

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

FORM 8-K

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

Date of Report (Date of earliest event reported): April 25, 2022

**Black Diamond Therapeutics, Inc.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39200**  
(Commission  
File Number)

**81-4254660**  
(IRS Employer  
Identification No.)

**One Main Street, 10<sup>th</sup> Floor**  
**Cambridge, MA**  
(Address of principal executive offices)

**02142**  
(Zip Code)

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

**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 April 25, 2022, Black Diamond Therapeutics, Inc. (the “Company”) issued a press release titled, “*Black Diamond Therapeutics Announces Pipeline Prioritization and Workforce Realignment*” 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 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.*

**Item 9.01. Exhibits**

(d) Exhibits

- [99.1](#) [Press Release issued by the Company, dated April 25, 2022, furnished herewith.](#)
  - [99.2](#) [Corporate Presentation of the Company, dated April 25, 2022, furnished herewith.](#)
  - 104 Cover Page Interactive Data File (embedded within the Inline XBRL Document).
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**SIGNATURES**

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.

April 25, 2022

**BLACK DIAMOND THERAPEUTICS, INC.**

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

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### **Black Diamond Therapeutics Announces Pipeline Prioritization and Workforce Realignment**

*– Strategic areas of focus on development of BDTX-1535 and BDTX-4933 as well as MAP platform enabled small molecule drug discovery efforts –*

*– Company to discontinue development of BDTX-189 and reduce workforce to extend its cash runway into 3Q 2024, supporting execution of key milestones –*

CAMBRIDGE, Mass. and NEW YORK, April 25, 2022 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a precision oncology medicine company pioneering the discovery and development of MasterKey therapies, today announced that it is realigning its resources to focus on key near-term value drivers and to extend its cash runway into the third quarter of 2024, supporting the execution of important clinical and preclinical milestones.

“Black Diamond’s mission of expanding the reach of precision cancer medicines through the development of our novel MasterKey therapies is at the core of our daily work, and we believe that our MAP discovery engine offers a novel approach to addressing major unmet needs within the oncology treatment landscape,” said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “In order to increase our operational efficiency and execute on our mission, we have made the difficult decision to reduce our workforce by approximately 30%. We are incredibly grateful to every member of the Black Diamond team who has helped to advance MasterKey therapies for the many patients in need of new therapeutic options as well as to the patients and investigators involved in the clinical trial of BDTX-189. The actions announced today enable us to focus and strengthen our organizational priorities, reduce our operating expenses, and continue to invest in value generating clinical development activities to bring us to the next inflection points for BDTX-1535 and BDTX-4933.”

Black Diamond has discontinued the development of BDTX-189 and realigned its workforce to focus on progressing its pipeline through important upcoming milestones for BDTX-1535, BDTX-4933 and discovery efforts. Since its announcement regarding the status of BDTX-189 in January 2022, the Company has been reviewing the development program for BDTX-189, an orally available, irreversible small molecule inhibitor targeting oncogenic driver mutations of the epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (HER2) kinases, while continuing to enroll patients in the safety expansion cohort of the Phase 1 study. As part of its strategic review, Black Diamond has decided to discontinue development of the program due to the rapid evolution of the treatment landscape in non-small cell lung cancer (NSCLC) harboring either EGFR or HER2 Exon 20 insertion mutations.

Black Diamond is aligning its operational and scientific efforts on two priority programs, in addition to its discovery efforts.

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**BDTX-1535**

- BDTX-1535 is designed as a potent, selective, brain-penetrant and irreversible MasterKey inhibitor of EGFR mutations expressed in glioblastoma multiforme and of intrinsic and acquired resistance EGFR mutations to third generation EGFR inhibitors in NSCLC.
- Black Diamond initiated the Phase 1 study of BDTX-1535 in the first quarter of 2022 and expects to provide a clinical data update in 2023.

**BDTX-4933**

- BDTX-4933 is a central nervous system (CNS)-penetrant BRAF inhibitor against a family of Class I, II, III canonical and non-canonical mutations being developed for the treatment of patients with or without brain tumors driven by oncogenic BRAF mutations. BDTX-4933 is designed to be highly selective and potent, with the ability to avoid paradoxical activation.
- Black Diamond initiated investigational new drug (IND)-enabling studies in the first quarter of 2022 and expects to submit an IND for BDTX-4933 in the first half of 2023.

**Discovery Efforts**

- Black Diamond will continue the advancement of its discovery efforts generated from its Mutation-Allosteric-Pharmacology (MAP) Drug Discovery Engine focused on predicting and validating novel oncogenic mutant families from population level tumor genomics. Black Diamond anticipates announcing a development candidate for its FGFR program in 2022 in addition to disclosing a new small molecule development candidate in 2023.

**About Black Diamond**

Black Diamond Therapeutics is a precision oncology medicine company pioneering the development of novel MasterKey therapies. Black Diamond is addressing the significant unmet need for novel precision oncology therapies for patients with genetically defined cancers who have limited treatment options. Black Diamond is built upon a deep understanding of cancer genetics, onco-protein function, and drug discovery. The Company's proprietary Mutation-Allosteric-Pharmacology, or MAP drug discovery engine, is designed to allow Black Diamond to analyze population-level genetic sequencing tumor data to predict and validate oncogenic mutations that promote cancer across tumor types as MasterKey mutations. Black Diamond discovers and develops selective MasterKey therapies against these families of oncogenic mutations. Black Diamond was founded by David M. Epstein, Ph.D., and Elizabeth Buck, Ph.D. For more information, please visit [www.blackdiamondtherapeutics.com](http://www.blackdiamondtherapeutics.com).

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## 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 planned realignment of resources and pipeline prioritization, the ongoing development of BDTX-1535 and BDTX-4933, including timing of upcoming milestones, the nomination of a development candidate for the Company’s FGFR program and the Company’s 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 the Company’s 2021 annual report on Form 10-K filed with the United States Securities and Exchange Commission and its other 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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# Black Diamond Therapeutics, Inc.


Pioneering the Development of MasterKey Therapies



## Important Notice and Disclaimers

This presentation contains “forward-looking statements” of Black Diamond Therapeutics, Inc. (“Black Diamond,” “we” or “our”) within the meaning of the Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding our plans to advance and expand the MAP drug discovery engine, the potential timing and advancement of our clinical trial and preclinical studies, including clinical data updates for BDTX-1535 and the timing of filing investigational new drug (“IND”) application for BDTX-4933, the timing and potential milestones to advance our product candidate pipeline, including development candidate nomination for our FGFR2/3 program and our target program, and our cash runway. Any forward-looking statements in this presentation are based on management’s current expectations 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 such forward-looking statements. Our actual future results may be materially different from what we expect due to factors largely outside our control, including results of clinical trials, clinical trial patient enrollment, changes in regulatory requirements or decisions of regulatory authorities, commercial timelines if approved, the actions of our third party clinical research organizations, suppliers and manufacturers, and the impact that the COVID-19 pandemic will have on our clinical trials, pre-clinical studies, and operations. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, if new information becomes available in the future. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause actual results to differ from those contained in the forward-looking statements, see the section entitled “Risk Factors” in our 2021 annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission. This presentation is as of the date hereof, and we undertake no duty to update this information unless required by law.

Certain information contained in this presentation relates to, or is based on, studies, publications, surveys and other data obtained from third parties, as well as our own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, it has not been independently verified and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third party sources. In addition, market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy of such data. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.



# Black Diamond Therapeutics Overview



# Expanding the Reach of Precision Medicine Through the Development of MasterKey Therapies

**MasterKey** therapies address oncogene mutation families; providing precision oncology medicines to greater numbers of patients with genetically defined tumors

Clinical and late-preclinical pipeline of **MasterKey** inhibitors derived from our MAP drug discovery engine targeting oncogenic ErbB1/2, BRAF, FGFR2/3 and additional undisclosed targets

**BDTX-1535**: a brain-penetrant, mutant selective, irreversible inhibitor of EGFR for the treatment of patients with GBM and NSCLC driven by EGFR intrinsic and acquired resistance mutations

**BDTX-4933**: a brain-penetrant inhibitor of Class I, II, and III oncogenic BRAF mutations currently in enabling studies

Our proprietary **MAP drug discovery engine** is designed to:

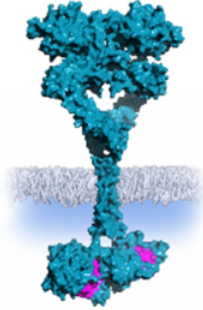
- Predict and validate novel oncogenic mutant families from population level tumor genomic data
- Pioneer mutant family conformation-based MasterKey drug design
- Provide opportunities beyond oncology and small molecules



# Black Diamond's MasterKey Approach Designed to Address Overlooked Mutation Families

## Classic/Current Approach:

Targeting active site kinase domain mutations

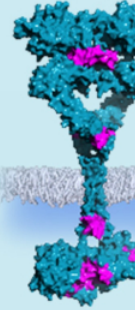


Targeting single mutations in individual tumor types



## Black Diamond Approach

Targeting mutation families opportunity for precision





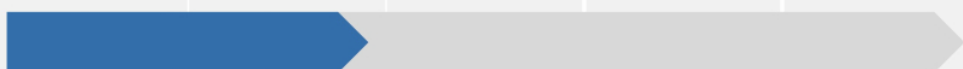
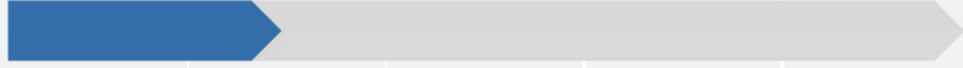
Mutation families yield significant opportunities for population precision therapies



With expanding genetic profiling of cancer patients via Next Generation Sequencing (NGS)

Less than 15% patients<sup>1</sup> with metastatic cancer eligible for approved precision oncology medicines

# Wholly-Owned Novel MasterKey Precision Medicines

Target	Drug Candidate	Indication	Discovery	Optimization	IND-Enabling	Phase 1	Phase 2/3	
EGFR	<b>BDTX-1535</b>	EGFR-driven GBM & NSCLC ± CNS mets						
			<b>Clinical Data (2023)</b>					
BRAF	<b>BDTX-4933</b>	BRAF-driven solid tumors ± CNS mets						
			<b>IND (1H 2023)</b>					
FGFR	<b>Undisclosed</b>	FGFR3-driven solid tumors						
			<b>Development Candidate (2022)</b>					
Un- disclosed	<b>Undisclosed</b>	Solid tumors						
			<b>Development Candidate (2023)</b>					

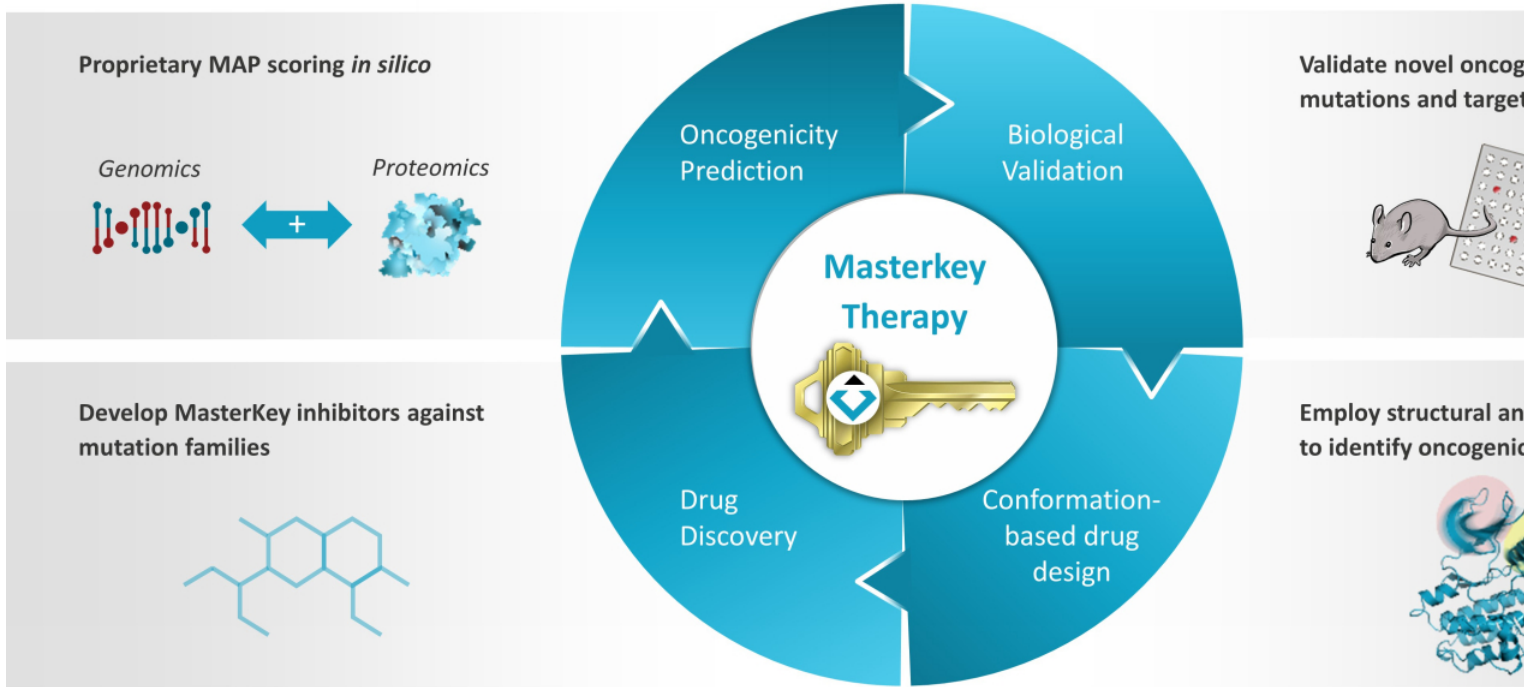




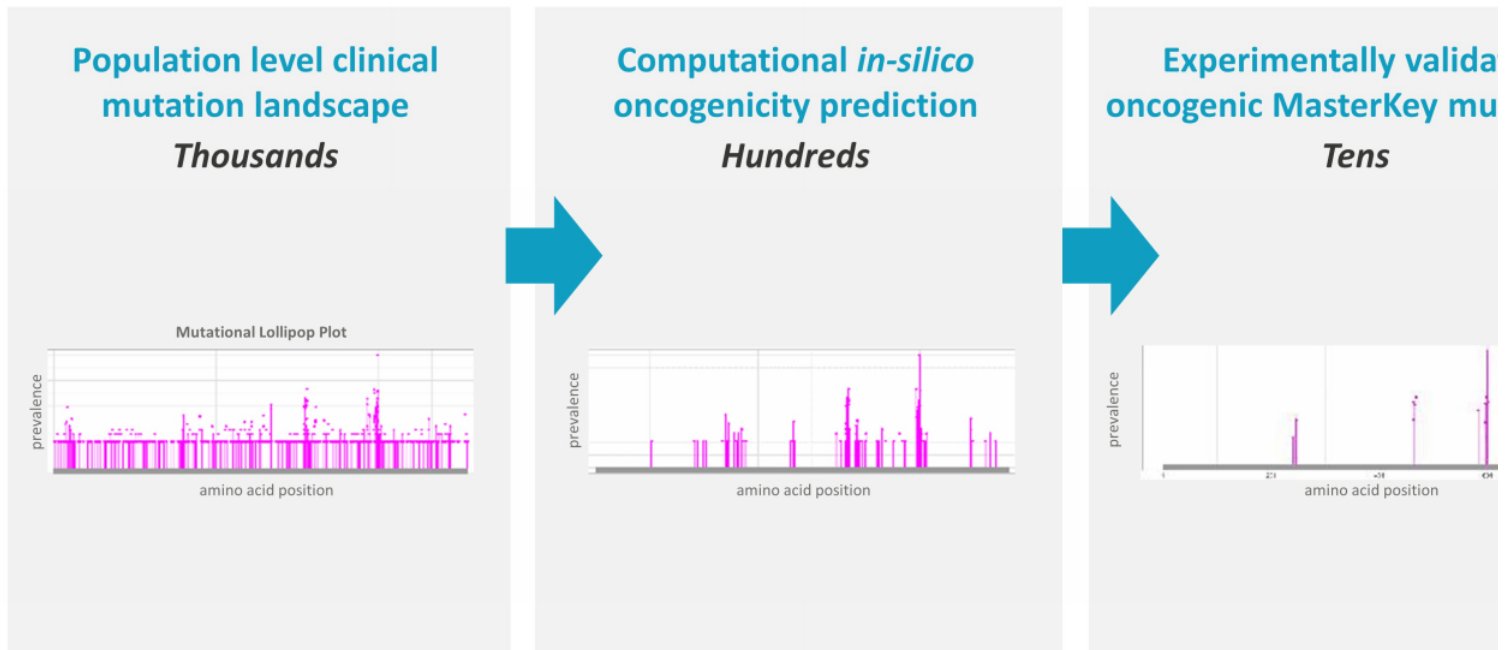
# MAP Drug Discovery Engine



# MAP Drug Discovery Engine Unlocks Precision Medicine with a “Master

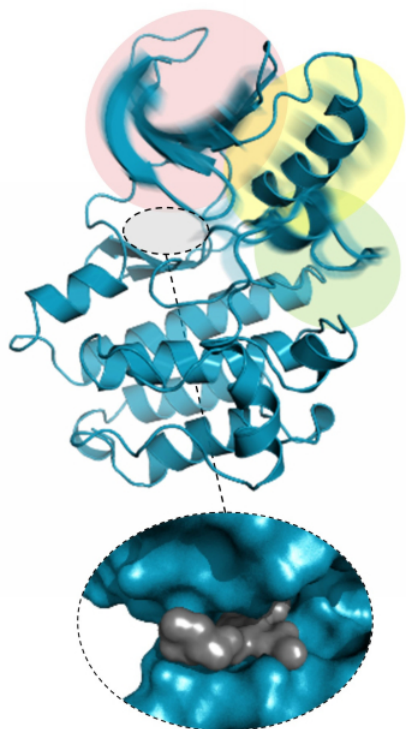


# MAP Drug Discovery Engine: A Scaled Approach to Extract Oncogenic MasterKey Mutation Families

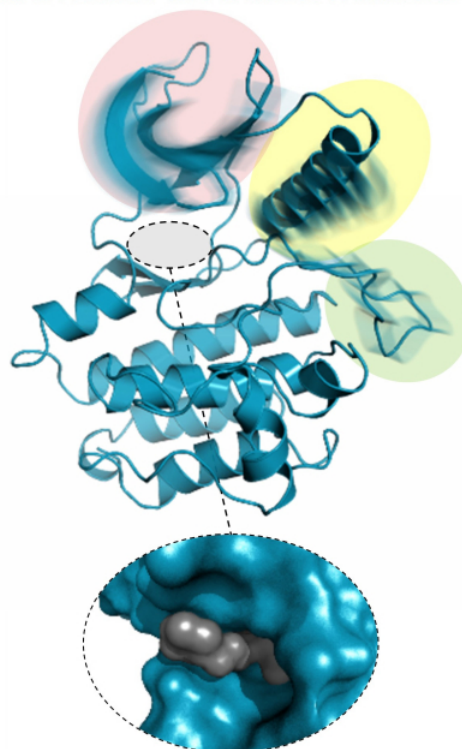


# Conformation Based Drug Design Enabled by MAP Drug Discovery Eng

WILD TYPE




MASTERKEY MUTATION FAMILIES



MasterKey  
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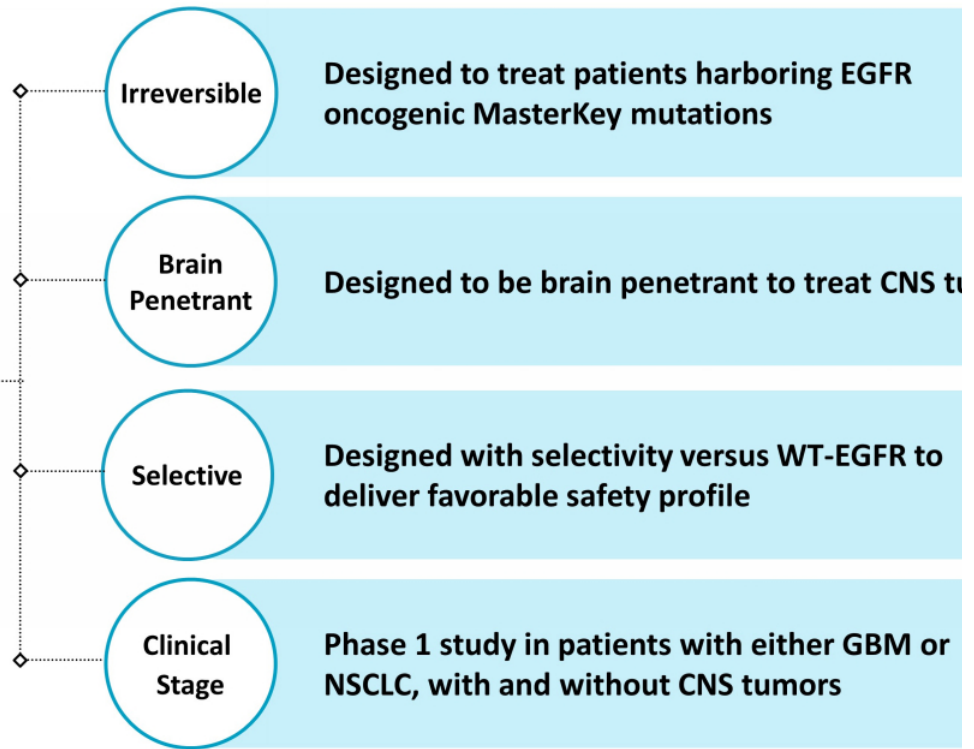


BDTX-1535

Brain-Penetrant Inhibitor of GBM and NSCLC MasterKey EGFR Mutations



# BDTX-1535: Oral, Brain Penetrant, Selective Inhibitor of Oncogenic EGFR MasterKey Mutations



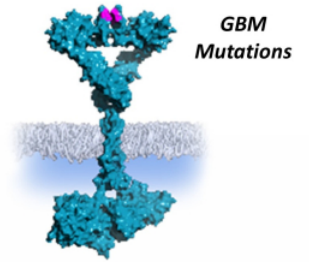
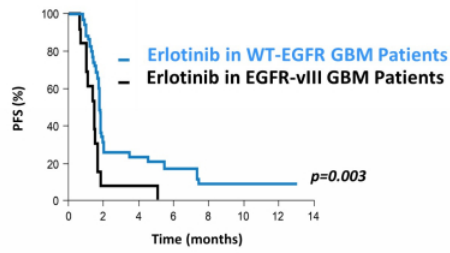


# Reversible EGFR Inhibitors Show Potentially Detrimental Pharmacology Driven GBM

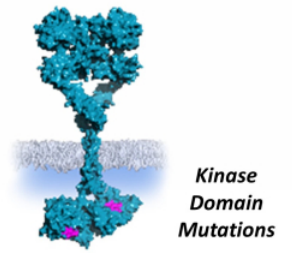
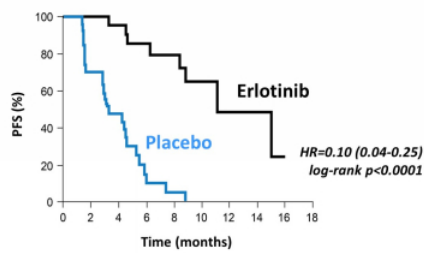
Current EGFR TKIs Do Not Extend PFS in Patients with GBM Mutations

EGFR TKIs Extend PFS in Patients with Kinase Domain Mutations

GBM Trial<sup>1</sup>

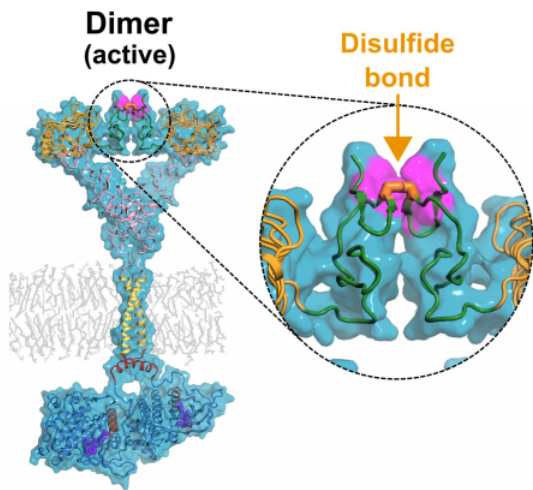


NSCLC Trial<sup>2</sup>

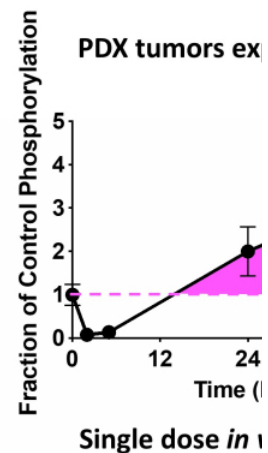
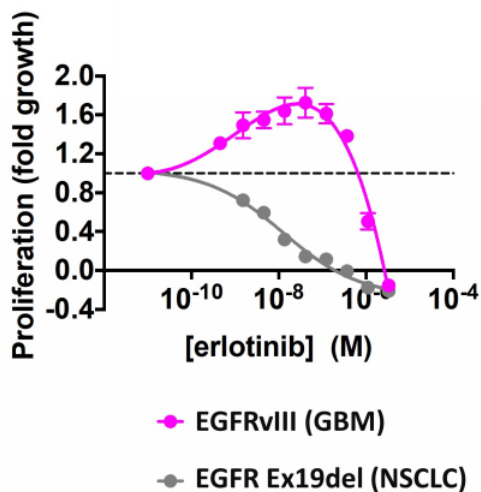


# Black Diamond Revealed the Potential for Unwanted Paradoxical Activity in GBM Mutations by Reversible EGFR TKIs

The oncogenic conformation of mutant EGFR in GBM is a locked dimer



Reversible TKIs can stimulate the activity of mutant EGFR

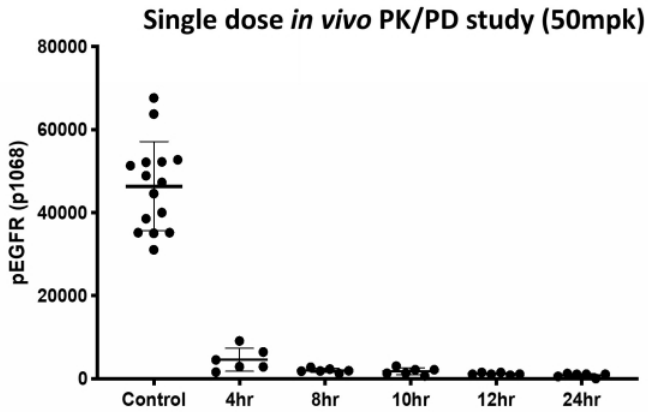


Inhibitors against EGFR mutants in GBM should be potent, selective & *irreversible* to avoid paradoxical activity

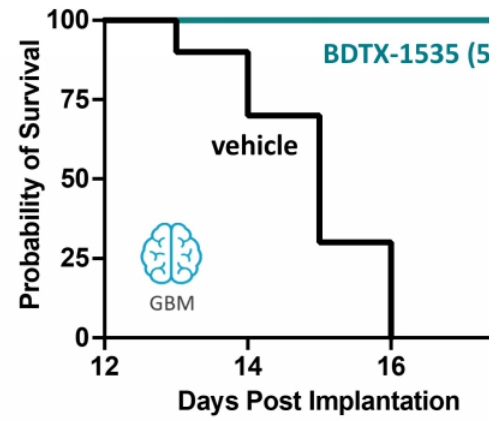


# BDTX-1535 Addresses Unique Pharmacology of EGFR Mutations in GB Achieve Sustained Inhibition and Activity in Preclinical Models

## Complete & sustained inhibition of pEGFR/pERK



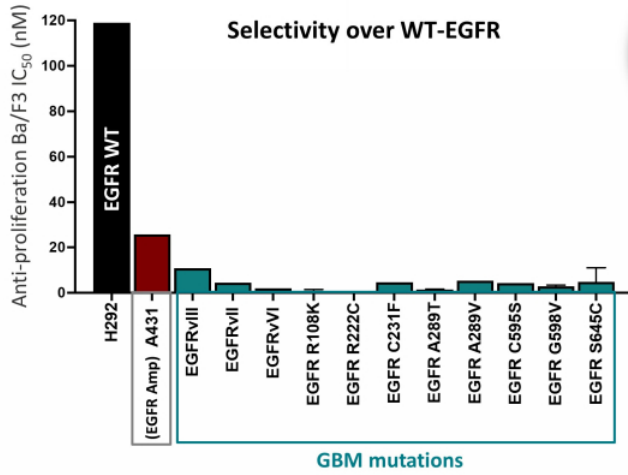
## Increased survival of intracranial P



Average oral unbound brain fraction ( $K_{p_{uu}}$ ) = 0.55 in Rats

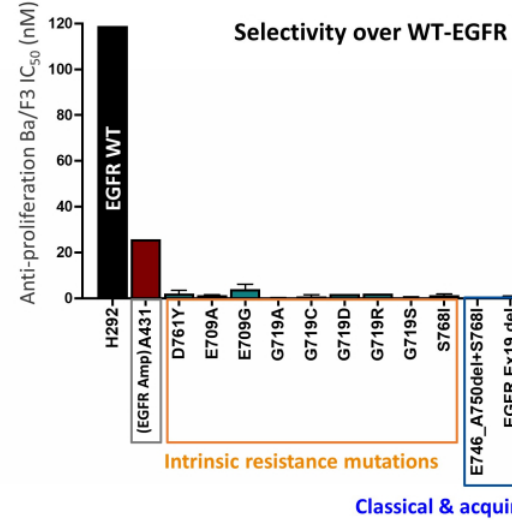
# BDTX-1535 Optimized to Address a Wide Range of Oncogenic EGFR Mutations and Amplification in GBM and NSCLC

## Potency against EGFR variants and mutations prevalent in GBM



Average IC<sub>50</sub> = 3.8 nM

## Potency against EGFR mutations intrinsic resistance and acquired resistance

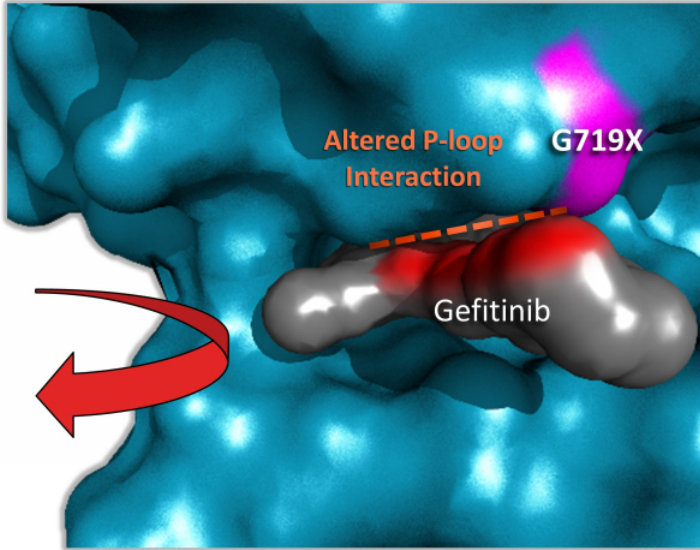


Average IC<sub>50</sub> = 3.5 nM

# BDTX-1535 Designed to Potently Inhibit EGFR Intrinsic and Acquired Resistance Mutations in NSCLC

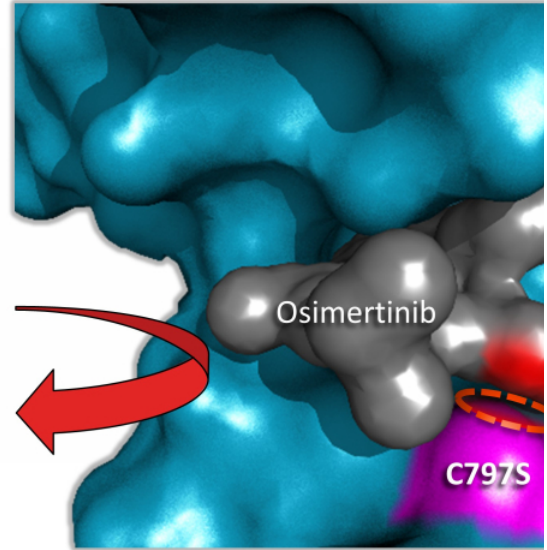
## Intrinsic Resistance Mutations

Designed for potent & selective inhibition across mutant families



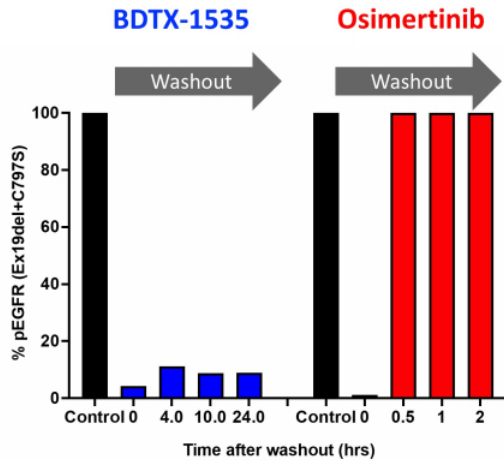
## Acquired Resistance Mutation

Designed to covalently target C797S

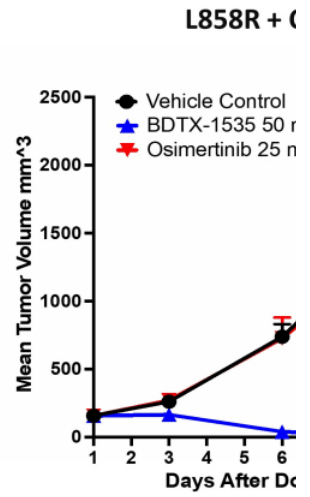
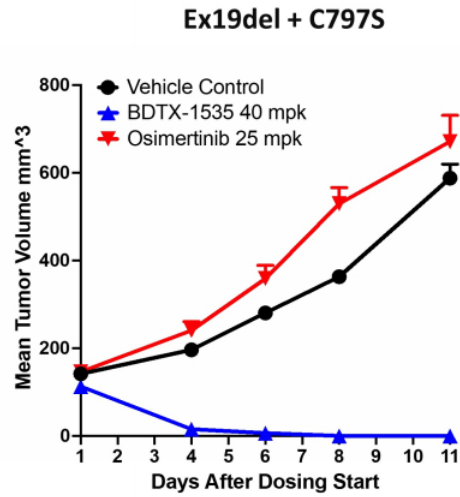


# BDTX-1535 Achieves Dose-dependent Tumor Regression in EGFR Mouse Models, Including Acquired Resistance Mutation C797S

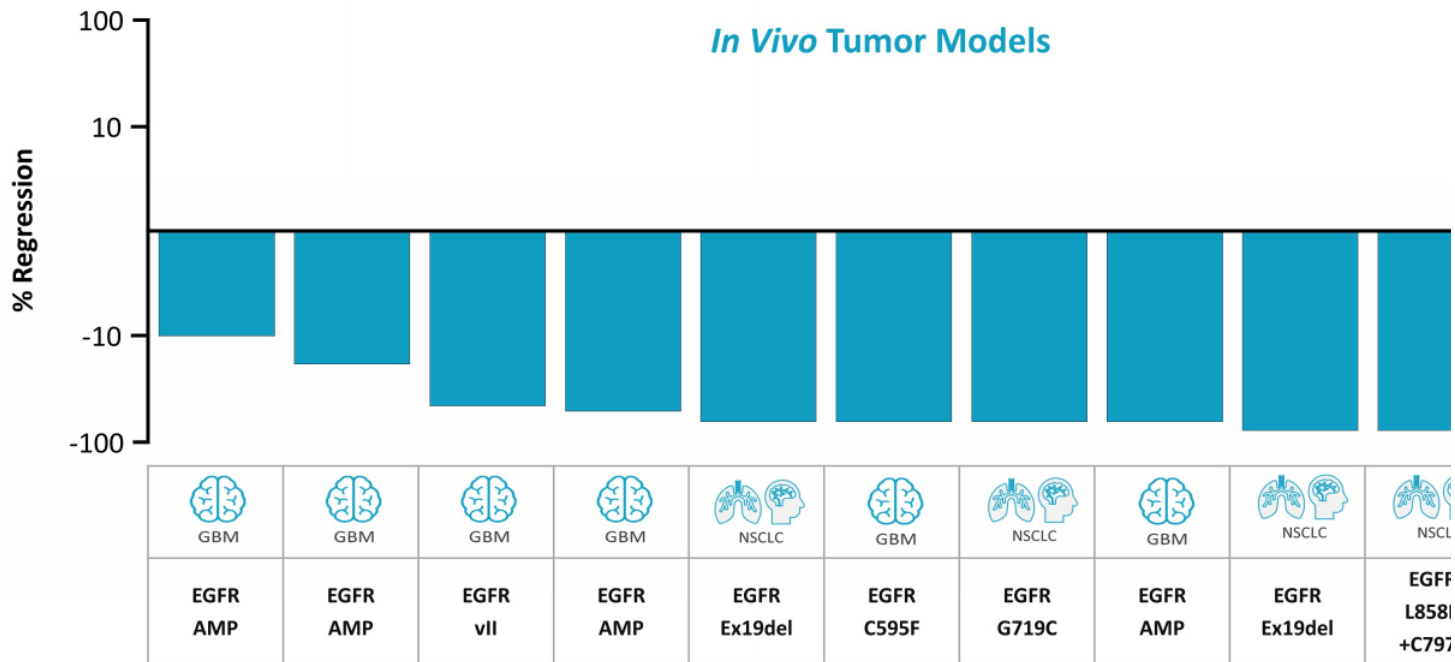
**BDTX-1535 retains irreversible binding against C797S mutant**



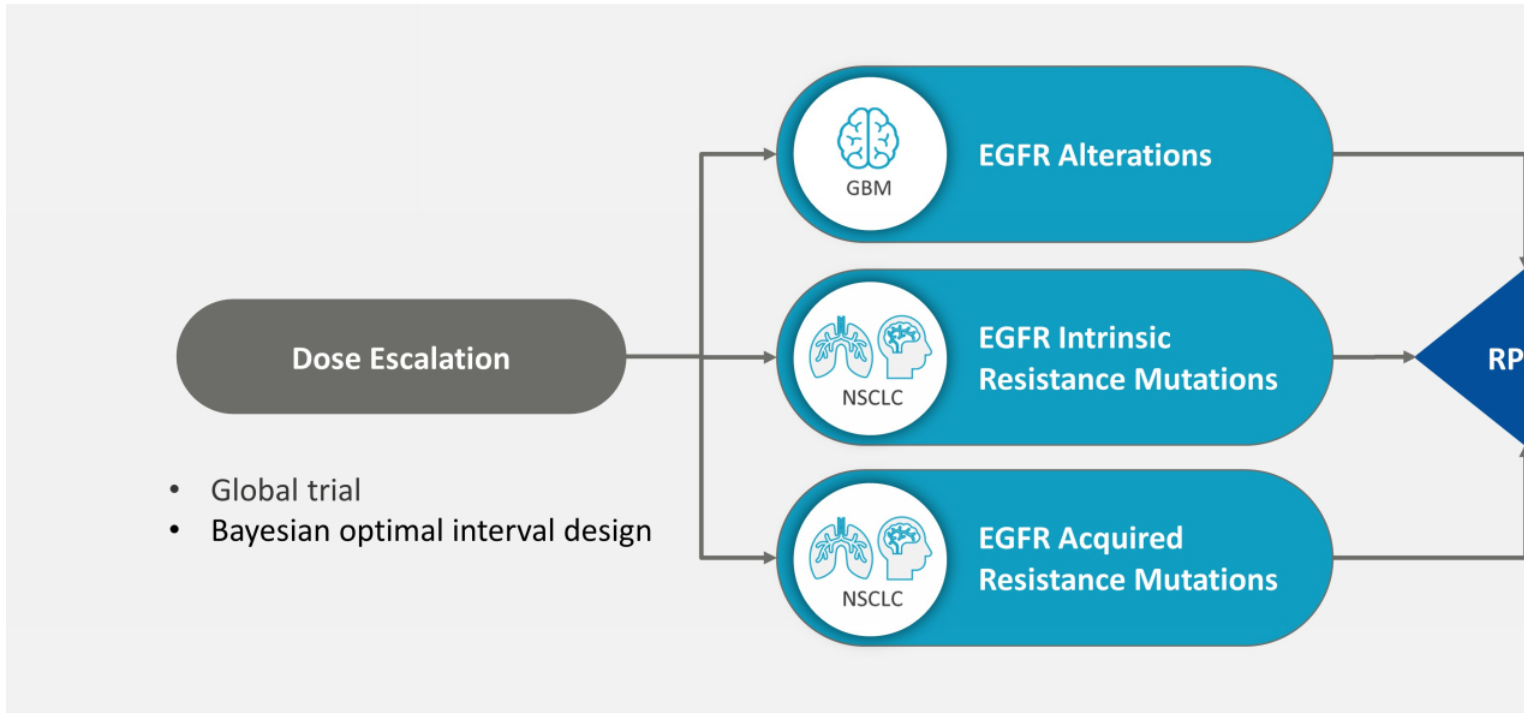
**BDTX-1535 demonstrates dose-dependent tumor regression in Ex19del + C797S and L858R + C797S tumor models**



# BDTX-1535 Promotes Regression Across Range of GBM & NSCLC Tumors Expressing MasterKey EGFR Mutations & EGFR Amplification

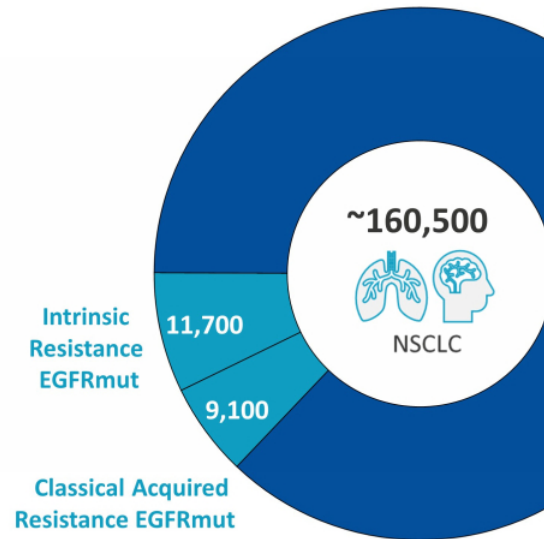
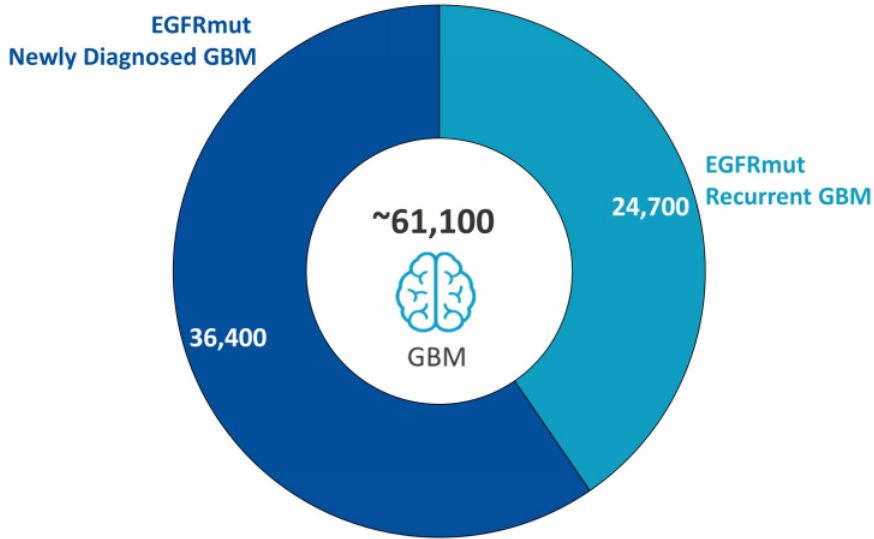


# BDTX-1535: Focused, Biomarker-Driven First-in-Human Phase 1 Study



# Large Addressable Patient Population Harboring MasterKey Mutations GBM and NSCLC

## Addressable Patient Population (US / EU / Japan / China)



Sources: Epidemiology data from EvaluatePharma

# BDTX-1535 is Well Positioned to Address Unmet Needs in EGFR Muta GBM/NSCLC



## Potent & selective inhibition of EGFR mutations (Avg $IC_{50}$ ~3nM) that drive intrinsic & acquired resistance to current generation TKIs

- Irreversible inhibition of GBM mutations to avoid paradoxical activation
- Irreversible binding to C797 and C797S acquired resistance in NSCLC
- Regression across panel of *in vivo* tumor models harboring EGFR mutations in GBM



## Robust brain penetration to treat patients with EGFR mutations and CNS tumors


- Unbound brain fraction ( $K_{p_{uu}}$ ) = 0.55 in rat; activity demonstrated in intracranial GBM



## Favorable drug like properties

- Prolonged blood stability
- Projected  $t_{1/2}$  of 15 hours for QD dosing



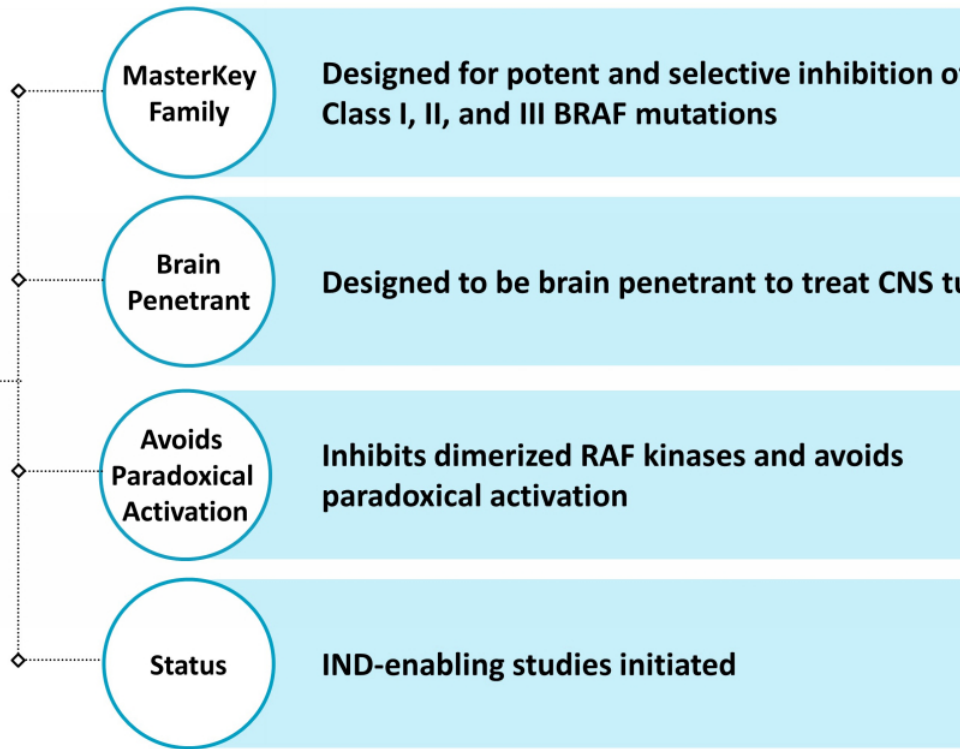


**BDTX-4933**

Brain-Penetrant Inhibitor of Class I, II, & III MasterKey Oncogenic BRAF Mutations



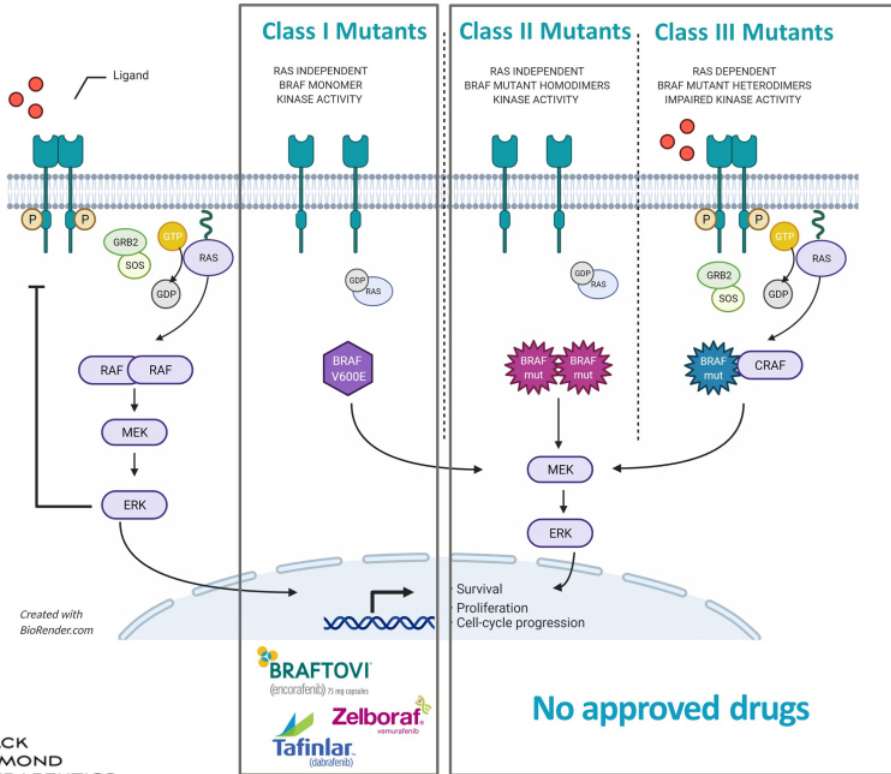
# BDTX-4933: Oral, Brain Penetrant Inhibitor of Oncogenic BRAF Mutations



# BRAF Alterations Drive Oncogenesis Through Hyperactivation of the MAP Kinase Pathway

NORMAL RAS/BRAF SIGNALING

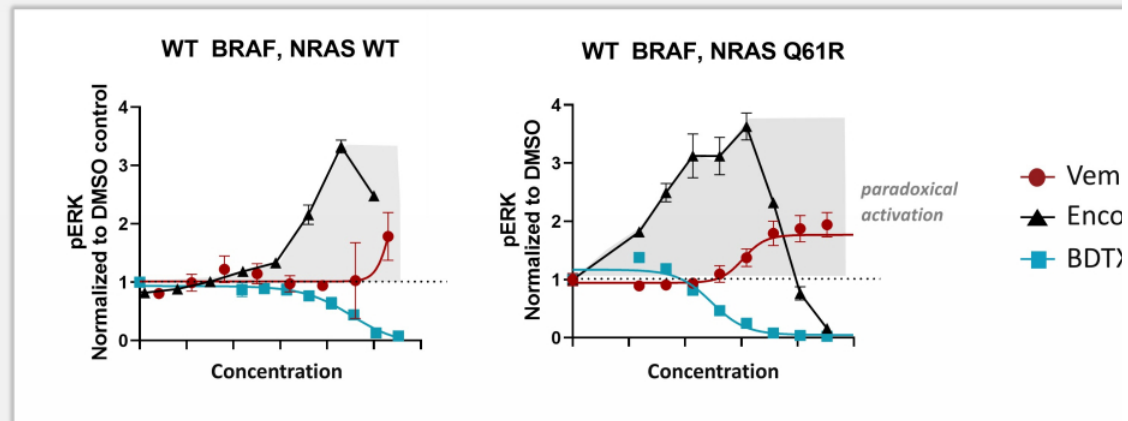
ABERRANT BRAF SIGNALING



- MAPK signaling is a central regulating cellular proliferation, and survival
- Hyperactivation responsible human cancer cases
- Activating BRAF alterations with various cancers including melanoma and NSCLC
- Currently approved BRAF inhibitors address Class I V600 mutant CNS activity

# BDTX-4933 Designed to Deliver Superior Activity by Avoiding Paradoxical Activation Independent of Context

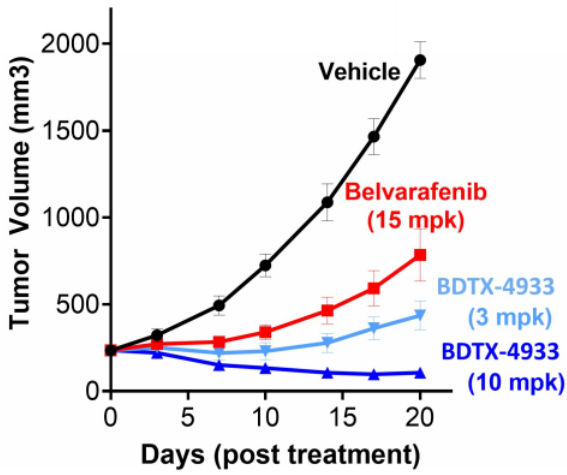
## Avoidance of Paradoxical Activation



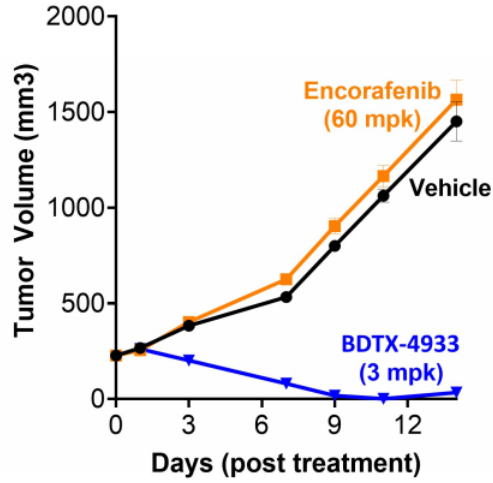
- Paradoxical activation occurs through activation of the non-inhibited RAF molecule in dimer —Limits efficacy through secondary malignancies and/or cutaneous toxicities
- Approved BRAF inhibitors demonstrate paradoxical activation
- Some investigational “paradox breaker” agents demonstrate context-dependent paradoxical act

# BDTX-4933 Exhibits Strong Anti-Tumor Activity Across All BRAF Mutant Classes in *In Vivo* Models

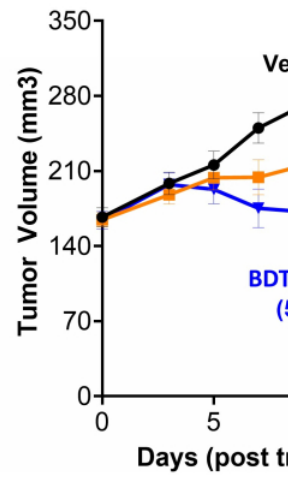
**BRAF Class I**  
Mutant Tumor Model



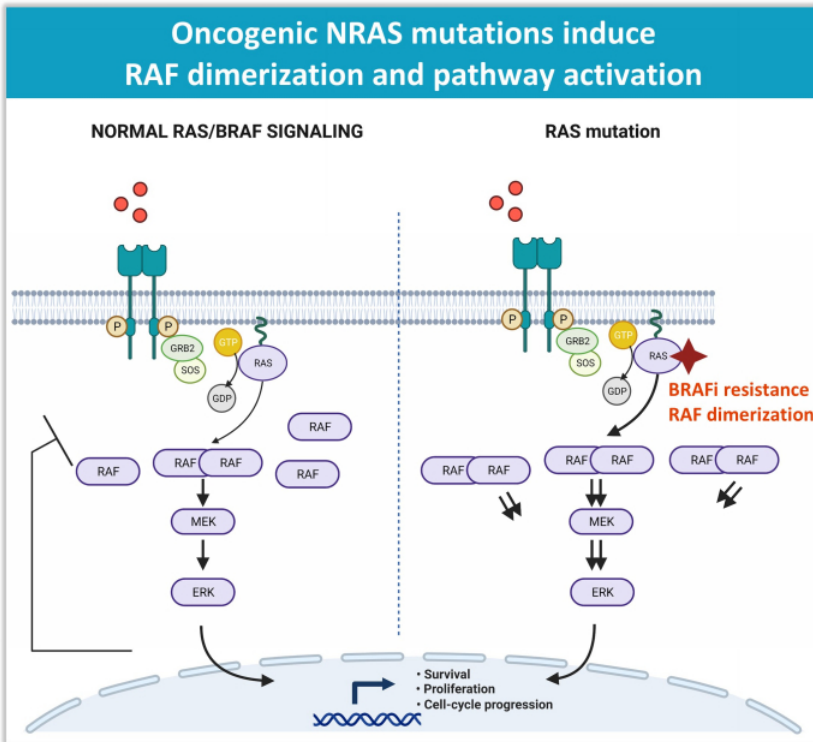
**BRAF Class II**  
Mutant Tumor Model



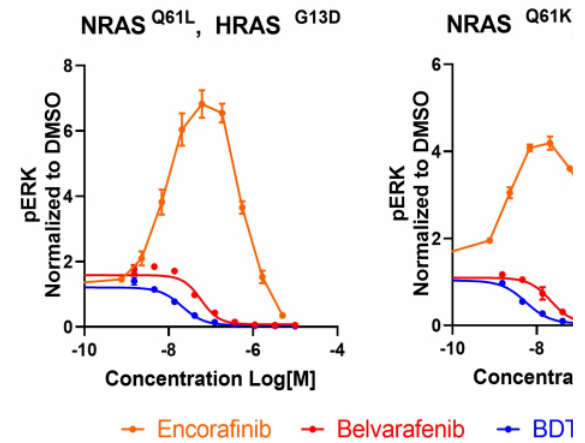
**BRAF C**  
Mutant Tumor Model



# NRAS-mutant Driven Cancers: Additional Clinical Opportunity for BDT

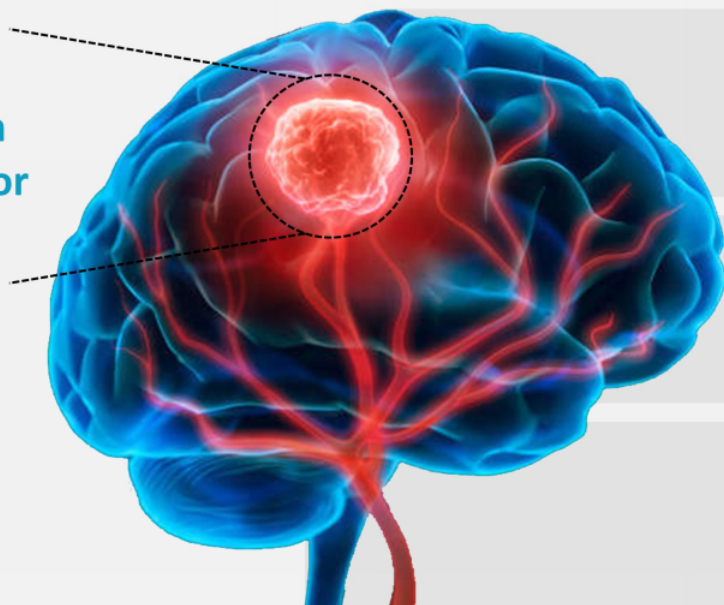


- NRAS-mutant melanoma represent ~2%
- Acquired NRAS mutations associated with BRAFi resistance and brain metastases
- Clinical proof of concept: Belvarafenib 44% in NRAS-mutant melanoma trial



## BDTX-4933 Designed to be Brain Penetrant to Treat CNS Disease

Brain  
Tumor

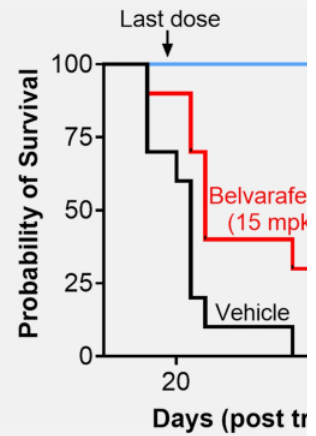
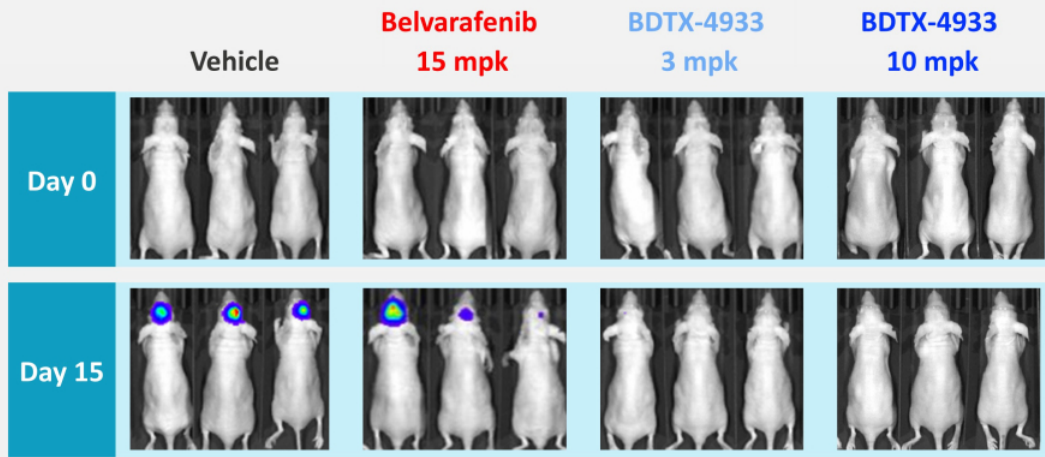


- CNS metastasis occurs in ~30-40%<sup>1</sup> of driven cancers
  - ~17,000<sup>2</sup> patients/year in the US
- BRAF mutations drive primary CNS tumors (e.g., glioma) in ~1,500<sup>2</sup> patients/year
- Currently approved therapies are not penetrant



# BDTX-4933 Is Brain Penetrant and Exhibits Robust Activity in Treating C Disease in *in vivo* models

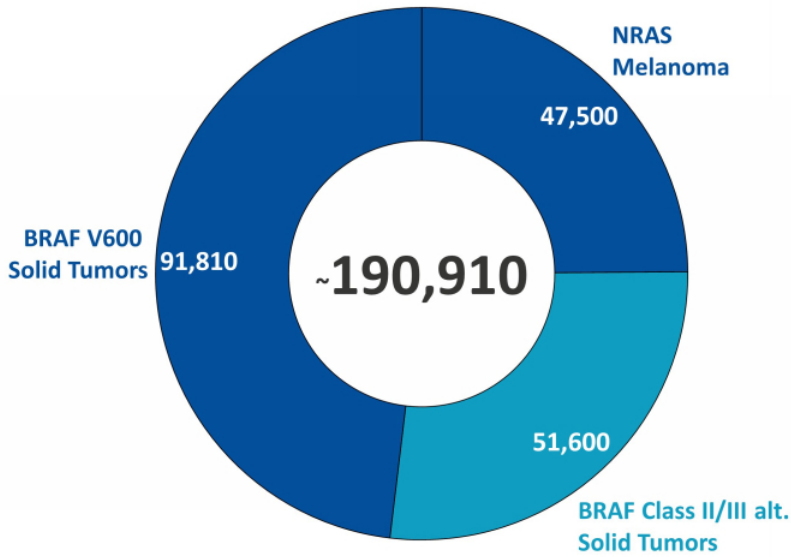
## BDTX-4933 prolongs survival in BRAF-V600E intracranial tumor model



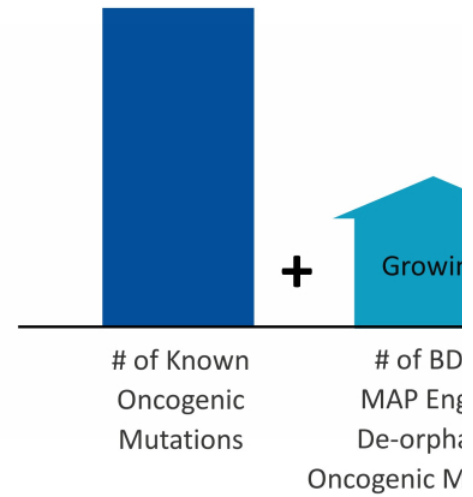


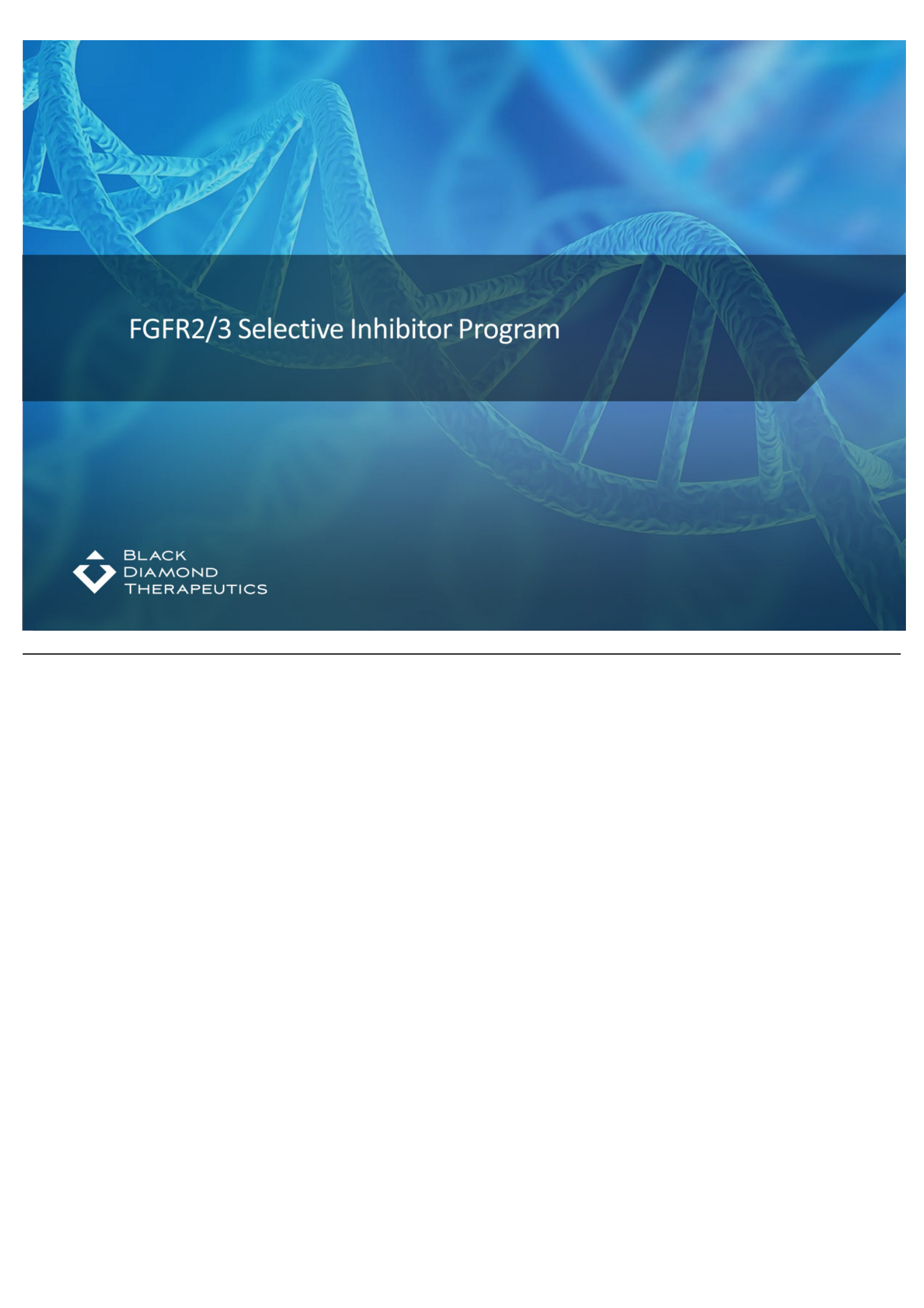
# BDTX-4933: Potential *Best-in-Class*, Masterkey Inhibitor For A Greater Of Patients With Overlooked Oncogenic Mutations

Addressable US / EU / JP Patient Population



BDTX Is Growing The Addressable Patient Population Through De-Orphaning of Overlooked Mutations

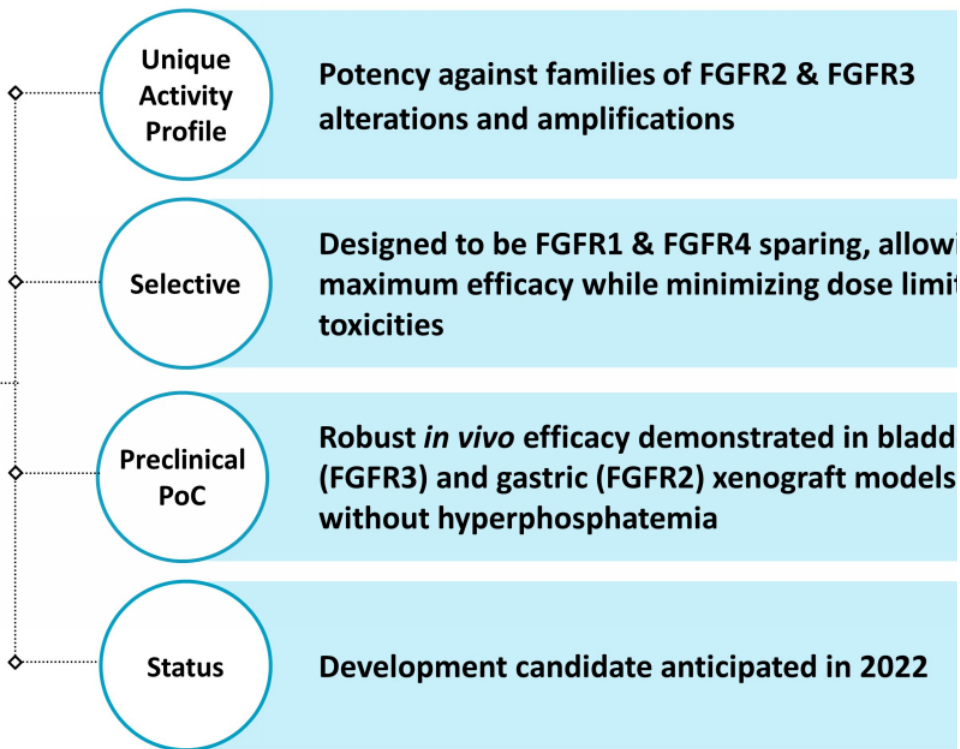


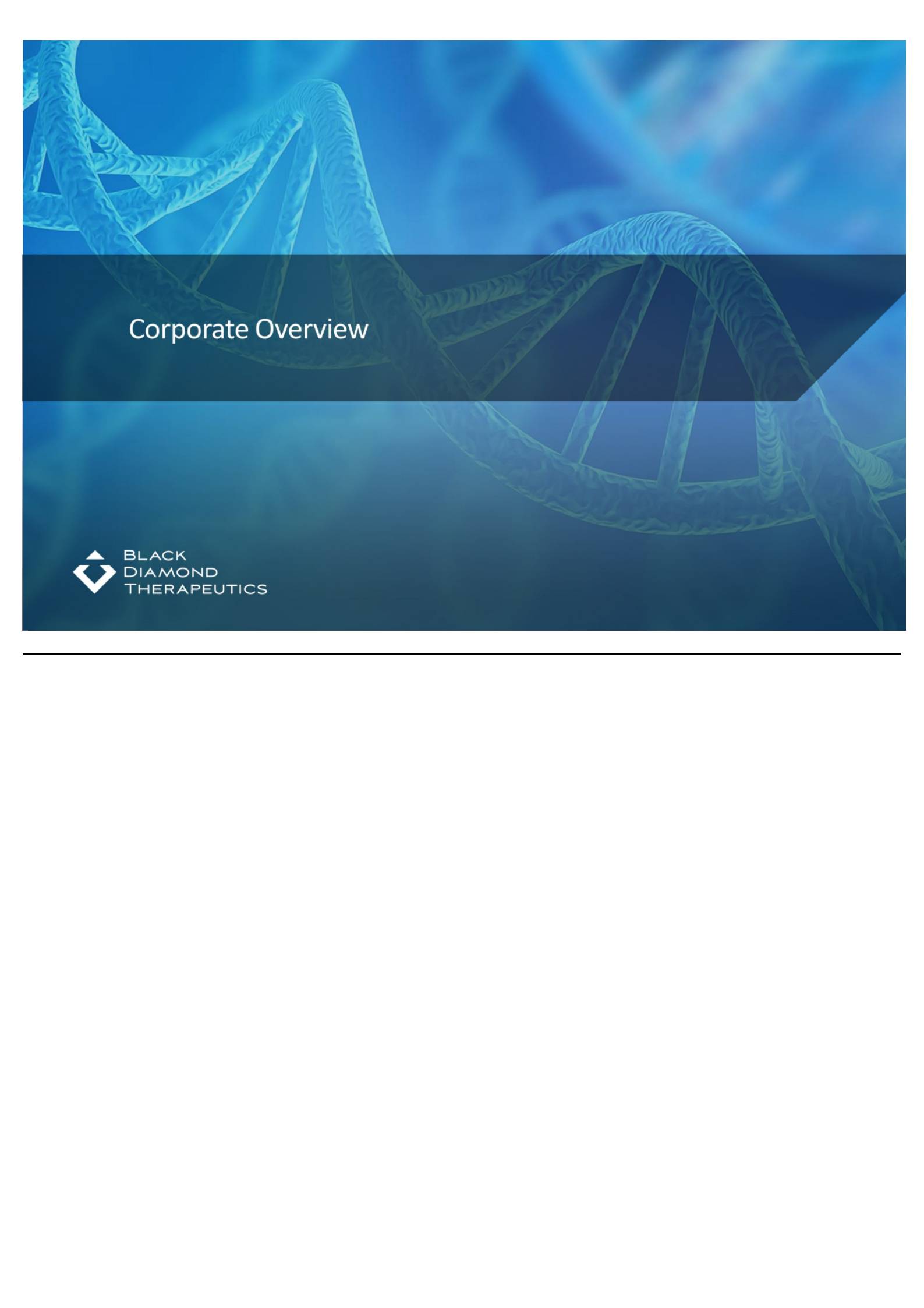


# FGFR2/3 Selective Inhibitor Program



# BDTX-FGFR: Oral, Selective Small-Molecule FGFR2 & FGFR3 Inhibitor





## Corporate Overview



# Deep Oncology and Small Molecule Drug Discovery and Development Experience

## Leadership Team



**David M. Epstein, Ph.D.**  
President & CEO



**Liz Buck, Ph.D.**  
Chief Scientific Officer



**Fang Ni, Pharm.D.**  
Chief Business Officer and  
Chief Financial Officer



**Brent Hatzis-Schoch, J.D.**  
COO and General Counsel



**Elizabeth L. Montgomery**  
Chief People Officer



**Karsten Witt, M.D.**  
Interim Chief Medical Officer



## Board of Director

**Ali Behbahani, M.D.**  
General Partner, NEA

**Kapil Dhingra, M.D.**  
Managing Member, KAPital C

**Wendy Dixon, Ph.D.**  
Former Global Marketing Hea

**David M. Epstein, Ph.D.**  
CEO, Black Diamond Therapeu

**Bob Ingram – Chairman**  
General Partner, Hatteras Ver

**Sam Kulkarni, Ph.D.**  
CEO, CRISPR Therapeutics AG

**Alex Mayweg, Ph.D.**  
Managing Director, Versant V

**Garry Menzel**  
CEO, TCR2

**Rajeev Shah**  
Managing Director, RA Capital

**Mark Velleca, M.D., Ph.D.**  
CEO, StrideBio, Inc.

# Cash Runway Expected to Enable Multiple Upcoming Milestones

## Upcoming program milestones

- BDTX-1535 clinical data update in 2023
- BDTX-4933 IND filing in 1H 2023
- FGFR program development candidate nomination in 2022
- Undisclosed program development candidate nomination in 2023

## Strong balance sheet

- \$209mm in cash, cash equivalents and investments as of December 31, 2021
- Cash runway into 3Q 2024



# Expanding the Reach of Precision Medicine Through the Development of MasterKey Therapies

**MasterKey** therapies address oncogene mutation families; providing precision oncology medicines to greater numbers of patients with genetically defined tumors

Clinical and late-preclinical pipeline of **MasterKey** inhibitors derived from our MAP drug discovery engine targeting oncogenic ErbB1/2, BRAF, FGFR2/3 and additional undisclosed targets

**BDTX-1535**: a brain-penetrant, mutant selective, irreversible inhibitor of EGFR for the treatment of patients with GBM and NSCLC driven by EGFR intrinsic and acquired resistance mutations

**BDTX-4933**: a brain-penetrant inhibitor of Class I, II, and III oncogenic BRAF mutations, currently in enabling studies

Our proprietary **MAP drug discovery engine** is designed to:

- Predict and validate novel oncogenic mutant families from population level tumor genomic data
- Pioneer mutant family conformation-based MasterKey drug design
- Provide opportunities beyond oncology and small molecules



## Thank You

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