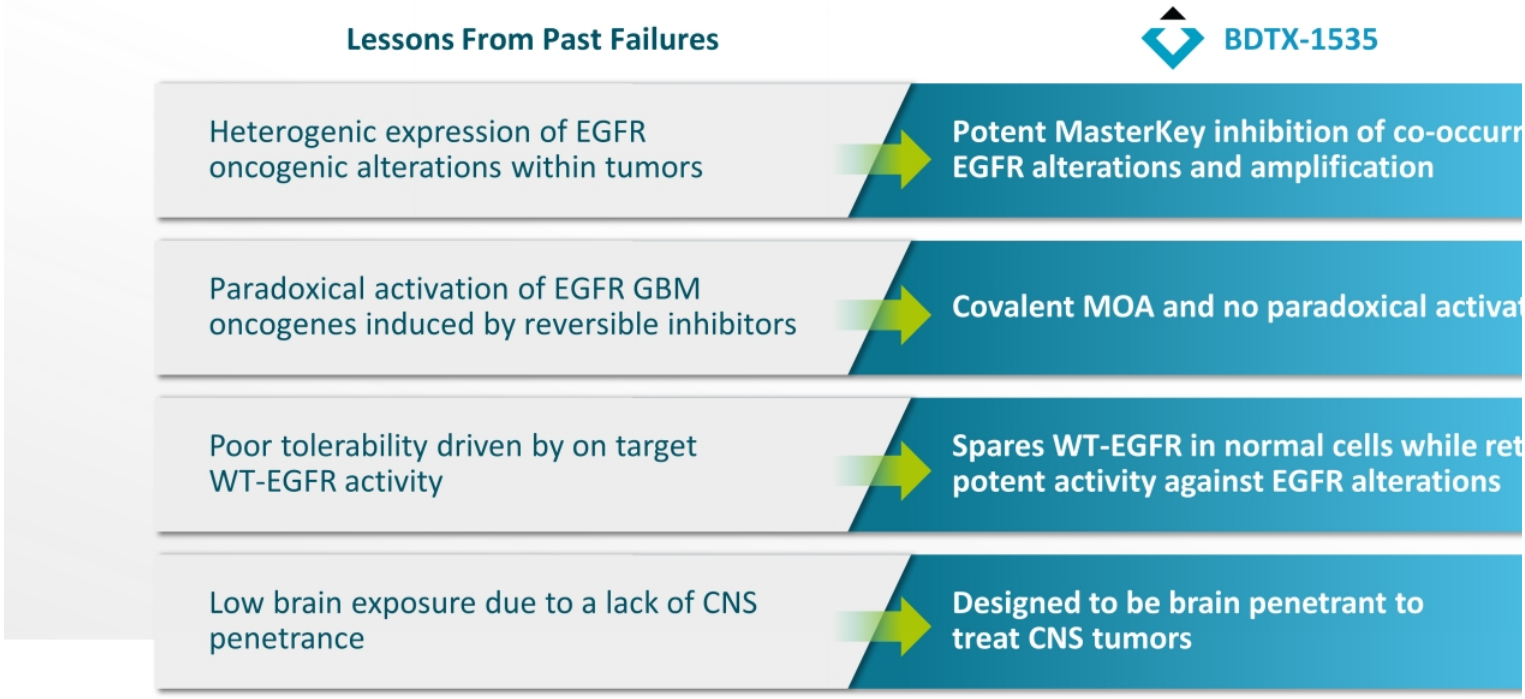
EGFR-WT reflects anti-proliferative activity in H292 WT-EGFR expressing cell line. Data for all mutations derived from Ba/F3 transformants.
Kp_{uu} Partition Coefficient Calculation: $AUC_{brain:blood}$ x plasma Fu/brain Fu

BDTX-1535: Potential to Overcome Limitations of Prior Attempts to EGFR in GBM



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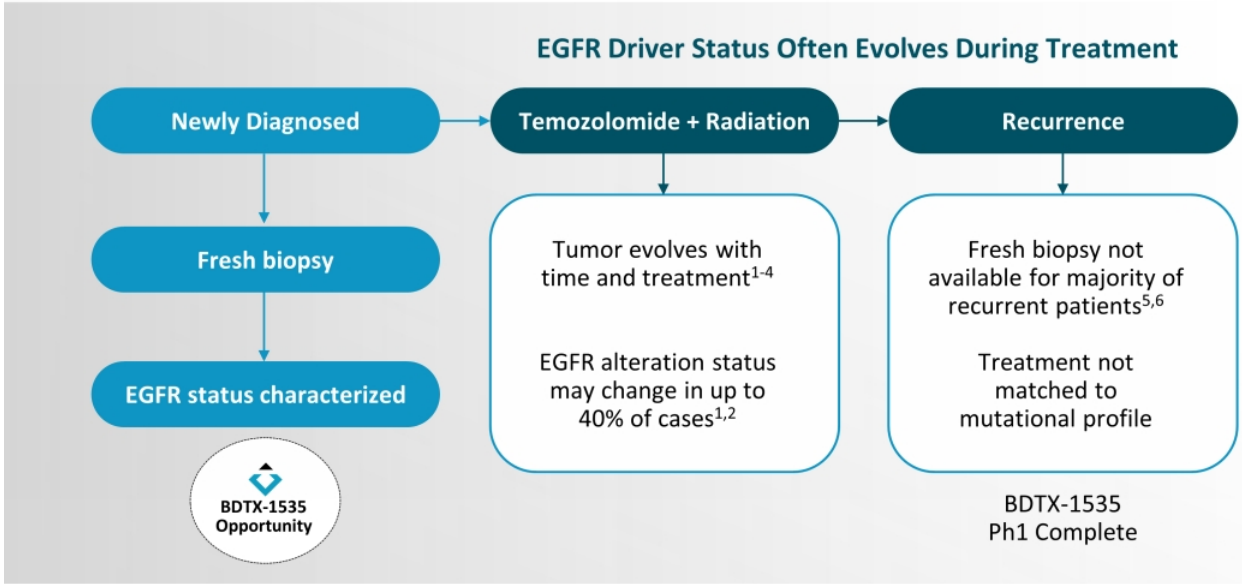
MOA=mechanism of action; CNS=Central Nervous System; WT=Wild-Type; GBM=Glioblastoma Multiforme; NSCLC=Non-Small Cell Lung Cancer

BDTX-1535 Opportunity in Newly Diagnosed EGFRm GBM Patients

GBM Treatment Paradigm



Opportunity fo in Newly Diagn

Fresh bio used for

Up-to-da guide tre

Treatmer tumor alt

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1. Schäfer, J. Transl. Med. 2019; 2. Wang, Nat. Genet. 2016; 3. Johnson, Science 2014; 4. López, Acta Neuropathol. 2019; 5. Weller, Neuro-Oncology 2013; 6. Audureau, J. Neurooncol. 201

Promising Clinical Activity in Heavily Pre-treated GBM Patients From Dose Escalation Portion of Phase 1 Study

- Recurrent, heavily pre-treated **(2L/3L+)**
- Historical PFS ~ 2-4 months
- EGFR status ***not*** confirmed at dosing

- ✓ Well tolerated, with favorable plasma PK
- ✓ Of 22 efficacy evaluable heavily pre-treated GBM pati
  - *3 patients on therapy longer than 10 months*
    - *1 remains on therapy at 15 months (100mg QD progressed on TMZ after 3 months*
  - *1 patient on therapy longer than 6 months*
  - *5 patients on therapy longer than 4 months*
- ✓ Of 19 patients with measurable disease assessable by
  - *1 confirmed partial response (200 mg QD), on the*
  - *8 patients with stable disease*

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RANO: Response Assessment in Neuro-Oncology

BDTX-1535 in GBM: Immediate Next Steps and 2024 Milestones

Window of Opportunity (WOO) Study Overview

- 2L patients receive 5 days of dosing with BDTX-1535 as monotherapy
- Surgical resection following day 5 of dosing
- CNS PK/PD evaluated in resected tissue and CSF
- Potential to confirm EGFR status

Anticipated Upcoming Milestones

- Phase 1 full data set at medical meeting Q2
- "Window of Opportunity" trial currently en
  data expected at a medical meeting Q2 202

If go forward criteria met:

Opportunity to benefit 1L patients with confirme
status at diagnosis

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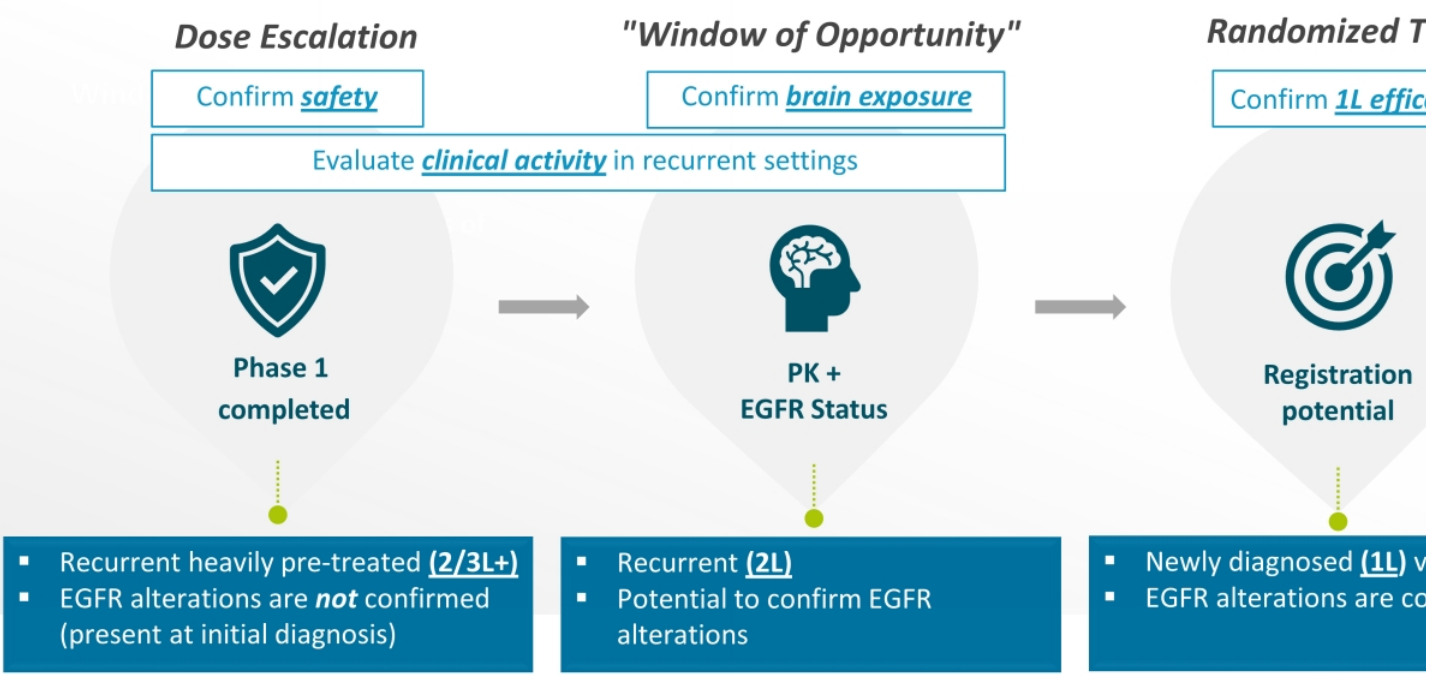
CNS=Central Nervous System; CSF=Cerebrospinal fluid

BDTX-1535 GBM Development Path Designed for Sequential De-Ris



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CNS=Central Nervous System; CSF=Cerebrospinal fluid

BDTX-1535 Summary: NSCLC and GBM Opportunities

Leading Position	**First and potential best-in-class 4th gen EGFR TKI**	**Robust clinical POC in a heavily pre-treated Phase 1 NSCLC population** • 5 cPR + 1 uPR out of 13 efficacy-evaluable patients • Durable responses and clinical evidence of CNS anti-tumor activity • Well tolerated with manageable (similar to osimertinib), on-target EGFR TKI • Phase 2 enrolling, data expected in Q3 2024
Compelling Asset	**Differentiated profile**	**Clear differentiation against standard of care and emerging treatment optio** • WT-EGFR sparing with favorable clinical tolerability vs chemo/ADC-based co • Brain penetrant to address CNS disease • Highly potent against all major, clinically relevant EGFR mutations • Once daily oral administration
Large Markets	**Robust near-term commercial opportunity in 2L and 1L NSCLC** **Emerging potential in GBM**	**Real-world evidence[1,2] demonstrates a growing commercial opportunity in N** • 2L: Post osimertinib – C797S, classical/non-classical drivers and complex mu • 1L: Non-classical driver mutations • 1L: Post-osimertinib adjuvant therapy **Potential in 1L GBM with EGFR alterations (>50% of all newly diagnosed GBM**

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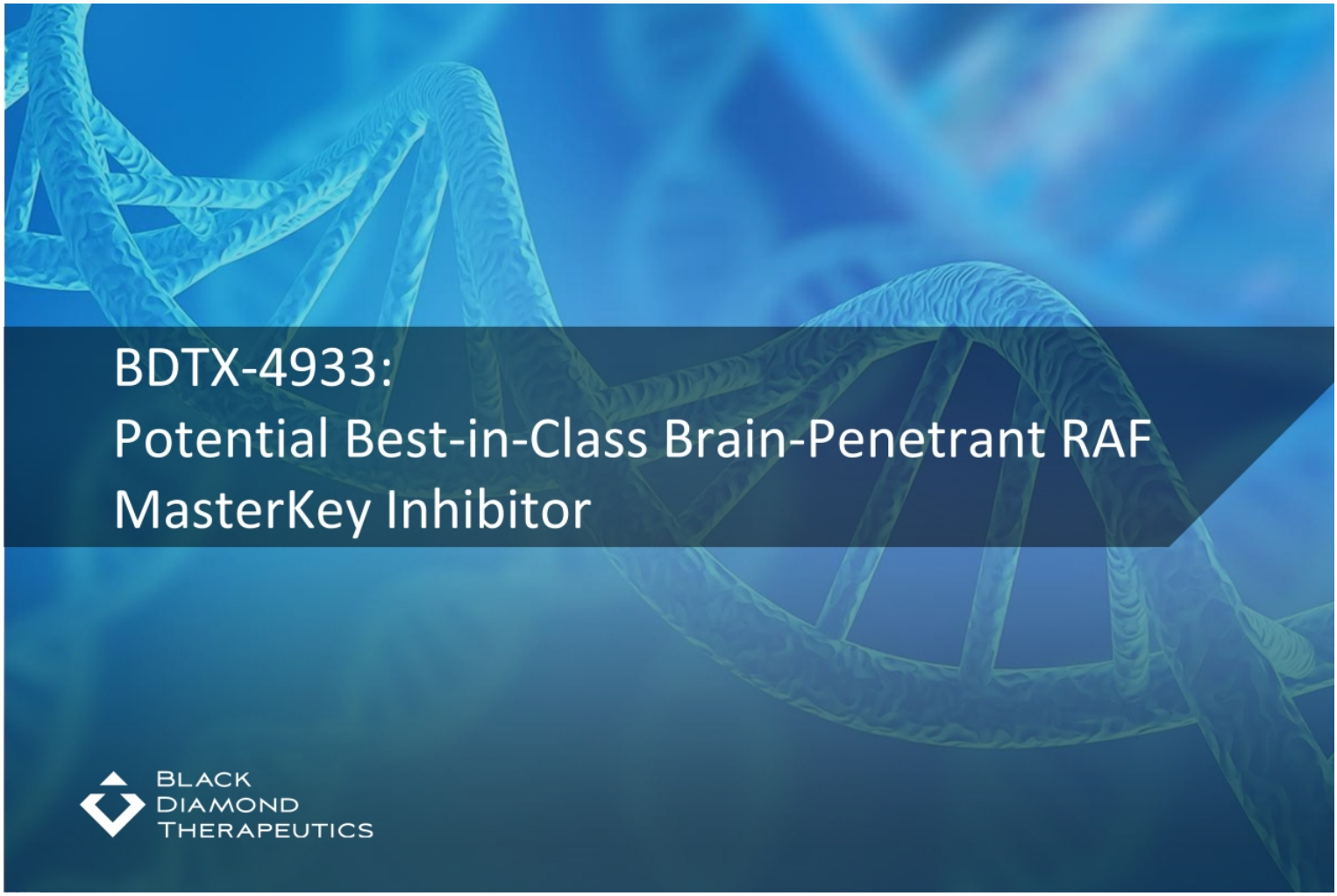
1. Real world treatment patterns and outcomes in patients with advanced non-small cell lung cancer (NSCLC) post-EGFR tyrosine kinase inhibitor (TKI) therapy Source: AACR 2023 Poster
2. Rotow, JK., et al., Journal of Thoracic Oncology, 2023.


BDTX-4933:
Potential Best-in-Class Brain-Penetrant RAF MasterKey Inhibitor
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BDTX-4933: Oral, Brain-Penetrant, RAF MasterKey Inhibitor

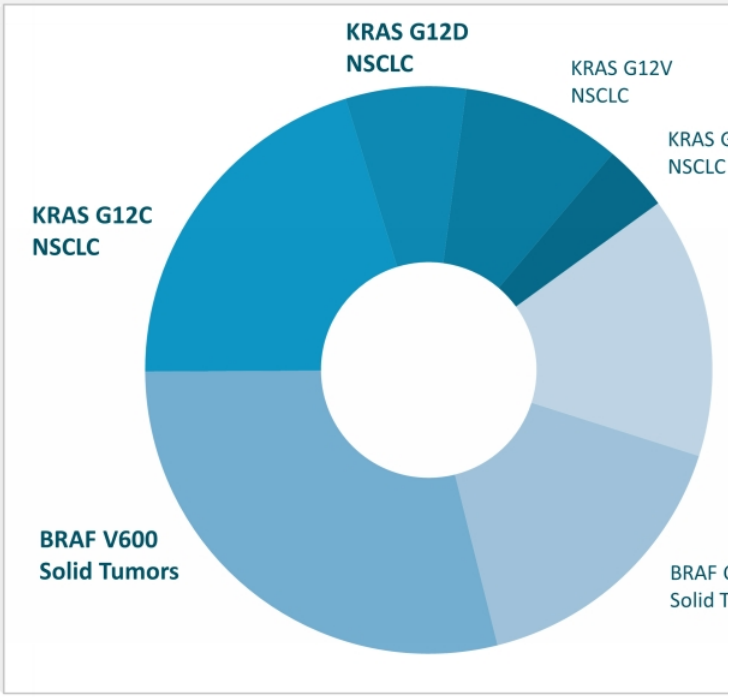
MasterKey	Potent preclinical inhibition of BRAF, KRAS, NRAS alterations ("RAF-RAS clamp")
Unique Pharmacology	Designed to target oncogenic conformation and avoid paradoxical activation
Brain Penetrant	Designed to be brain penetrant to treat CNS
Status	Phase 1 data expected Q4 2024

MAPK Pathway Mutations Affecting KRAS/NRAS/BRAF are Among t
Common Oncogenic Mutations in Cancer

Addressable US / EU5 / JP
Patient Population

~318,660

~112,00 with
CNS metastasis



Source: EvaluatePharma, TCGA, GENIE-11

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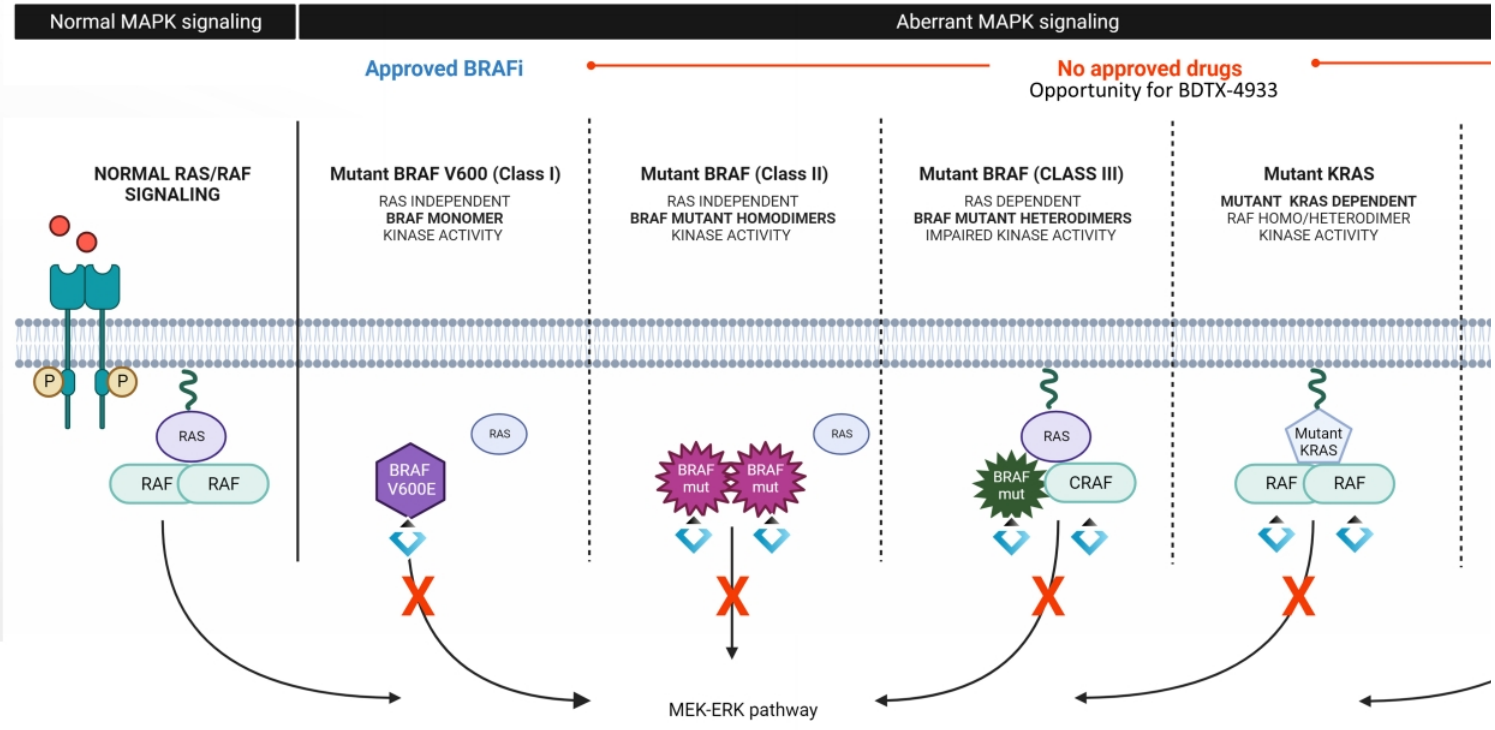
BRAF Alterations Drive Oncogenesis Through Hyperactivation of th RAS-MAP Kinase Pathway: Multiple Opportunities for BDTX-4933



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1. Zhang, W., Cell Res. (2002); 2. Yuan, J., J Hematol Oncol 13, 113 (2020); 3. Yao Z, Cancer Cell (2015); 4. Karoulia Z, Cancer Cell (2016); 5. J. Wang, Pharmacol. Res. 129, 414–423 (2018); 6. I Dispos. 45, 646–656 (2017); 7. R. K. Mittapalli, J. Pharmacol. Exp. Ther. 342, 33–40 (2012); 8. R. K. Mittapalli, J. Pharmacol. Exp. Ther. 344, 655–664 (2013); 9. Belum VR, Ann Oncol. (2015); 1((2012); 11. Hatzivassiliou G, Nature. (2010); 12. Poulikakos PI., Nature, (2010)

BDTX-4933 Demonstrates Potent Preclinical Inhibition of a Spectru
BRAF/RAS and KRAS Mutations in Cell Lines and PDX Models

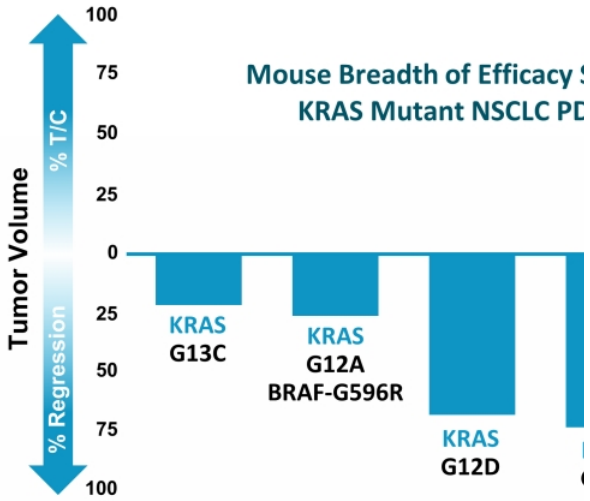
Potential Best-in-Class Potency Compared to Other RAF Inhibitors

Potent and selective inhibition of proliferation across tumor cell lines with MAPK pathway mutations

		Cell Proliferation IC50				
Mutation		BDTX-4933	Naporafenib	Belvarafenib	Exarafenib	Encorafenib
BRAF Class I	V600E					
BRAF Class II & non-V600	BRAF fusion					
	BRAF fusion					
	L597V					
	L245F					
	BRAF indel					
NRAS	NRAS Q61K					
	NRAS Q61L				Not available	
NRAS BRAF	WT					Paradoxical Activation

pERK IC_{50} color code

< 50nM 50-500nM >500nM



No significant body weight loss observed
BDTX-4933: 10 mg/kg QD x 28 or 5 mg/kg BID x 56

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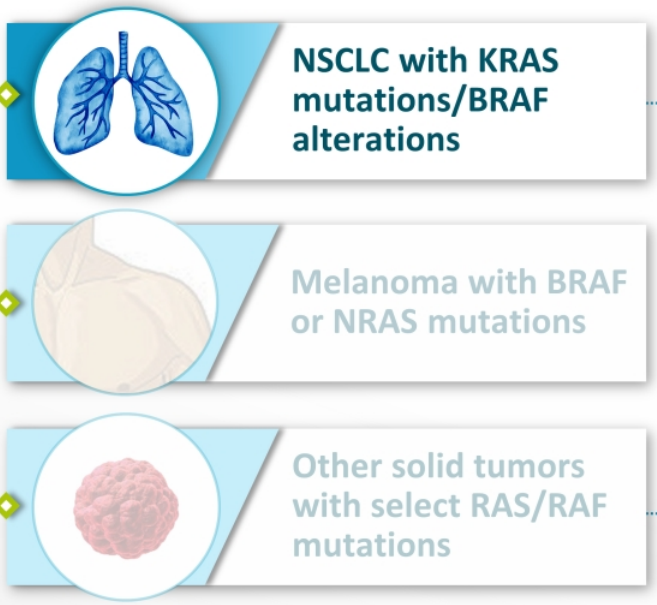
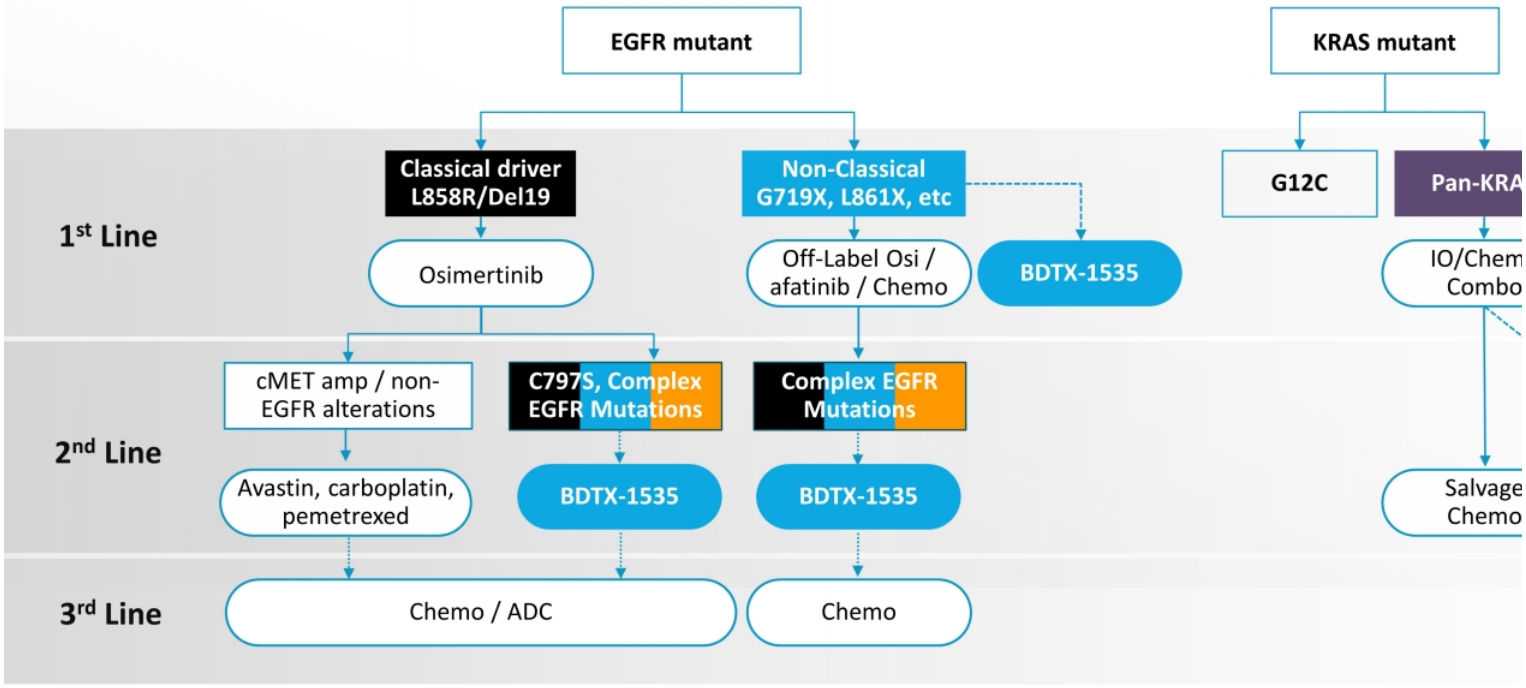
Adapted from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

BDTX-4933: Focused, Biomarker-Driven Phase 1 Trial Initiated Data Anticipated in Q4 2024



- Bayesian optimal interval design
- Mutations and alterations confirmed by local tests

BDTX-1535 and BDTX-4933: Potential for NSCLC Franchise



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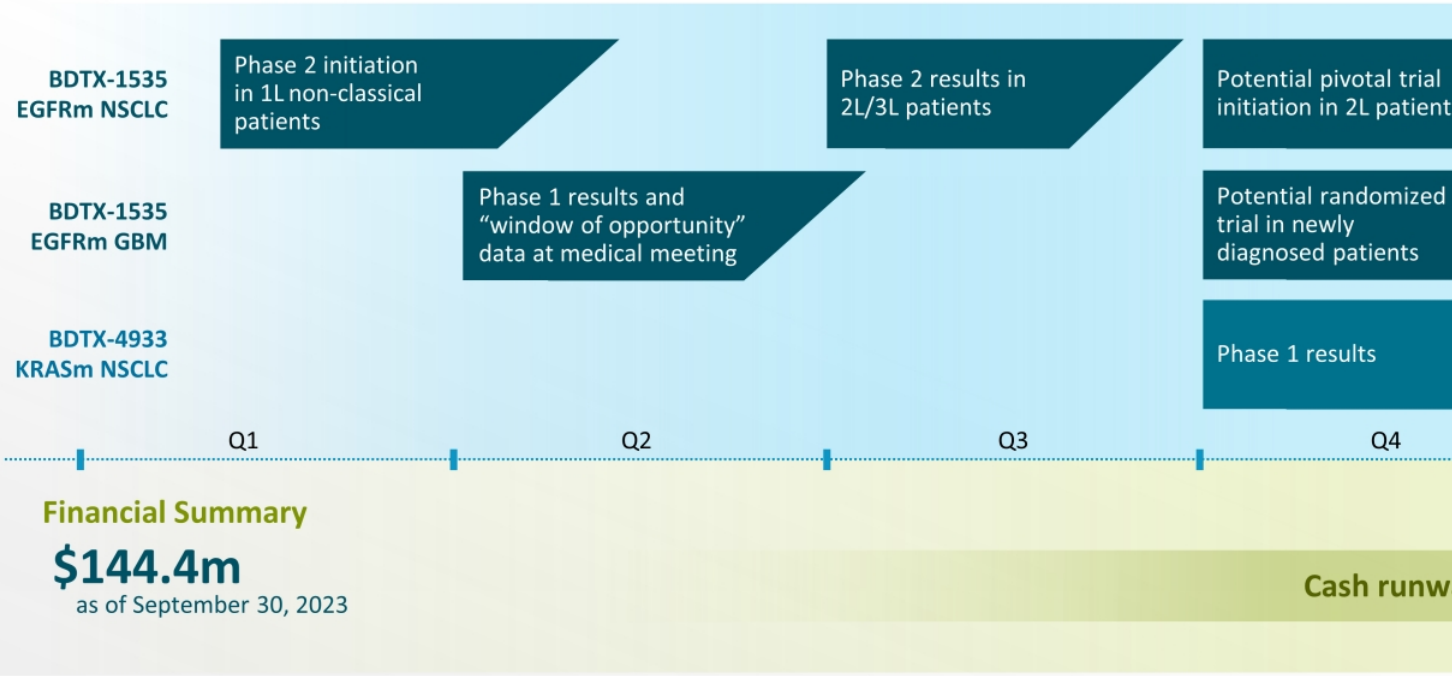
Anticipated 2024 Key Milestones



Financial Summary

$144.4m
as of September 30, 2023

Cash runw

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Thank You
Partnership: partnership@bdtx.com
Investors: investors@bdtx.com
Media: media@bdtx.com
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