

DEFEAT DEGENERATION

CORPORATE OVERVIEW
FEBRUARY 2024



DISCLAIMERS

Forward-Looking Statements. This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements do not relate strictly to historical or current facts and they may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expected,” “forecast,” “intend,” “may,” “plan,” “potential,” “possible,” “future,” “will” and other words and terms of similar meaning. All statements other than statements of historical facts contained in this presentation, including, without limitation, statements regarding future results of operations and financial position of Denali Therapeutics Inc. (“Denali” or the “Company”); Denali’s business strategy and business plans, expected progress and expansion, and expected key milestones for Denali’s therapeutic portfolio in 2023 and beyond; Denali’s ability to execute on its tailored commercial strategies and accelerate commercial launch readiness; expectations relating to the potential for Denali’s product candidates to treat various neurodegenerative diseases including MPS I, MPS II (Hunter Syndrome), MPS IIIA (Sanfilippo Syndrome), ALS, MS, PD, AD, FTD-GRN, UC, and related peripheral inflammatory diseases, planned preclinical studies and clinical trials and the expectations regarding the timing and availability of results and data from such studies and trials; plans, timelines, expectations, breadth of indications, and current and future therapeutic and commercial opportunities related to Denali’s Transport Vehicle (TV) platform, including its Enzyme Transport Vehicle (ETV), Antibody Transport Vehicle (ATV), Protein Transport Vehicle (PTV), and Oligonucleotide (OTV) technologies, and other programs enabled by these platforms, as well as potential targets and differentiation strategies; plans, timelines, and expectations relating to DNL310, including the timing and availability of data from the ongoing Phase 1/2 study and enrollment in the Phase 2/3 COMPASS study; plans, timelines, and expectations related to DNL126, including the timing and availability of data from the Phase 1/2 study; plans and expectations regarding DNL593; plans, timelines, and expectations relating to ATV:Abeta and its therapeutic potential; plans, timelines, and expectations relating to the Biogen-led development of DNL151, including enrollment in the Phase 2b LUMA trial; expectations relating to LRRK2 inhibitor DNL201 for the treatment of PD; plans, timelines, and expectations related to DNL343, including enrollment in the ongoing Phase 2/3 HEALEY ALS platform trial; Denali’s and Sanofi’s plans, timelines, and expectations related to DNL788 and DNL758, including with respect to the availability of data and the initiation of future clinical trials; the potential benefits and results of the collaborations with Denali’s partners, including Biogen, Sanofi, and Takeda, and expected milestone payments; Company priorities, regulatory approvals, timing and likelihood of success and expectations regarding collaborations; and plans and expectations regarding Denali’s global organization and clinical operations and the expected timing and likelihood of success of its commercial growth, are forward-looking statements. Denali has based these forward-looking statements largely on its current expectations and projections about future events.

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OUR PURPOSE: **DEFEAT DEGENERATION**



LYSOSOMAL STORAGE DISEASES

Dominic, living with MPS II



ALS/FTD

Seth, living with ALS



PARKINSON'S DISEASE

Allan, living with PD



ALZHEIMER'S DISEASE

Denali Team at AD Walk 2023



Denali

The name captures the formidable challenges in fighting neurodegenerative diseases but also the unprecedented opportunities enabled by new scientific insights and technologies. With a relentlessly committed team and rigorous effort, breakthroughs appear to be within reach.

PATH TO DEFEAT DEGENERATION

DISCOVER

Invent medicines and platforms using our deep **scientific** expertise in neurodegeneration biology and the blood-brain barrier

DEVELOP

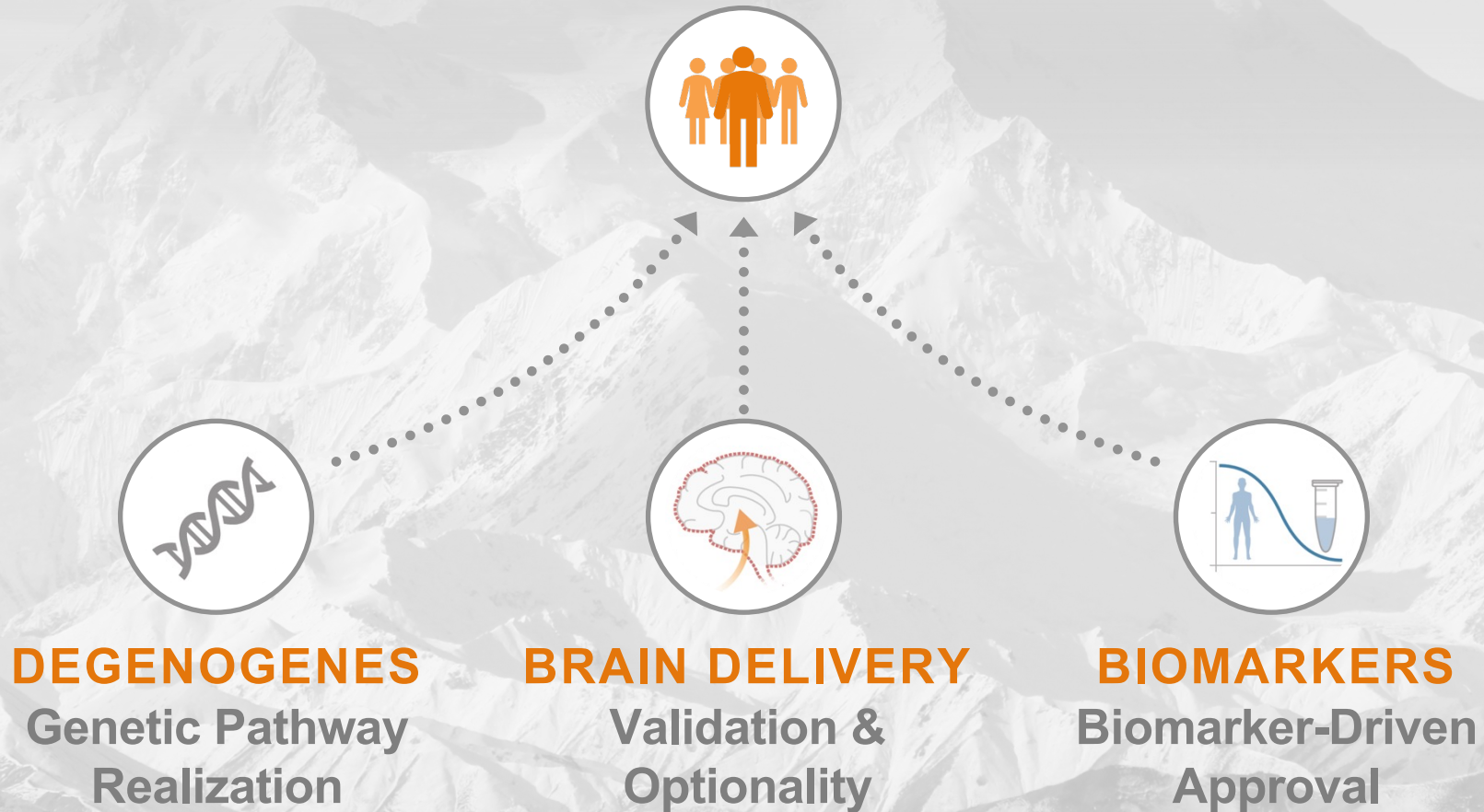
Advance broad **clinical** portfolio for patients with neurodegenerative and lysosomal storage diseases

DELIVER






Bring medicines to patients and achieve **commercial** success, continuing to fuel pipeline

APPROACH TO DEFEAT DEGENERATION

Rigorously applying our scientific principles to increase the likelihood of success



DEVELOPMENT PORTFOLIO: COMMON & RARE DISEASES

DRUG CANDIDATE*	DISEASE INDICATION	DEVELOPMENT STAGE				PARTNER
		IND-ENABLING	EARLY	MID	LATE	
Neurodegeneration and Lysosomal Storage Diseases						
Tividenofusp alfa / DNL310 (ETV:IDS)	MPS II (Hunter)	[Orange bar spanning IND-ENABLING, EARLY, MID, LATE]				
DNL343 (eIF2B activator)	ALS	[Blue bar spanning IND-ENABLING, EARLY, MID, LATE]				
SAR443820 / DNL788 (RIPK1 inhibitor)	ALS	[Blue bar spanning IND-ENABLING, EARLY, MID, LATE]				
	Multiple sclerosis	[Blue bar spanning IND-ENABLING, EARLY, MID]				
BIIB122 / DNL151 (LRRK2 inhibitor)	Idiopathic Parkinson's Disease	[Blue bar spanning IND-ENABLING, EARLY, MID, LATE]				
TAK-594 / DNL593 (PTV:PGRN)	FTD-GRN	[Orange bar spanning IND-ENABLING, EARLY]				
DNL126 (ETV:SGSH)	MPS IIIA (Sanfilippo)	[Orange bar spanning IND-ENABLING, EARLY]				
DNL622 (ETV:IDUA)	MPS I (Hurler)	[Orange bar spanning IND-ENABLING]				
ATV:Abeta	Alzheimer's disease	[Orange bar spanning IND-ENABLING]				
OTV:MAPT	Alzheimer's disease	[Orange bar spanning IND-ENABLING]				
OTV:SNCA	Parkinson's disease	[Orange bar spanning IND-ENABLING]				
Peripheral Inflammatory Disease						
SAR443122 / DNL758 (RIPK1 inhibitor)	Ulcerative colitis	[Blue bar spanning IND-ENABLING, EARLY, MID]				

■ Transport Vehicle Programs
 ■ Small Molecule Programs
 ■ 50/50 US Commercial
 ■ Royalty

Broad, diverse, and differentiated portfolio, including multiple TV-enabled and small molecule programs in discovery

SUSTAINABLE VALUE GENERATION: MULTIPLE OPPORTUNITIES



**Potential to Reach \$10B in Peak Sales*
7 Current Clinical Programs**

Peak Sales	Program	Indication
>\$5B	DNL151	PD
\$1-5B	DNL788	ALS/MS
	DNL343	ALS
	DNL758	UC
Up to \$1B	DNL310	MPS II
	DNL126	MPS IIIA
	DNL593	FTD-GRN

● TV-Enabled ● Small Molecule



**Potential to Reach >\$10B in Peak Sales*
5 Discovery Programs in AD and PD**

Peak Sales	Program	Indication
>\$5B	ATV:Abeta	AD
	OTV:MAPT	AD
	OTV:SNCA	PD
	ETV:GCase	Gaucher/PD
	ATV:TREM2	AD
\$1-5B	Additional ETV/OTV	Various
Up to \$1B	–	–

Portfolio evolution to focus on TV-enabled programs in common neurodegenerative diseases

* Denali estimates of potential peak sales; PD – Parkinson’s disease; ALS – amyotrophic lateral sclerosis; MS – multiple sclerosis; UC – ulcerative colitis; MPS – Mucopolysaccharidosis; FTD-GRN – Frontotemporal dementia-granulin; AD – Alzheimer’s disease

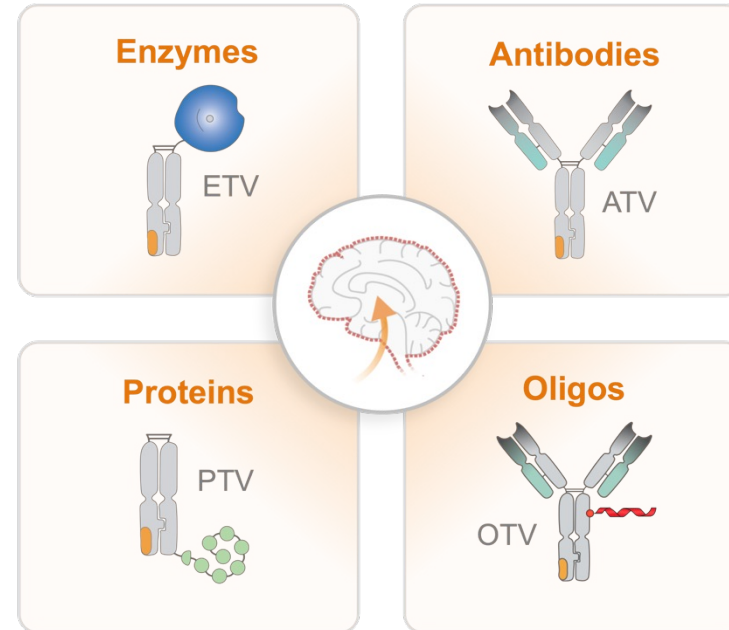
TRANSPORT VEHICLE (TV) PLATFORM

PIONEERING BBB-CROSSING TECHNOLOGY FOR BRAIN DELIVERY

Discovery Milestones

- 2011: Impact of TfR affinity on BBB crossing¹
- 2013: Addressing liabilities of targeting TfR²
- 2016: CD98hc characterization as BBB target³
- 2020: TV publication of invention (ATV)⁴
- 2020: TV-enabled enzyme delivery (ETV)⁵
- 2021: TV-enabled protein delivery (PTV)⁶
- 2022: ETV differentiated brain delivery⁷
- 2023: TV-enabled oligo delivery (OTV)⁸

Our Transport Vehicle (TV)



Key TV Achievements

392 Patents and Applications

8 Top-Tier Publications

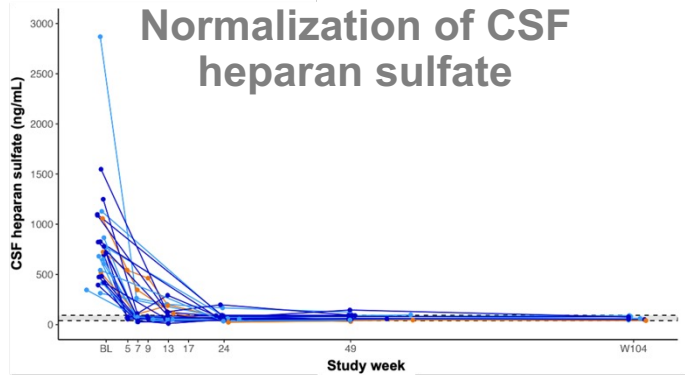
3 Clinical Programs

13 Preclinical Programs

We are leading the field in discovery and development of BBB-crossing technology to revolutionize the treatment of neurodegenerative diseases

TRANSPORT VEHICLE (TV): SOLVING THE BBB CHALLENGE

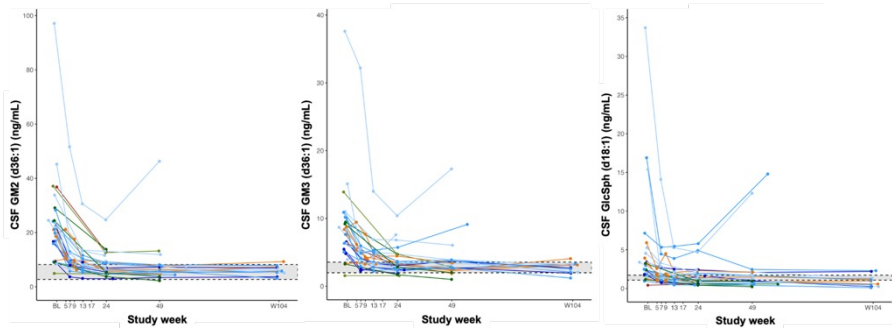
Substrate Correction



Cellular Correction



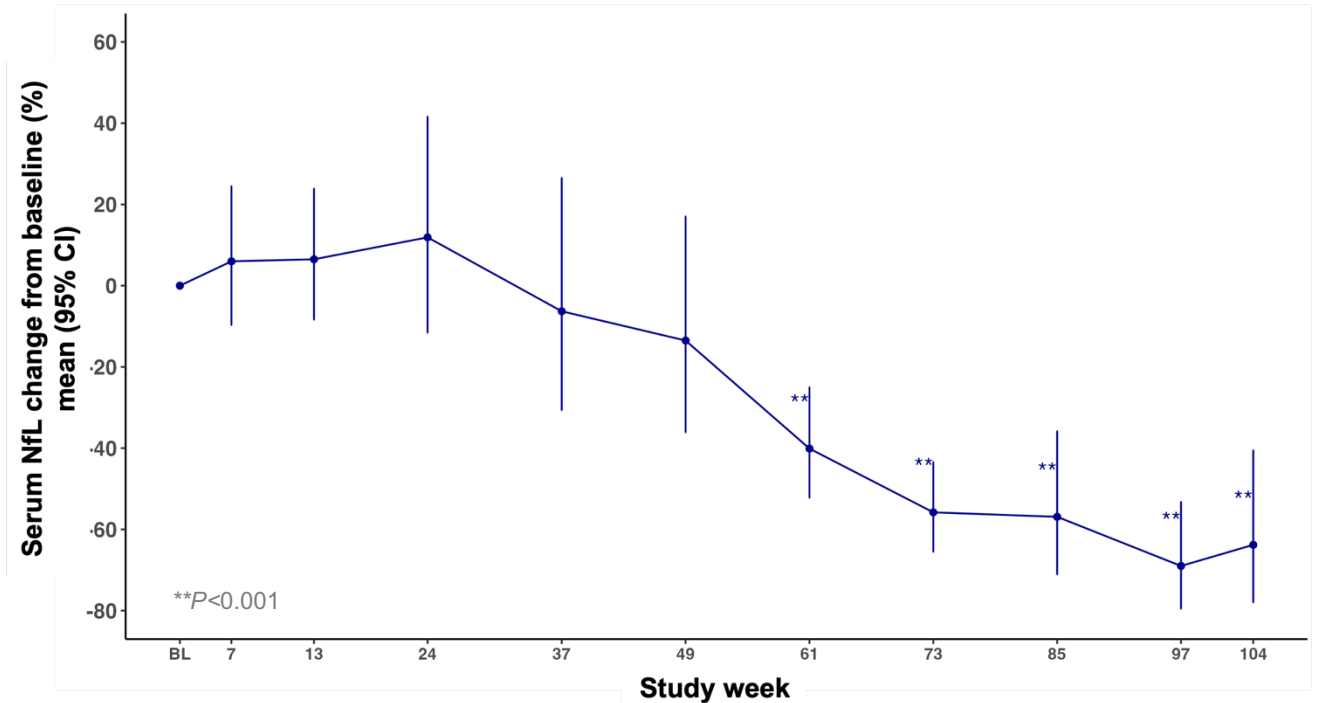
Near Normalization of Biomarkers of Lysosomal Function



Neurodegeneration Correction



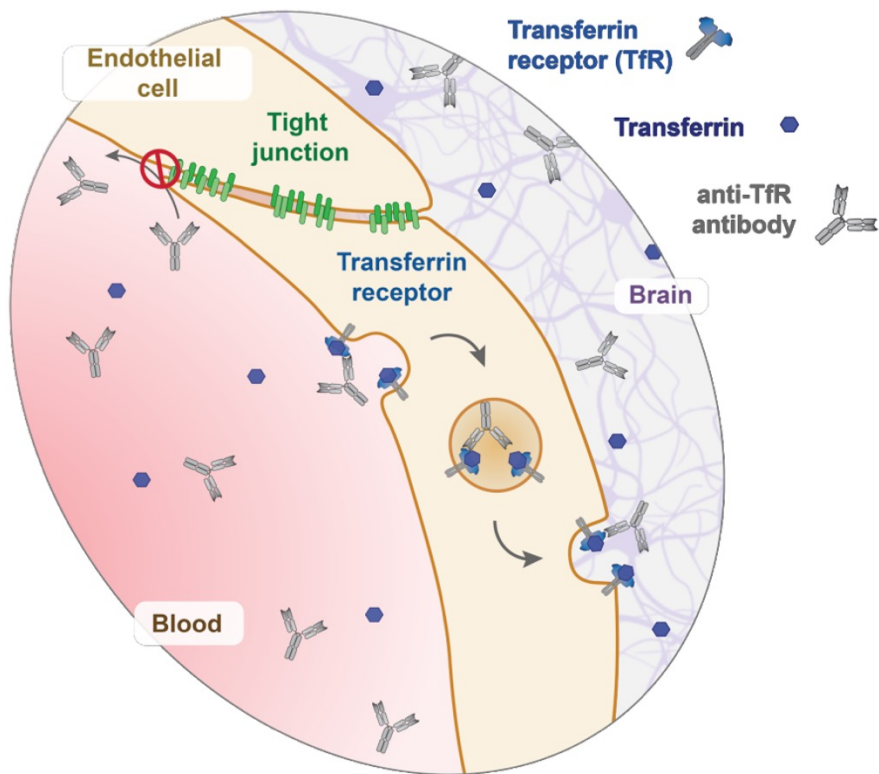
Robust Reduction in Neurofilament Light (NfL), a Key Marker of Neurodegeneration



TV proof of concept for targeting TfR achieved in DNL310 Phase 1/2 study for MPS II

LEADERSHIP IN THE BBB DELIVERY SPACE

TV Technology Leverages Receptor Mediated Transcytosis Into the Brain



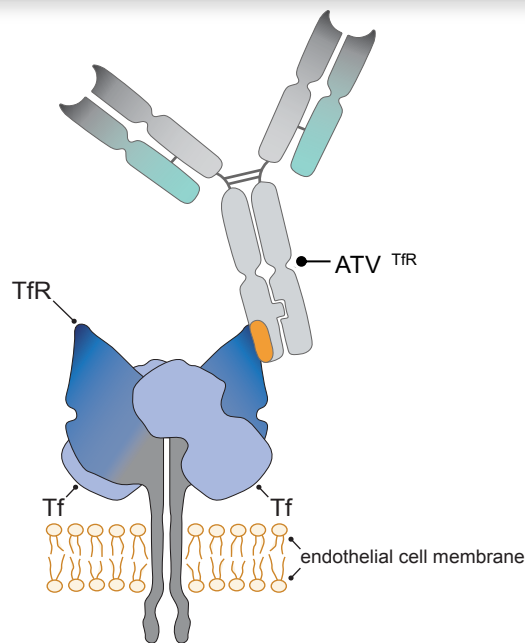
Transferrin Receptor (TfR) Most Clinically Advanced

SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

BLOOD-BRAIN BARRIER

Brain delivery of therapeutic proteins using an Fc fragment blood-brain barrier transport vehicle in mice and monkeys

May 2020



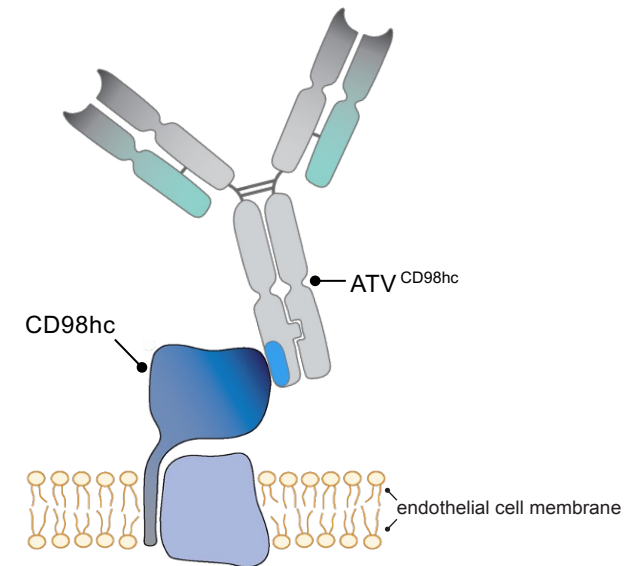
CD98hc Amino Acid Transporter TV Platform Expansion

nature communications

Article <https://doi.org/10.1038/s41467-023-40681-4>

CD98hc is a target for brain delivery of biotherapeutics

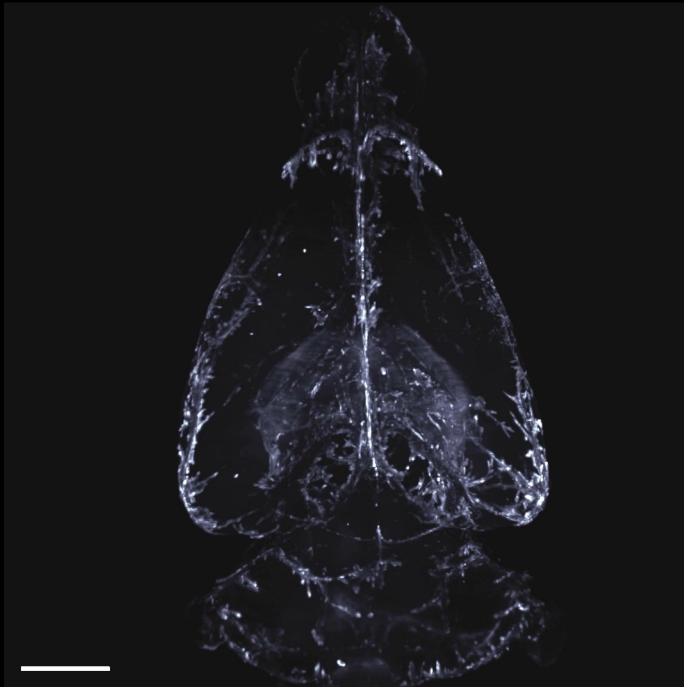
August 2023



We continue to invent differentiated BBB-crossing technologies that have the potential to optimize the target space

ATV ENABLES BROAD DISTRIBUTION THROUGHOUT THE BRAIN

Control IgG



ATV with TfR



ATV with CD98hc

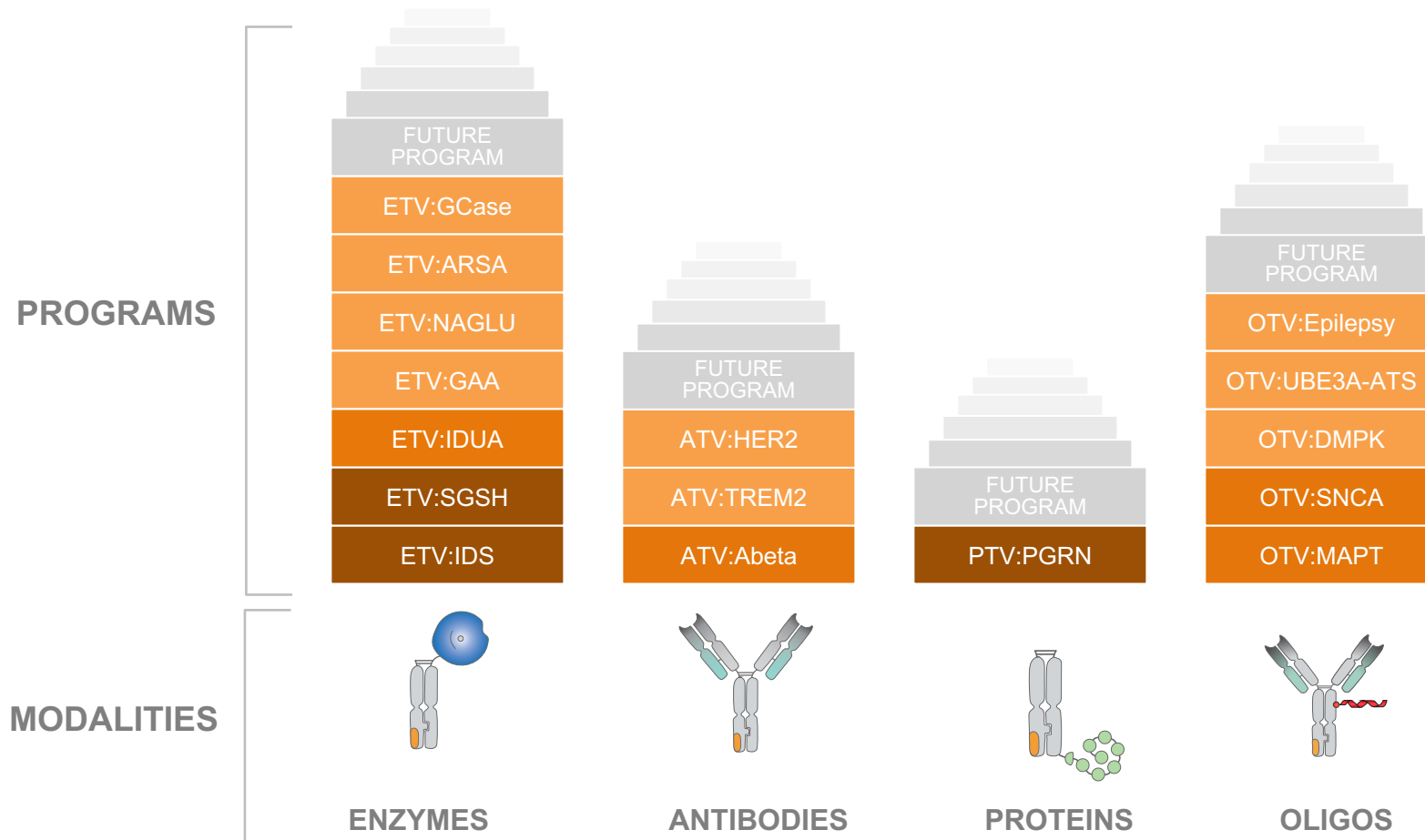


Tissue cleared brain movies

We continue to invent differentiated BBB-crossing technologies that have the potential to optimize the target space

DRIVING SUSTAINABLE VALUE CREATION WITH THE TV TECHNOLOGY

TRANSPORT VEHICLE (TV) PROGRAMS AND MODALITIES TARGETING THE TRANSFERRIN RECEPTOR (TfR)



CLINICAL
 IND-ENABLING
 DISCOVERY
 FUTURE PROGRAM

- Each TV modality is a platform opportunity
- Current focus on neurodegeneration and lysosomal storage diseases
- Future opportunities in oncology, infectious diseases, neuropsychiatry and pain
- New BBB receptors (CD98hc) further optimize the target space

PEAK 1

Current Clinical Pipeline

FOCUS ON CLINICAL EXECUTION AND COMMERCIAL READINESS

Four Late-Stage Clinical Trials



- Tividenofusp alfa (DNL310, ETV:IDS)*
- MPS II (Hunter syndrome)
- Complete enrollment in Phase 2/3 COMPASS in 2024



- DNL343 (eIF2B activator)*
- Amyotrophic lateral sclerosis (ALS)
- Complete enrollment in Phase 2/3 HEALEY in 2024



- SAR443820/DNL788 (RIPK1 inhibitor)
- Amyotrophic lateral sclerosis (ALS)
- Phase 2 HIMALAYA study
- Enrollment complete; topline data in 1H 2024

sanofi



- BIIB122/DNL151 (LRRK2 inhibitor)
- Parkinson's disease
- Phase 2b LUMA study enrolling

Biogen

ENZYME TRANSPORT VEHICLE (ETV) FRANCHISE OPPORTUNITY

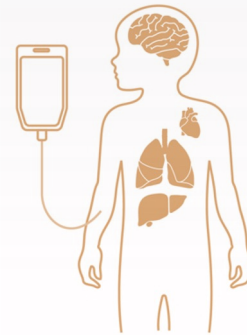
Lysosomal Storage Diseases (LSDs)

- Monogenic diseases (enzyme deficiency)
- 30,000 people with LSDs worldwide
- High likelihood (~90%) of historical ERT approvals¹
- Up to \$1B per indication²



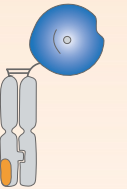
Large Unmet Need to Treat CNS Manifestations

- Approved ERTs partially address somatic symptoms and do not address CNS symptoms of LSDs
- Unmet need for ERTs that can treat body and brain



ETV Has the Potential to Treat the Body and Brain

- DNL310 clinical proof of concept achieved in MPS II³
- Apply learnings to accelerate development in other LSDs⁴

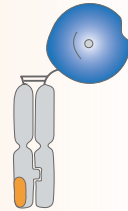


MPS IIIA DNL126 ETV:SGSH	PD, Gaucher ETV:Gcase	MLD ETV:ARSA
MPS IIIB ETV:NAGLU	MPS I ETV:IDUA	POMPE ETV:GAA

1. Denali estimates based on historical approvals of ERTs without a blood-brain crossing technology and designed to treat somatic manifestations of LSDs; 2. Denali estimates of potential peak sales; 3. Includes interim biomarker and other data from open-label Phase 1/2 study of DNL310 (ETV:IDS); 4. DNL310 (ETV:IDS) and DNL126 (ETV:SGSH) are in clinical development; other ETV programs are in earlier stages of development; **ERTs** – Enzyme Replacement Therapies; **CNS** – Central Nervous System; **ETV:IDS** – Enzyme Transport Vehicle: Idursulfase

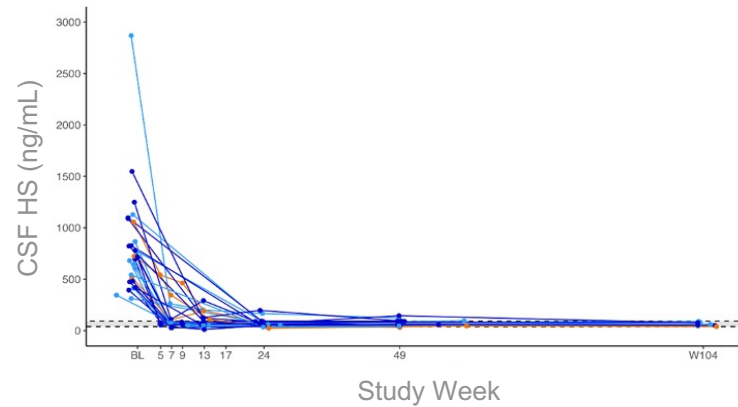
DNL310 (ETV:IDS): KEY INTERIM, OPEN-LABEL, PHASE 1/2 RESULTS

- Generally well tolerated; safety profile based on 33 participants (median treatment duration 100 wks)
- First and only therapy in development shown to normalize CSF HS and reduce NfL in MPS II
- Improvement in measures of hearing and behaviors most important to families



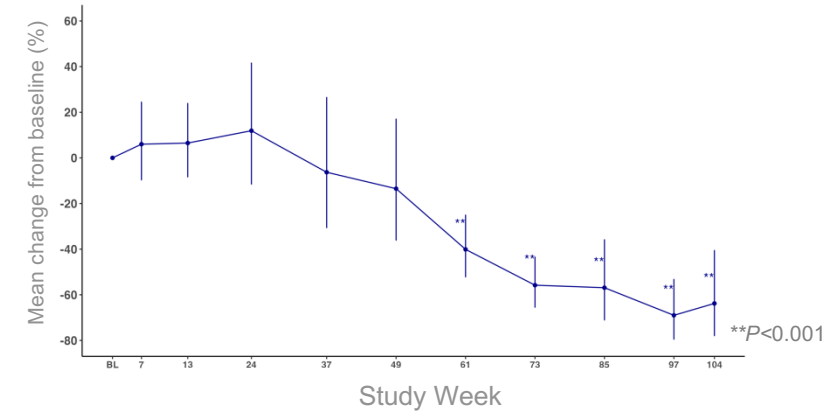
Normalization of CSF HS

Biomarker of neuronopathic disease



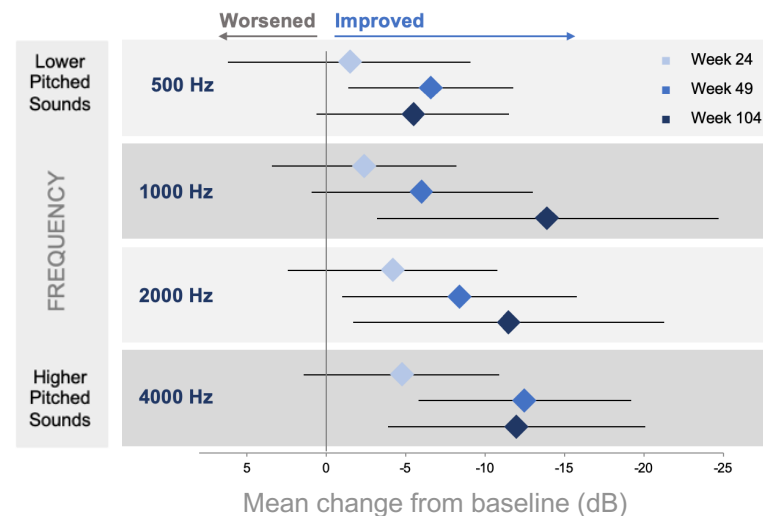
Robust Reduction in Serum NfL

Biomarker of neuronal damage



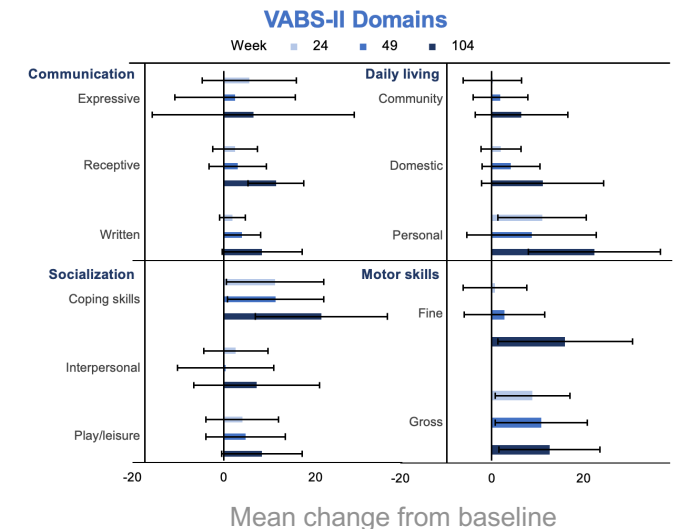
Improvement in Hearing

Auditory brainstem response



Improvement in Adaptive Behavior

VABS-II raw score



DEVELOPMENT AND REGULATORY PATH FOR DNL310 IN MPS II

Global Phase 1/2 (enrolling)

- Open-label study
- Up to 18 years of age
- 14 participants with more than 2 years of DNL310 treatment¹
- Measuring biomarkers, safety and exploratory clinical outcomes

>40
participants²

Global Phase 2/3 (enrolling)

- Randomized, double blind, controlled study
- Ages ≥ 2 to < 6 y.o. (Cohort A, neuronopathic)
- ≥ 6 to < 17 y.o. (Cohort B, non-neuronopathic)
- Co-primary endpoints: CSF HS and VABS-III
- Peripheral endpoints: liver/spleen volume, 6MWT, ABR and others

54
participants²



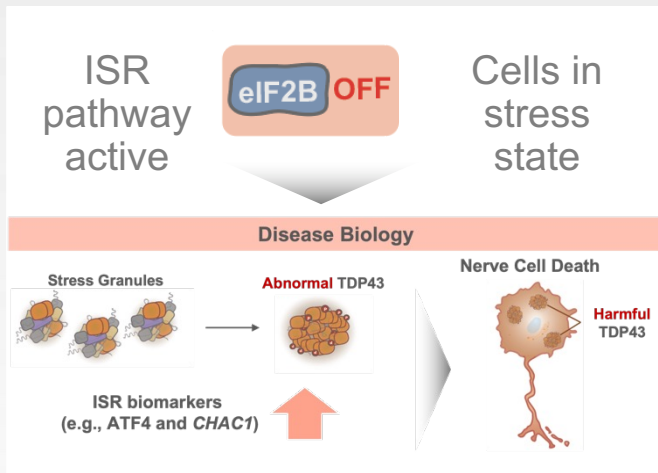
Regulatory Path and Target Indication

- Executing the Phase 2/3 COMPASS study; continue to generate Phase 1/2 data
- Ongoing regulatory interactions; prepared to pursue a faster path to approval
- Target indication – the full MPS II phenotype spectrum

~100
participants²
robust data package

DNL343 (eIF2B AGONIST): AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Targeting the Integrated Stress Response (ISR)

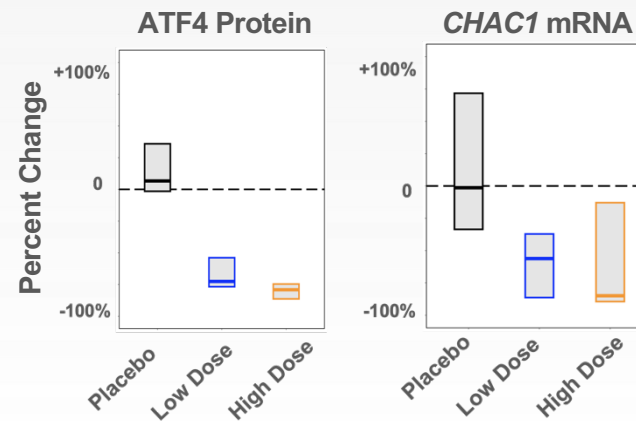


- ISR is implicated in stress granule formation and TDP43 aggregation, a hallmark of ALS
- DNL343 is designed to inhibit ISR & slow disease progression

DNL343 Inhibits the ISR

- Phase 1/1b studies in 95 healthy and 27 participants with ALS
- DNL343 was generally well tolerated
- DNL343 inhibited ISR biomarkers (shown in blood)

ALS Participant Data



Phase 2/3 HEALEY Study



- Platform trial in ALS
- 240 participants expected to enroll in DNL343 regimen
- Randomized 3:1 (DNL343:placebo)
- Primary endpoint ALSFRS-R at 24 weeks

PEAK 2

Focus on TV Programs in Alzheimer's Disease and Parkinson's Disease

OPPORTUNITY IS BREAKING OPEN IN ALZHEIMER’S DISEASE (AD)

Recent Advances Bring New Hope to People Living with AD

- New anti-amyloid therapies are the first disease modifying treatments
- New biomarkers and imaging tools
- New targets show promise in clinical testing, e.g., tau
- TfR-based targeting technology shows promise in clinical testing

Opportunity for New Therapies to Improve Efficacy and Safety

Unmet Needs Include:

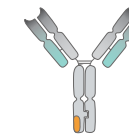
- Faster plaque reduction
- Lower doses
- More convenient delivery
- Reduced risk of ARIA



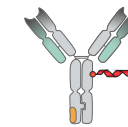
Denali is Positioned to Deliver the Next Generation of AD Therapies

- Discovery programs for multiple AD targets
- Best in class opportunities to improve efficacy and safety

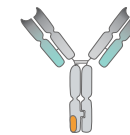
ATV:Abeta



OTV:MAPT



ATV:TREM2

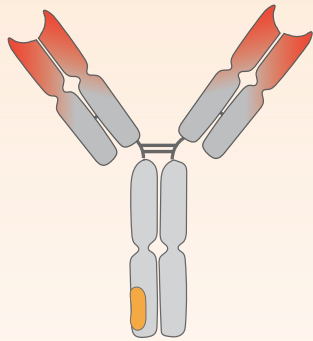


55 Million People Live with AD and Other Forms of Dementia

We Aim to Deliver Effective Medicines with Broad Societal Impact

ATV:Abeta: SUPERIOR AMYLOID PLAQUE BINDING AND REDUCTION

Optimally Engineered to Reduce Plaque & Improve Safety



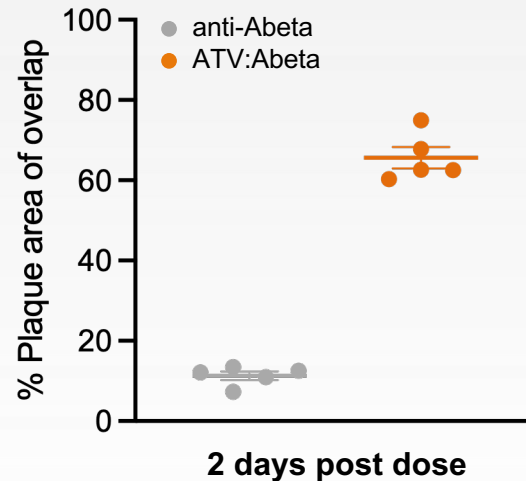
ATV:Abeta

Biogen leads development and commercialization

Greater Plaque Binding with ATV:Abeta

A β and hulgG colocalization

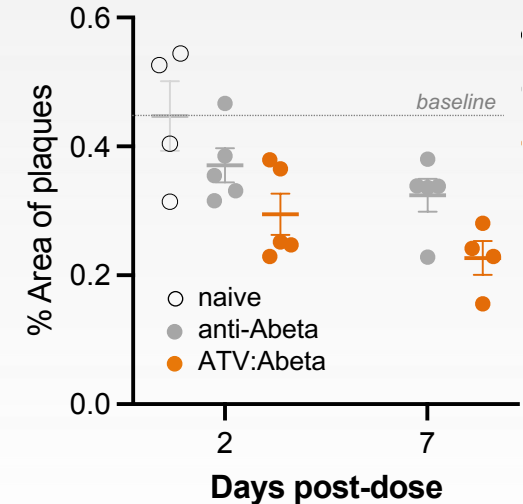
Single, mid dose, APP^{SAA KI1}



Greater Plaque Reduction with ATV:Abeta

A β Plaque Load

Single, mid dose, APP^{SAA KI}



ATV:Abeta may enable a wider therapeutic window in treating AD as compared to conventional anti-Abeta therapy

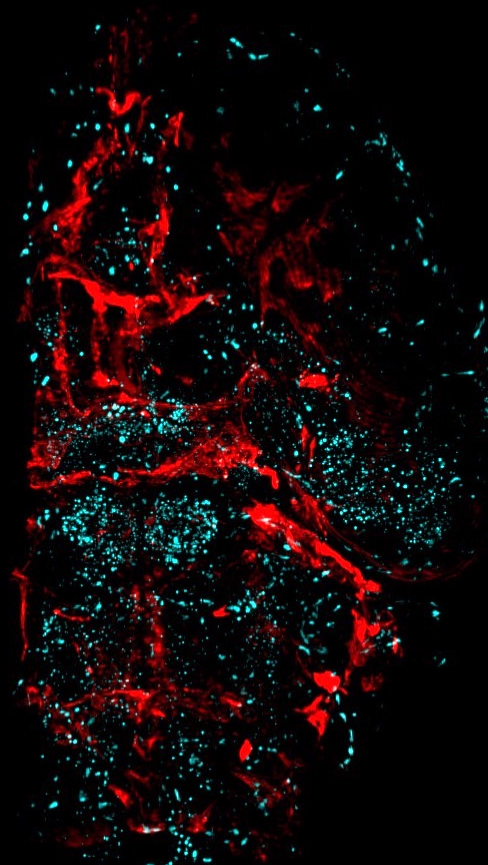
3D IMAGING SHOWS SUPERIOR AND DIFFERENTIATED ATV:Abeta BIODISTRIBUTION



Brain Arteries



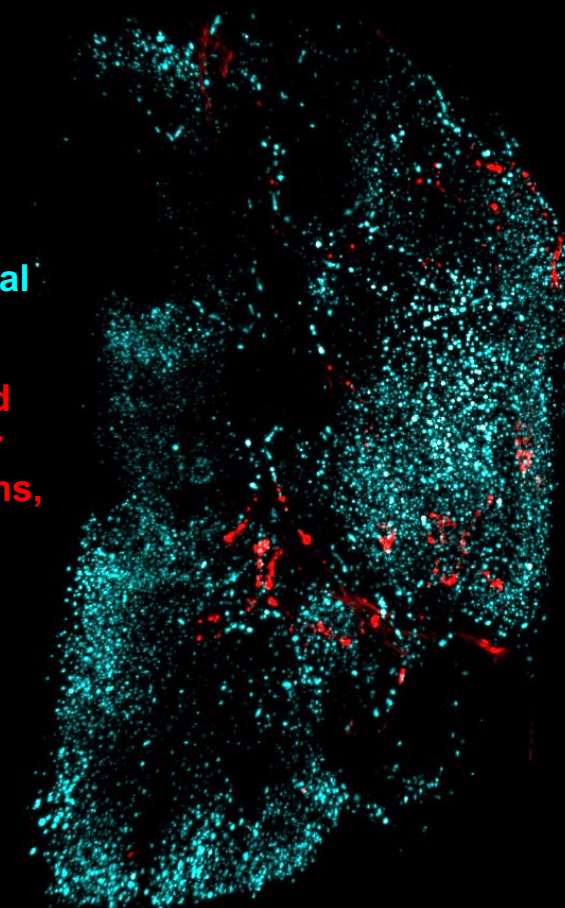
Anti-Abeta



hulgG, parenchymal
(on plaques)

hulgG, associated
with perivascular
spaces, CSF cisterns,
leptomeninges

ATV:Abeta



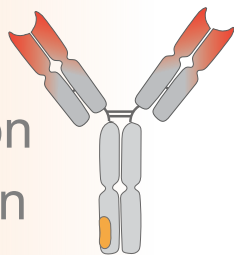
ATV leads to higher parenchymal **plaque** binding and lower **perivascular** localization compared to standard antibody

ATV:Abeta HAS POTENTIAL TO REDUCE ARIA RISK IN AD TREATMENT

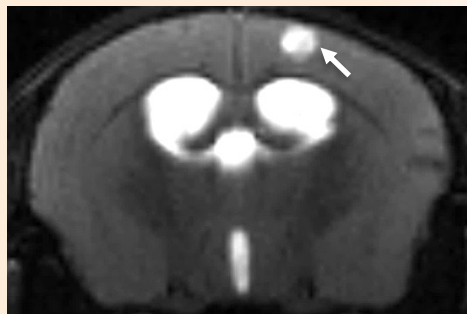
Optimally Engineered to Reduce Plaque & Improve Safety

Preclinical profile:

- Superior plaque reduction
- Less vascular localization
- Fewer ARIA events



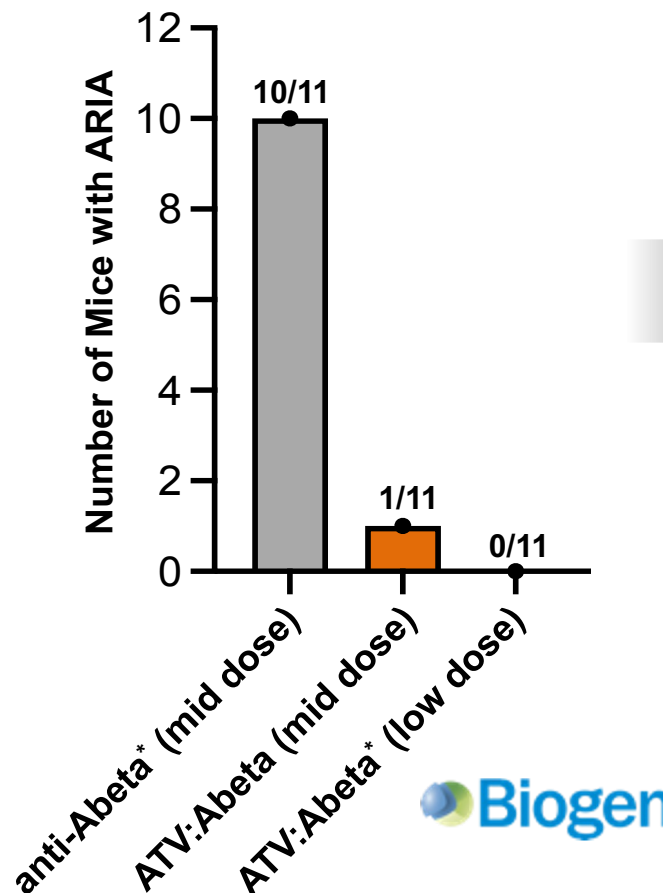
ARIA as Seen in a Mouse Model of AD



ARIA-like MRI events



Weekly dosing x 11 wks, 5xFAD Tfr^{mu/hu} KI

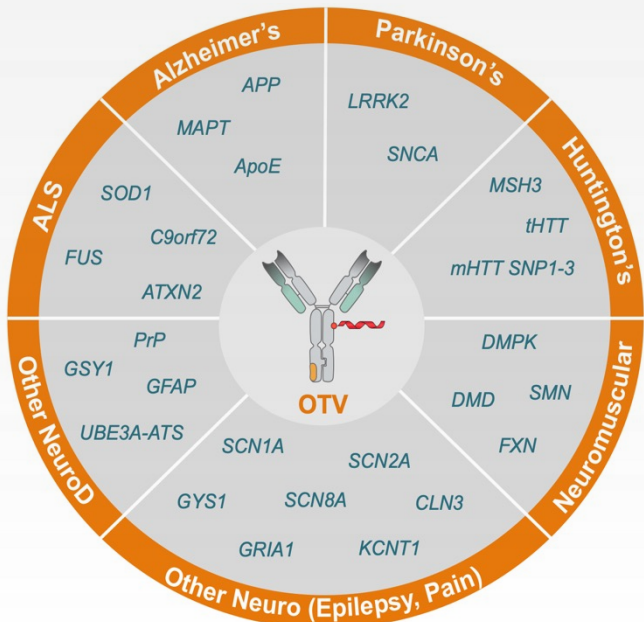


Fewer/no ARIA events observed with **ATV:Abeta** compared to a conventional Abeta antibody

OLIGONUCLEOTIDE TRANSPORT VEHICLE (OTV) OPPORTUNITY

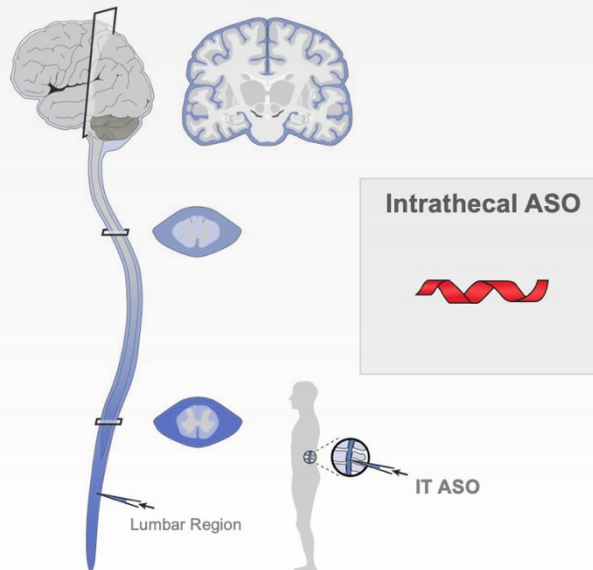
Oligonucleotide Therapies Enable New Disease Targets

- Oligonucleotides open a large potential indication space in neurodegeneration and beyond



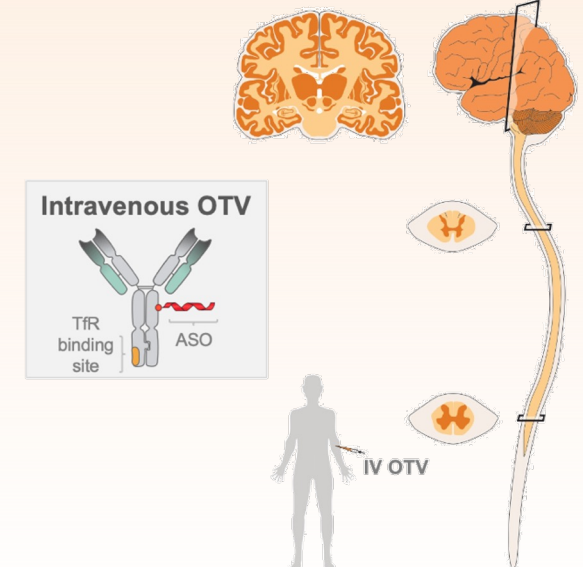
Opportunity for Improving Oligo Delivery and Therapeutic Profile

- Limited biodistribution with intrathecal ASO
- Sharp gradient limits biodistribution in brain and along the spinal cord



OTV has Potential to Revolutionize Oligos for Treating CNS Disease

- Homogenous biodistribution of ASOs across brain regions
- Superior knockdown of target gene expression across all brain regions and cell types



OTV PROVIDES UNIFORM ASO DEPOSITION ACROSS THE CNS WITH IV DELIVERY

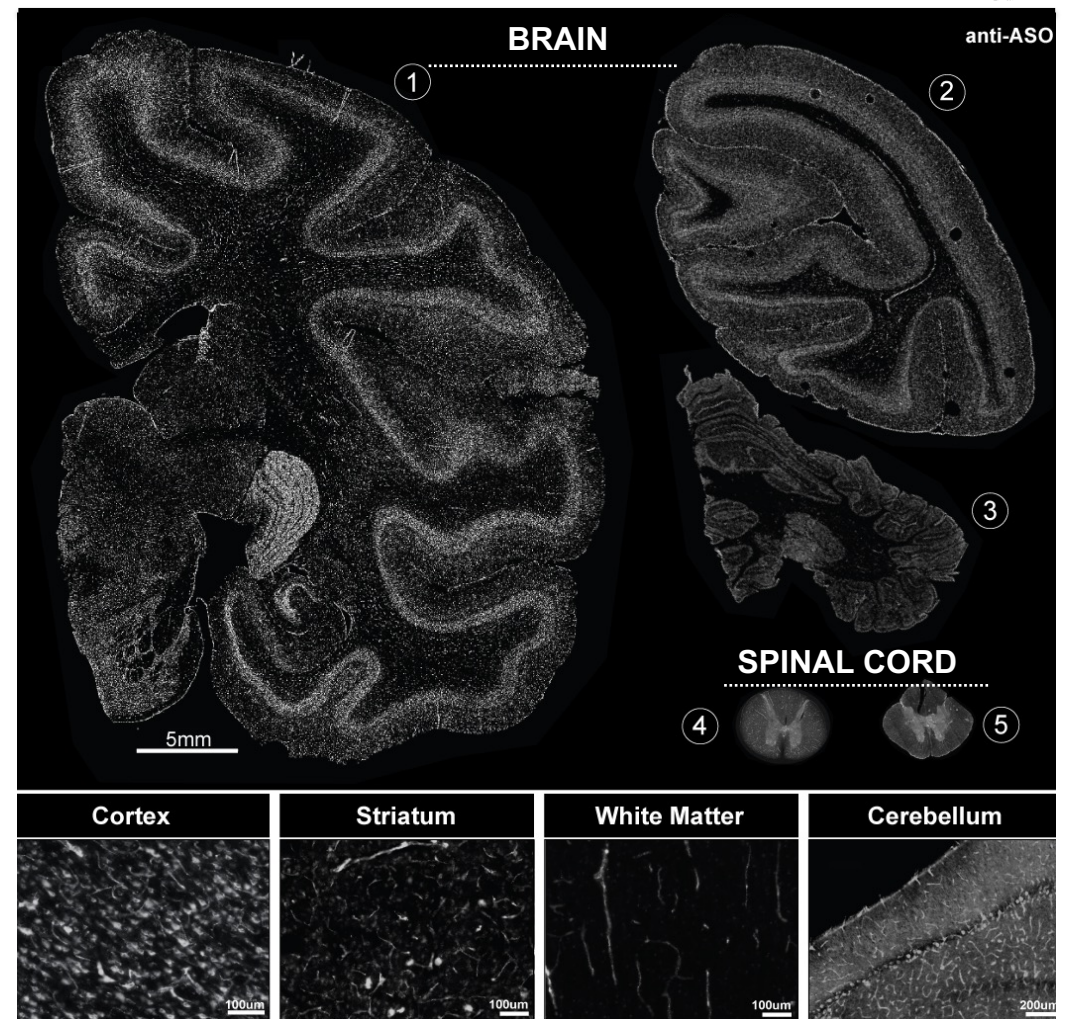
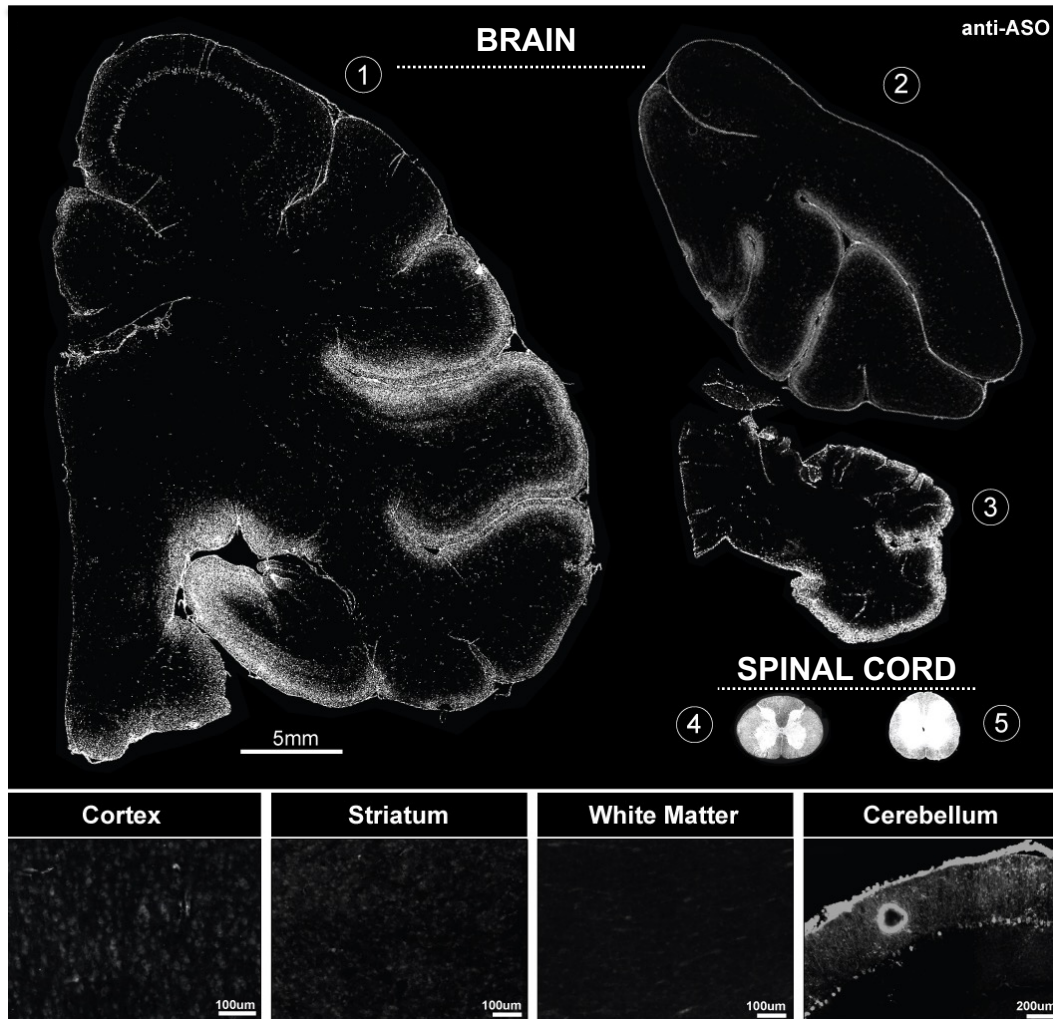
NAKED ASO INTRATHECAL (IT) DELIVERY

Limited ASO Biodistribution



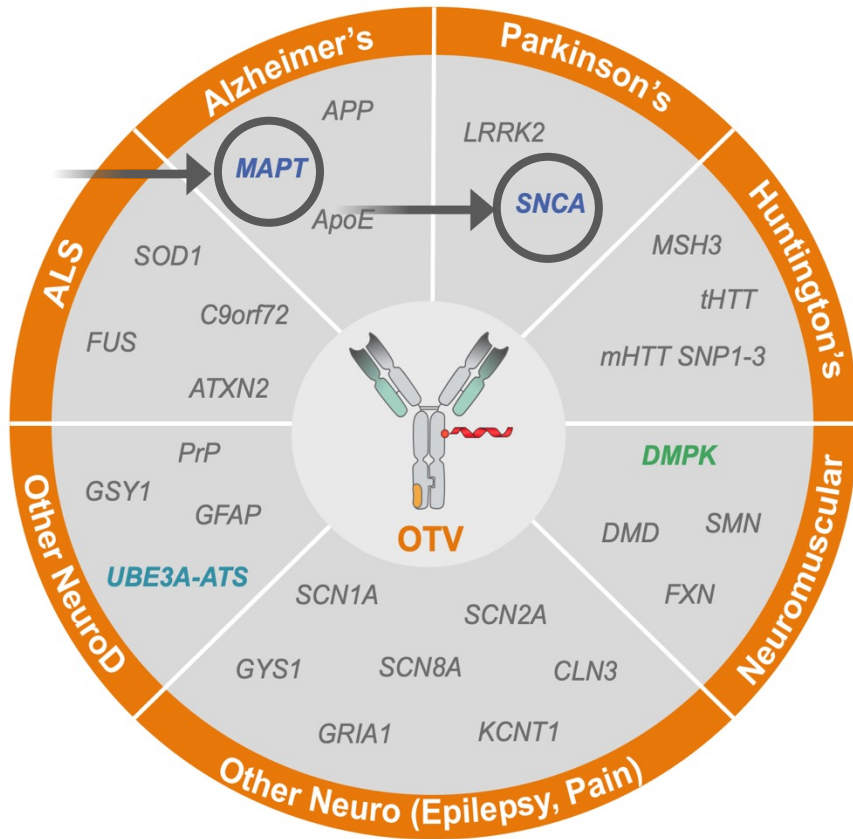
OTV INTRAVENOUS (IV) DELIVERY

Widespread ASO Biodistribution



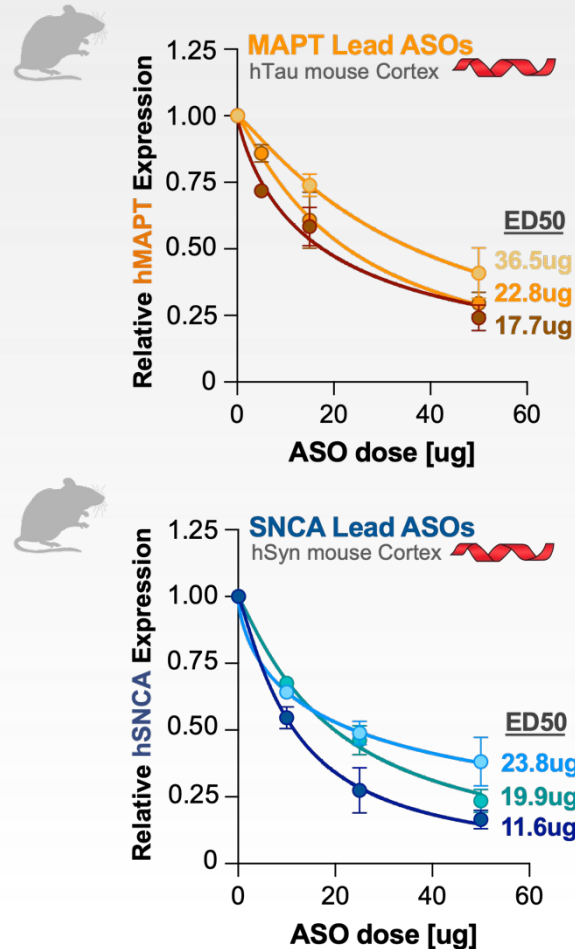
- ① Full Hemibrain Section
- ② Posterior Cortex overlaying Cerebellum
- ③ Cerebellum
- ④ Cervical Spinal Cord
- ⑤ Lumbar Spinal Cord

MAPT AND SNCA ARE LEAD IND-ENABLING OTV PROGRAMS



- MAPT (tau) and SNCA (α synuclein) are lead OTV programs in IND-Enabling stage
- Discovery programs include UBE3A-ATS, DMPK, and an epilepsy target

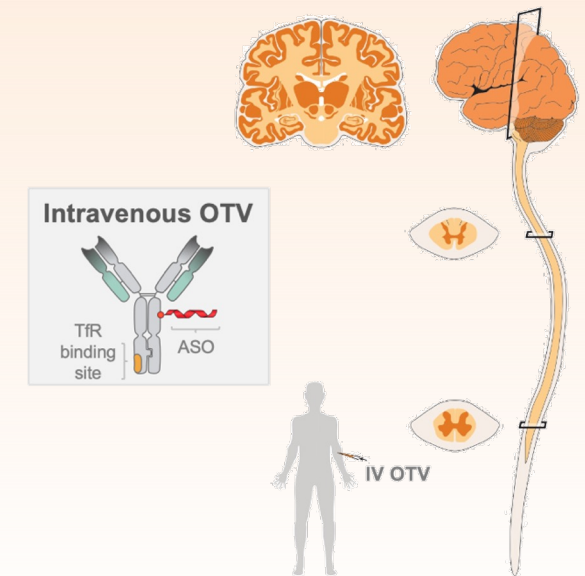
Highly Potent ASO Leads



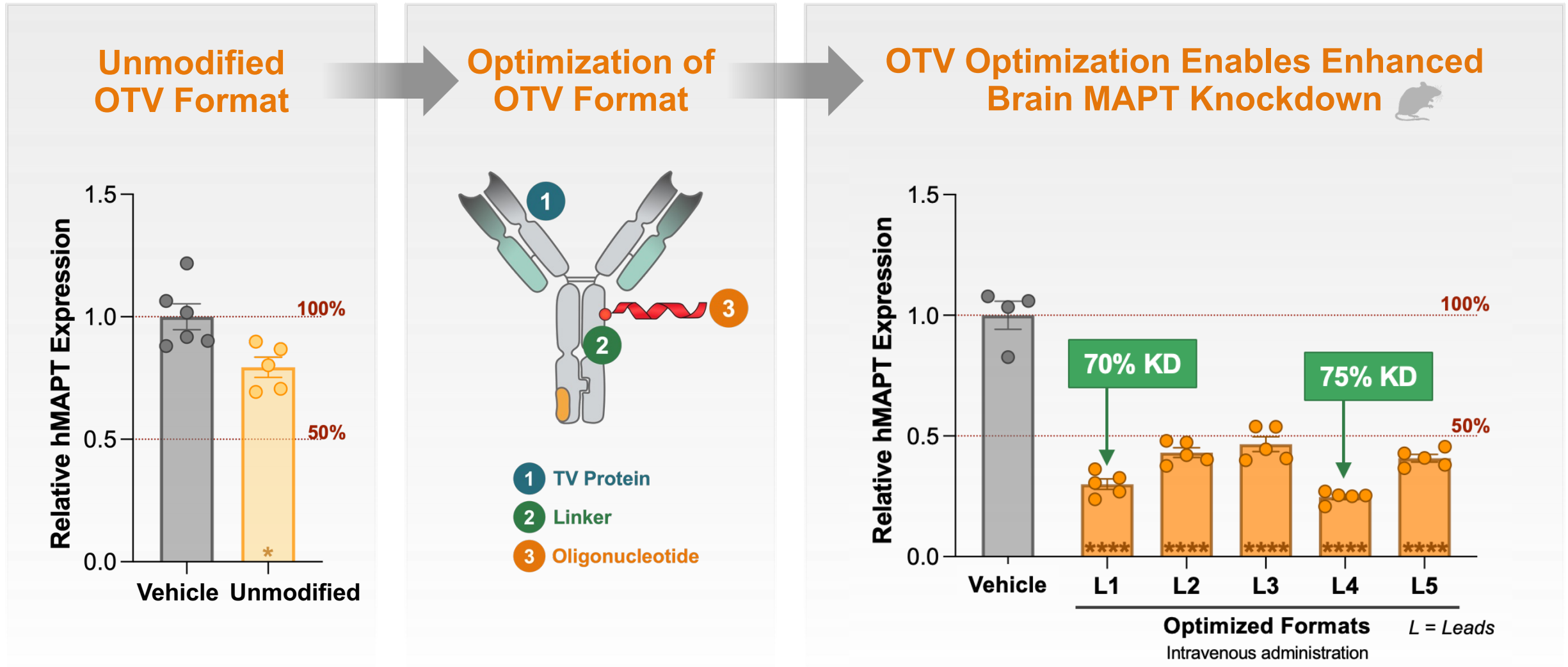
ICV bolus in transgenic mice, 1.5wk after dose
 Data shown as Mean +/- SEM; n=2-5/group
 Relative gene expression normalized to Gapdh (housekeeping gene);
 expression relative to Vehicle Control

Optimize on OTV Format

- Enables brain delivery of ASOs via intravenous (IV) administration



OPTIMIZING GENE KNOCKDOWN IN BRAIN WITH OTV PLATFORM



hTau x TfR^{mu/hu} KI mice dosed IV at 1mg/kg ASO eq. on d1, d8, d15, d22; Collect d29. Data shown as Mean +/- SEM; Student t-test (left), One-way ANOVA w/ Dunnett's multiple comparisons test (right)

Relative gene expression normalized to Gapdh (housekeeping gene); expression relative to Vehicle Control
KD – knockdown

LOOKING AHEAD

POSITIONED TO **DELIVER** ON OUR GOALS

PLATFORM

- Proven and **expanding Transport Vehicle (TV)** platform for brain delivery



PEAK 1

- **Commercial readiness** for MPS II and ALS
- **Clinical execution** on PD, FTD-GRN, and MPS IIIA programs



PEAK 2

- Focus on **solving AD and PD** with TV-enabled programs

Capitalized to Achieve Value Creating Milestones in Peaks 1 & 2

\$1.12 B (as of 9/30/23) with Runway into 2027

2024 MILESTONES

Expected 2024 Key Milestones for Denali-Led Programs

PROGRAM	MILESTONE	TIMING
DNL310 (ETV:IDS)	• Additional interim Phase 1/2 data at WORLD	Feb 4-9
	• Additional Interim Phase 1/2 data at SSIEM	Sept 3-6
	• Complete enrollment of global Phase 2/3 COMPASS study in MPS II	2024
DNL593 (PTV:PGRN)	• Continue Part B of Phase 1/2 study in FTD-GRN	2024
DNL126 (ETV:SGSH)	• Preclinical data at WORLD	Feb 4-9
	• Initiate dosing in Phase 1/2	Early 2024
	• Biomarker proof of concept and safety data from Phase 1/2 study in MPS IIIA	Late 2024
DNL343 (eIF2B activator)	• Complete enrollment of Regimen G in Phase 2/3 HEALEY ALS Platform Trial	2024
OTV:MAPT	• IND enabling studies	2024
OTV:SNCA	• IND enabling studies	2024

Expected 2024 Key Milestones for Partner-Led Programs

PROGRAM	MILESTONE	STRATEGIC PARTNER
BIIB122/DNL151 (LRRK2 inhibitor)	• Continue Phase 2b LUMA study in early-stage PD	
ATV:Abeta	• IND-enabling studies	
SAR443820/DNL788 (CNS-penetrant RIPK1 inhibitor)	• Topline results of the Phase 2 HIMALAYA study in ALS (1H 2024)	sanofi
	• Continue Phase 2 K2 study in MS	
SAR443122/DNL758 (Peripherally-restricted RIPK1 inhibitor)	• Continue Phase 2 UC study	sanofi

OUR PURPOSE: **DEFEAT DEGENERATION**



LYSOSOMAL STORAGE DISEASES

Dominic, living with MPS II



ALS/FTD

Seth, living with ALS



PARKINSON'S DISEASE

Allan, living with PD



ALZHEIMER'S DISEASE

Denali Team at AD Walk 2023



Denali

The name captures the formidable challenges in fighting neurodegenerative diseases but also the unprecedented opportunities enabled by new scientific insights and technologies. With a relentlessly committed team and rigorous effort, breakthroughs appear to be within reach.

THANK YOU

www.denalitherapeutics.com