

**BIOARCTIC AB (PUBL)  
NASDAQ STOCKHOLM: BIOA B**

# Carnegie Healthcare Seminar 2023

Stockholm, March 14, 2023

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*Gunilla Osswald, PhD, CEO*



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# BioArctic – a unique Swedish biopharma company

## Improving life for patients with central nervous system disorders

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**High unmet need** for disease-modifying treatments for Alzheimer's and Parkinson's diseases creates **large commercial opportunity**



**World-class research and development driven organization** with basis in founder's breakthrough discoveries and fruitful collaborations with leading **academic researchers** and **pharma companies** generating and developing **innovative projects**



**Attractive and well-balanced project portfolio** with projects from discovery through Phase 3, regulatory and on the market. A combination of both proprietary projects with substantial marketing and out-licensing potential and partnered projects generating income



**Well-financed** with more than MSEK 805 (MUSD ~77) in cash and **valuable collaboration agreements**

# Attractive and well-balanced project portfolio

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory & Market	
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) ( <i>Clarity AD</i> )	Eisai <sup>1</sup>	Early Alzheimer's disease <sup>2</sup>						
	Lecanemab (BAN2401) ( <i>AHEAD 3-45</i> )	Eisai <sup>1</sup>	Preclinical (asymptomatic) Alzheimer's disease <sup>3</sup>						
	BAN2401 back-up	Eisai							
	BAN1503 (Trunc Abeta)								
	AD-BT2802								
	AD-BT2803 (Trunc Abeta with BT)								
	AD2603								
PARKINSON'S DISEASE	BAN0805 (alpha-synuclein)								
	PD1601 (alpha-synuclein)								
	PD1602 (alpha-synuclein)								
	PD-BT2238 (alpha-synuclein with BT)								
OTHER CNS DISORDERS	Lecanemab (BAN2401)							Down's syndrome <sup>4</sup> , Traumatic brain injury <sup>4</sup>	
	ND3014 (TDP-43)							ALS	
	ND-BT3814 (TDP-43 with BT)							ALS	
	GD-BT6822 (GCase with BT)							Gaucher's disease	
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform								

1) Partner with Eisai for lecanemab for treatment of Alzheimer's disease since 2007. Eisai entered partnership with Biogen regarding BAN2401 (lecanemab) in 2014

2) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease

3) Normal cognitive function with intermediate or elevated levels of amyloid in the brain








4) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury





## Alzheimer's disease

# Great partnership with Eisai on lecanemab preparing for co-promotion in the Nordics

Alzheimer's disease 			
<b>Partner track record</b>	<table border="1"><tr><td><p>Discovered and developed world's best-selling medicine for symptoms in Alzheimer's</p><p>Industry-leading pipeline in dementia area</p></td><td><p>Used to treat confusion (dementia) related to Alzheimer's disease</p></td></tr></table>	 <p>Discovered and developed world's best-selling medicine for symptoms in Alzheimer's</p> <p>Industry-leading pipeline in dementia area</p>	 <p>Used to treat confusion (dementia) related to Alzheimer's disease</p>
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<b>Collaboration and license</b>	<p>Milestones of up to</p> <h1>MEUR 136*</h1> <p>remains to be received</p> <p>Royalties High single digit %</p> <p><b>BioArctic retains rights to lecanemab in other indications and option to market in the Nordics</b></p>		

\*) including MEUR 35 to be paid to BioArctic in Q1 2023, based on regulatory approval and submissions

# Recent highlights relating to our lead drug candidate lecanemab

## USA

Granted accelerated approval Jan 6, 2023

Submission for full approval Jan 6, 2023.  
Priority review granted with PDUFA July 6, 2023

Veterans' Health Administration provided coverage for Leqembi March 13, 2023

## Japan

Marketing authorization application submitted on January 16, 2023.

The application was granted priority review on January 30

## The EU

Marketing authorization application (MAA) submitted on January 9, 2023.

Accepted for a standard review on January 26, 2023

## China

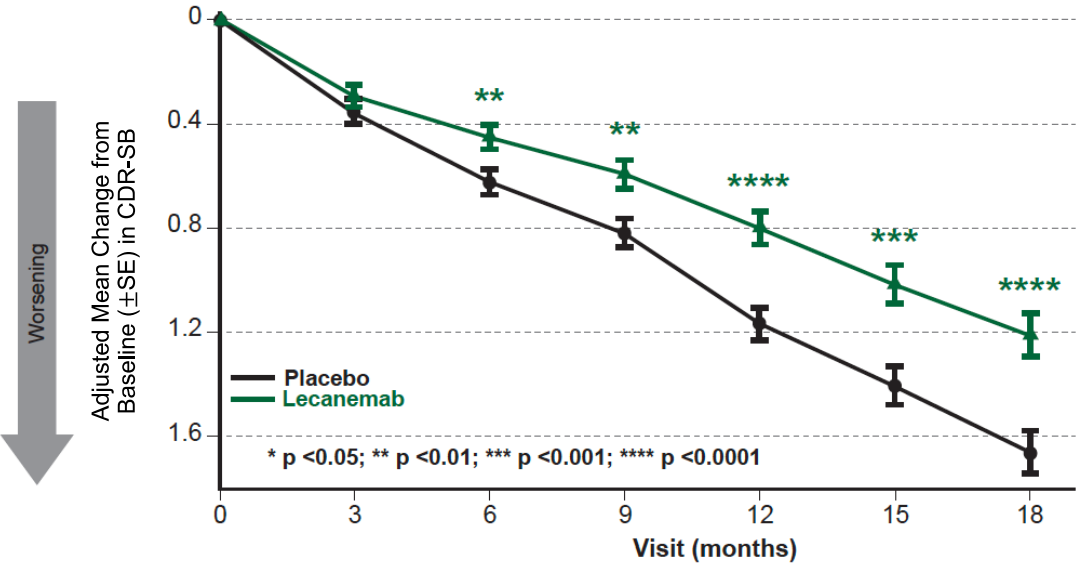
Initiated Biologics License Application (BLA) for lecanemab in December 2022.

Designated for priority review on February 28, 2023



# Clarity AD: lecanemab demonstrates Clinically Meaningful Effect

Lecanemab met primary and all key secondary endpoints in Phase 3 Clarity AD study in 1795 early AD subjects with highly statistically significant results, reducing disease progression by 27% as measured by the primary endpoint CDR-SB\* with relatively low frequency of the side effect ARIA



Clarity AD shows consistent highly statistically significant effects and confirms Phase 2b results

Safety profile confirmed in Phase 3 with low rates of ARIA, despite no titration and full dose from day 1

Slowing down disease progression means more time in less severe stages of Alzheimer’s disease<sup>1</sup>

Lecanemab modifies the underlying disease pathology<sup>2</sup>

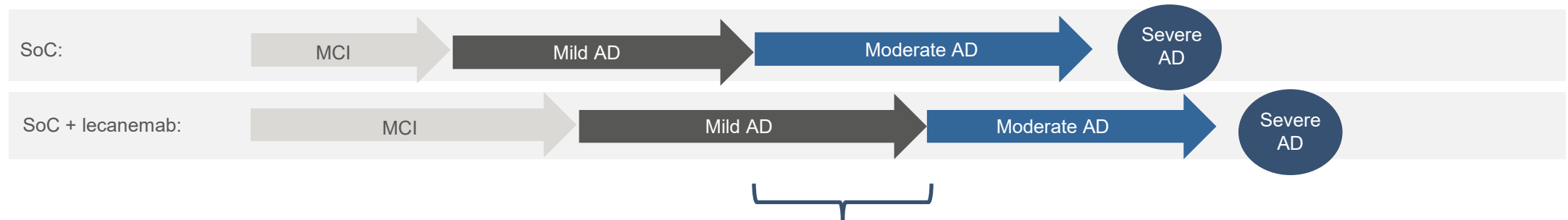
\*CDR-SB: Clinical Dementia Rating Scale Summary of Boxes, measures key cognitive and functional symptoms in Alzheimer’s Disease  
Source: 1. Monfared et al. "Long-Term Health Outcomes of Lecanemab in Patients with Early Alzheimer’s Disease Using Simulation Modeling". *Neurol Ther.* 2022.  
2. van Dyck et al. "Lecanemab in Early Alzheimer’s Disease" *N Engl J Med* 2023; 388:9-21.





# Disease modeling suggests that lecanemab could delay progression to moderate Alzheimer's Dementia by several years

*Estimated progression time to moderate Alzheimer's Disease (AD) for patients completing the full lecanemab dosing regime compared with patients subject to standard of care (SOC) only*

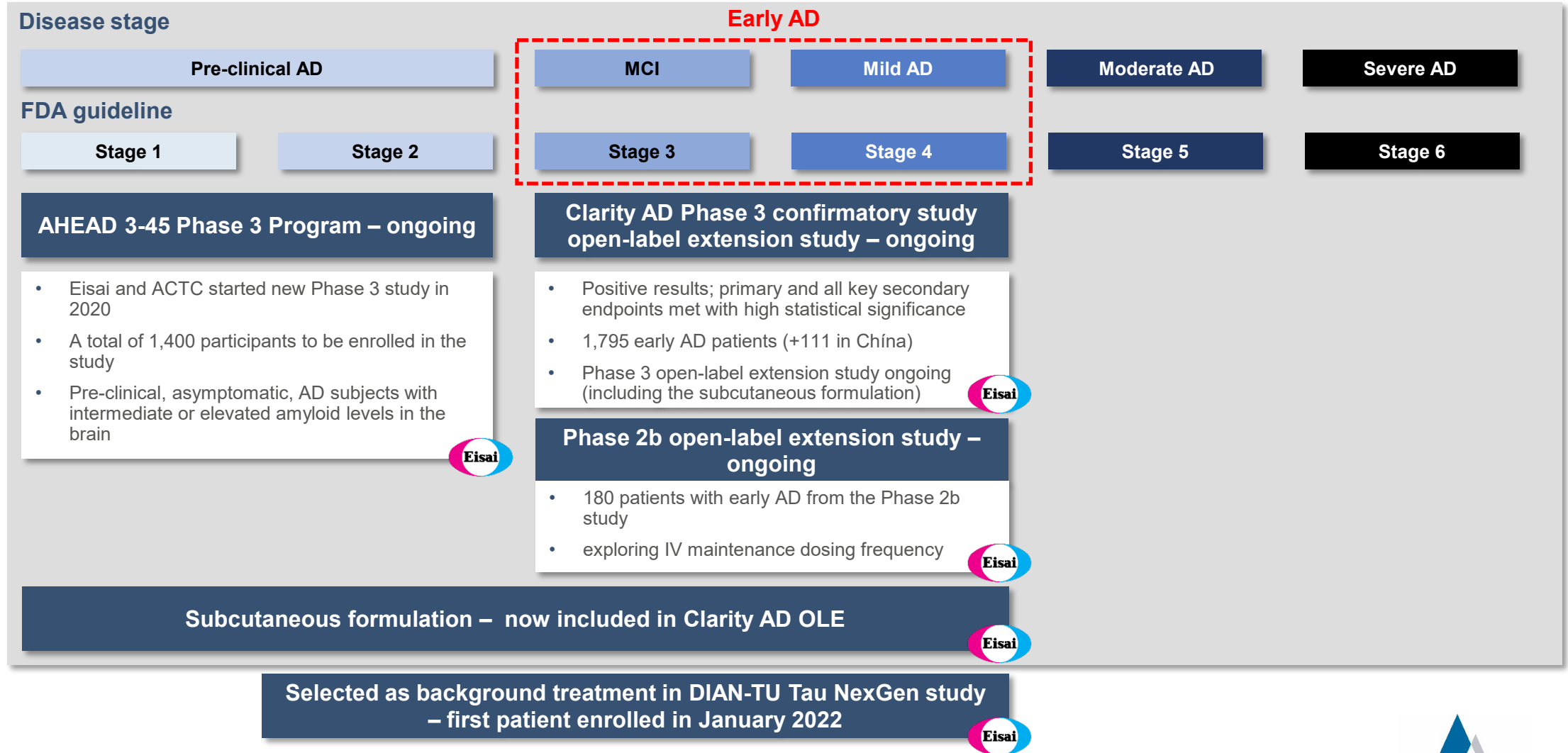


**Estimated time gained before reaching moderate AD: + 3.13 years**

**The results from the modeling show the potential clinical value of lecanemab for patients with early Alzheimer's disease and how it can slow the rate of disease progression, delay progression to moderate Alzheimer's dementia with several years and consequently reduce the need for institutionalized care**

1. Monfared et al. "Long-Term Health Outcomes of Lecanemab in Patients with Early Alzheimer's Disease Using Simulation Modeling". *Neurol Ther.* 2022. 2. Swanson et al. "A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-A $\beta$  protofibril antibody". *Alzheimer's Res Ther.* 2021. 3. ADNI (Alzheimer's Disease Neuroimaging Initiative) study.

# Lecanemab – broad late-stage clinical program





**Rich clinical and  
pre-clinical pipeline**

# Significant progress and expansion of the pipeline with several projects combined with the Brain transporter technology

## Parkinson's disease



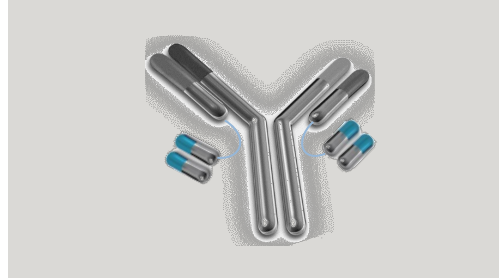
### BAN0805

- Potential disease modifying antibody with Phase 1 results supporting further development in Phase 2

### Discovery stage projects

- Pre-clinical stage alpha-synuclein projects
- PD-BT2238 – antibody combined with the BT-technology

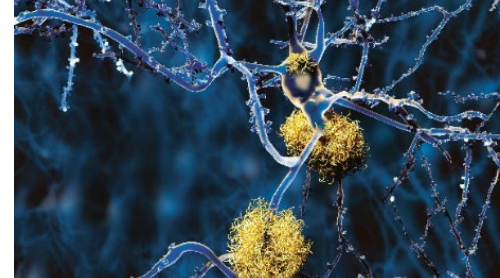
## Blood-brain barrier



### Brain Transporter (BT)

- Continued development of Brain Transporter (BT) technology platform
- Now combined with several internal programs

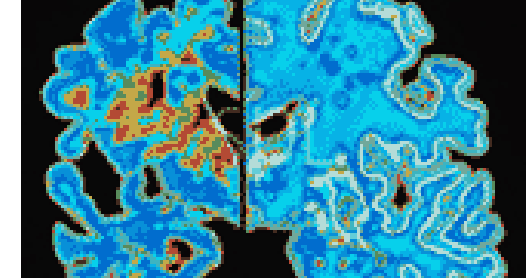
## Alzheimer's disease



### Discovery stage programs

- Five internal disease modifying antibody projects in Alzheimer's disease
- Two Alzheimer's disease projects combined with the BT-technology

## Other CNS disorders



### Neurodegeneration research

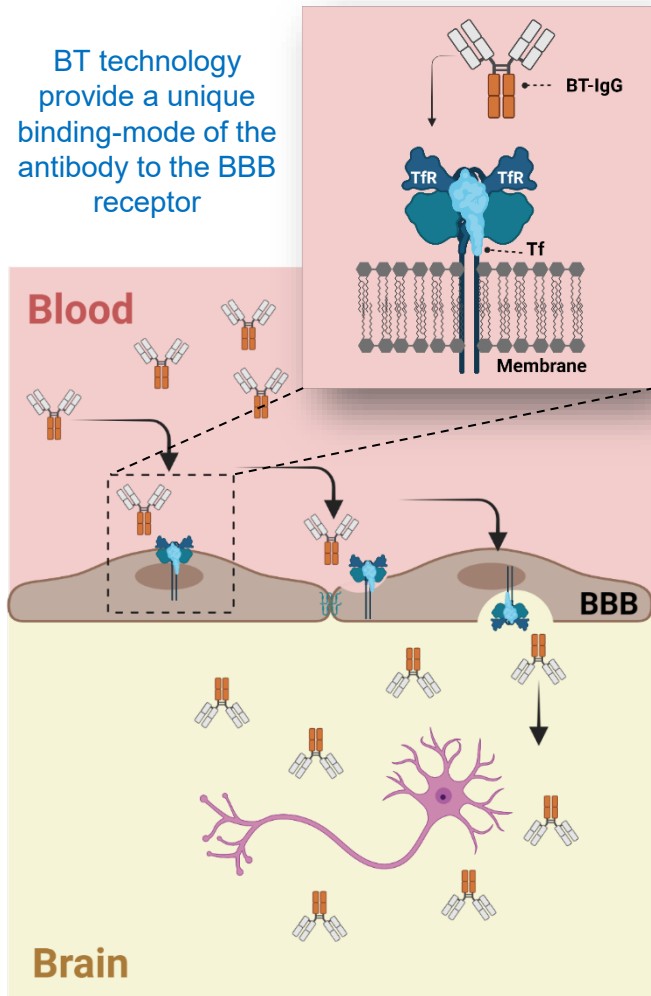
- Lecanemab in indications outside of Alzheimer's disease
- Research project in neurodegeneration ("ND") with potential in various CNS disorders, including orphan indications such as ALS<sup>1)</sup> and Gaucher's disease also combined with the BT-technology



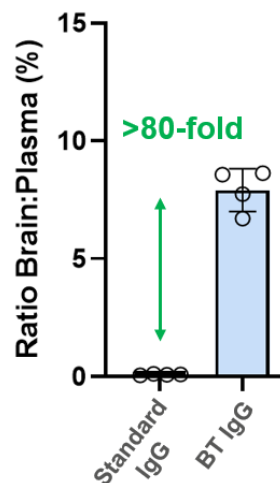
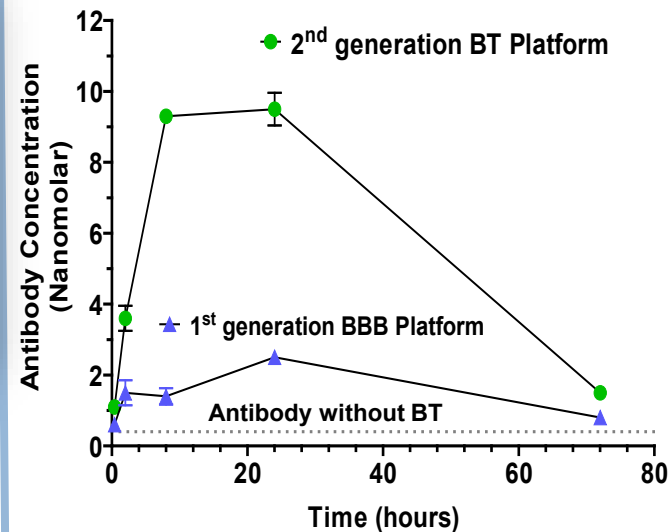
# Brain Transporter (BT) technology delivers biotherapeutics to the brain

## Novel platform achieves high exposure and broad brain distribution

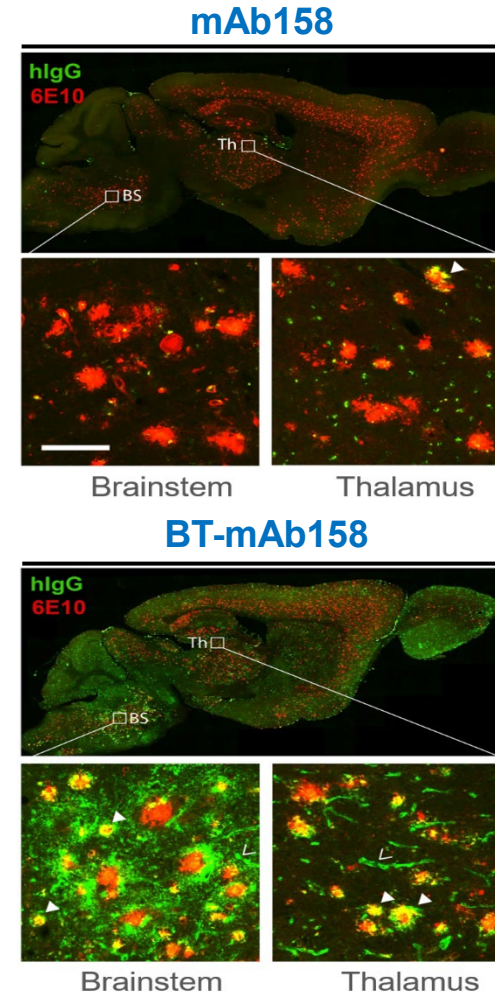
Brain Transporter technology mediate transport across the BBB



2nd – generation technology provide superior brain exposure



Rapid and global brain distribution



Red: Amyloid-β plaque in the brain  
Green: Antibody in the brain at the Amyloid-β target  
8-hour post-dose

### Short summary

- BT technology based on a novel approach using the Transferrin receptor (TfR) at the blood-brain barrier (BBB) (patent submitted)
- BT technology currently utilized in five portfolio projects (AD-BT2802, AD-BT2803, PD-BT2238, ND-BT3814, GD-BT6822)

### Opportunity

- Drug delivery across the BBB remains a key obstacle for the development of efficient neurological disease therapies
- Opportunity to combine BT technology with internal projects as well as external antibodies or proteins through several non-exclusive license deals



**Summary & upcoming  
news flow**



# Upcoming news flow

## Alzheimer's disease



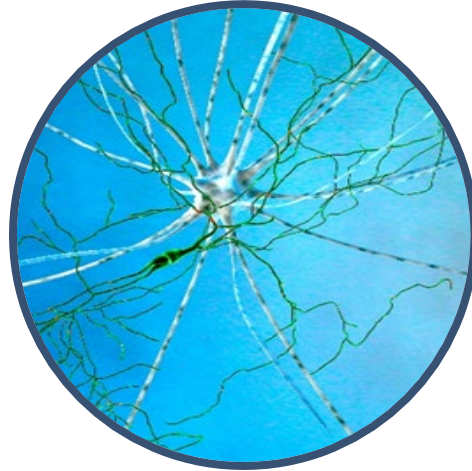
### Lecanemab (Eisai)

- Data to be disclosed at international congresses, including AD/PD in Gothenburg in March/April
- Regulatory progress

### Discovery stage programs

- Advancement of projects

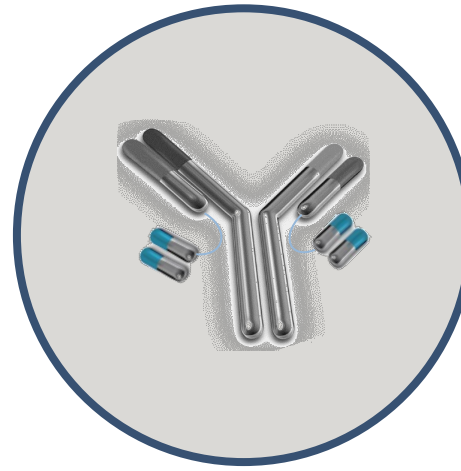
## Parkinson's disease



### BAN0805

Data presented at international congresses

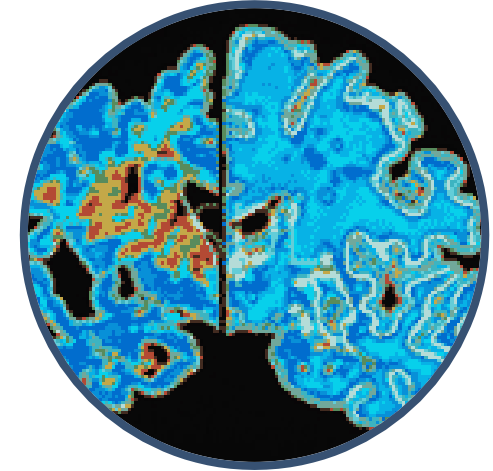
## Blood-brain barrier



### Brain Transporter (BT) technology platform

- Further development of the technology platform
- Data to be disclosed at international congresses
- BT supporting the expansion of the project portfolio

## Other CNS disorders



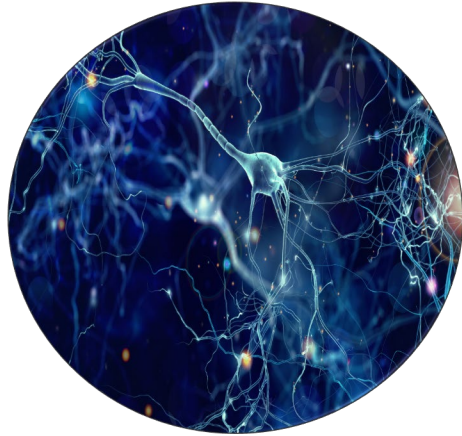
### Neurodegeneration

- Data to be disclosed at international congresses

# BioArctic: With Patients in Mind

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Great science



Great projects



Great partners



Great people





