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# Handelsbanken Nordic Small & Mid Cap Seminar 2023

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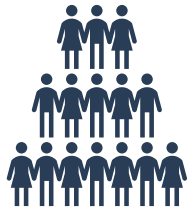
BioArctic will, through world-leading innovative research, create drugs that improve the lives of patients with neurodegenerative diseases.

# BioArctic – a unique Swedish biopharma company

## Improving life for patients with neurodegenerative disorders



Work with disease-modifying treatments for Alzheimer's disease and other **neurodegenerative diseases** where there is a high unmet need

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

**Attractive and well-balanced project portfolio** with projects from discovery through Phase III, 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 BSEK 1.1 (MUSD ~110) in cash and **valuable collaboration agreements**

1) FX as per March 31, 2022



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# Attractive and well-balanced project portfolio

| | Project | Partner | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 | Regulatory & Market |
|---|---|---|---|---|---|---|---|---|
| ALZHEIMER'S DSEASE | Lecanemab (BAN2401) *(Clarity AD)* | Eisai[1] | Early Alzheimer's disease[2] | | | | | |
| | Lecanemab (BAN2401) *(AHEAD 3-45)* | Eisai[1] | Preclinical (asymptomatic) Alzheimer's disease[3] | | | | | |
| | 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[4], Traumatic brain injury[4] | | | |
| | ND3014 (TDP-43) | | | ALS | | | | |
| | ND-BT3814 (TDP-43 with BT) | | | ALS | | | | |
| | GD-BT6822 (GCase with BT) | | | Gaucher 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



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# Partnership model to de-risk clinical development and optimize commercialization opportunity

**Alzheimer's disease**

**Partner track record**

Eisai

Discovered and developed world's best-selling medicine for symptoms in Alzheimer's disease

Industry-leading pipeline in dementia area

Aricept donepezil HCl tablet

Used to treat confusion (dementia) related to Alzheimer's disease

**Collaboration and license**

Milestones of up to

**MEUR 101**

remains to be received

**Royalties High single digit %**

**BioArctic retains rights to lecanemab in other indications and option to market in the Nordics**

In 2023, BioArctic has received milestones of MEUR 35 from Eisai based on the approval in the US and submissions in the EU and Japan



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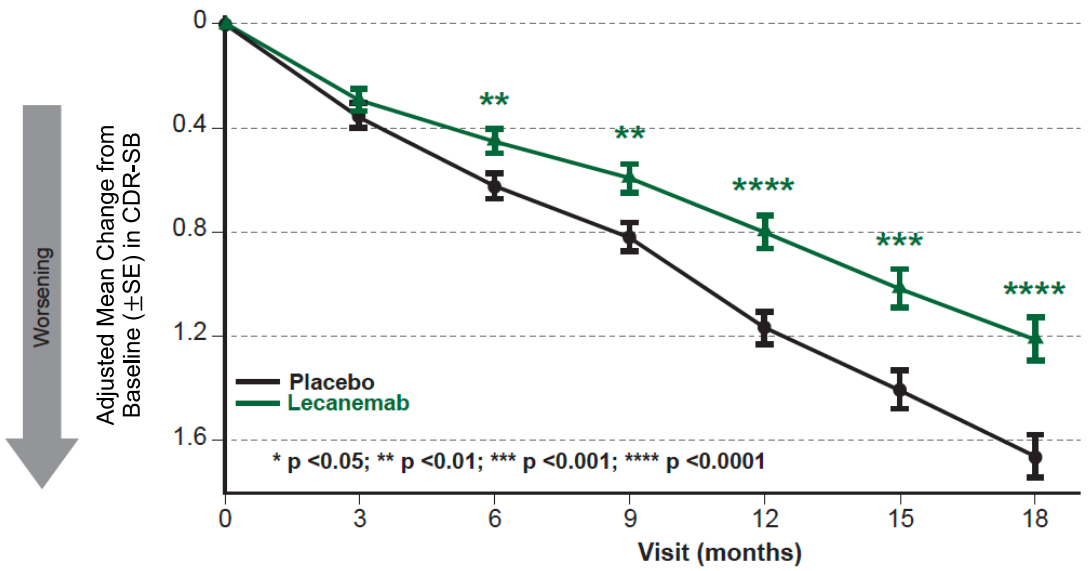
# Clarity AD: lecanemab demonstrates Clinically Meaningful Effect

**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[1]**

**Lecanemab modifies the underlying disease pathology[2]**



*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.*

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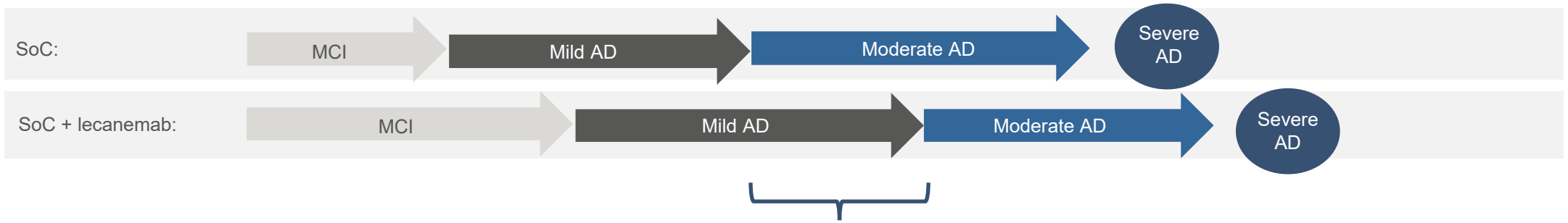
# Modeling study shows that lecanemab could delay progression to later stages of disease with 2-3 years

*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: + 2-3 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. Tahami Monfared, A.A., Ye, W., Sardesai, A. *et al.* A Path to Improved Alzheimer's Care: Simulating Long-Term Health Outcomes of Lecanemab in Early Alzheimer's Disease from the CLARITY AD Trial. *Neurol Ther* (2023). https://doi.org/10.1007/s40120-023-00473-w



MCI – Mild cognitive Impairment

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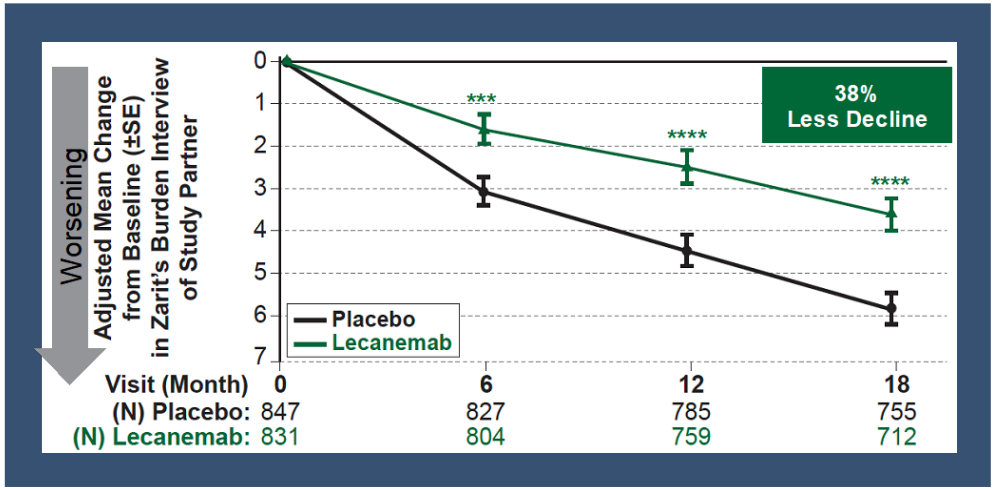
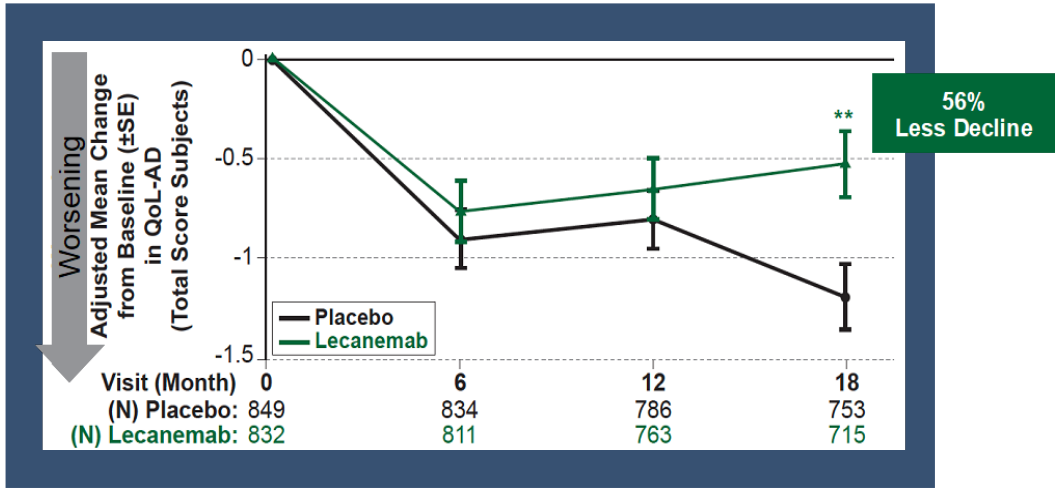
# Tangible differences in daily life activities for subjects with Alzheimer disease achieved with lecanemab treatment

## Study Partner Burden (total score)




## QOL-AD (Total Score Subject)




Consistent benefits seen on quality-of-life and caregiver burden scales, showing 38% to 56% less decline



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# Leqembi™ (lecanemab) has the potential to become the first anti-Aβ antibody to receive full approval globally

## 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

Eisai plans to submit s.c. formulation and maintenance dosing applications by Q1 2024

## Japan

Marketing authorization application submitted on January 16, 2023.

Granted priority review on January 30, 2023

Expected PMDA decision H2 2023

## EU

Marketing authorization application submitted on January 9, 2023

Accepted for a standard review on January 26, 2023

Expected EMA decision Q1 2024

## China

Initiated Biologics License Application in December 2022.

Granted priority review on February 28, 2023

Expected NMPA decision Q1 2024

## RoW

Canada: New Drug Submission accepted May 14, 2023

Great Britain: Market Authorization Application submitted May 19, 2023. ILAP designation


PDUFA – Prescription Drug User Fee Act
PMDA – Pharmaceuticals and Medical Devices Agency
EMA – European Medicines Agency
NMPA – National Medical Products Administration
s.c. – subcutaneous
ILAP - Innovative Licensing and Access Pathway



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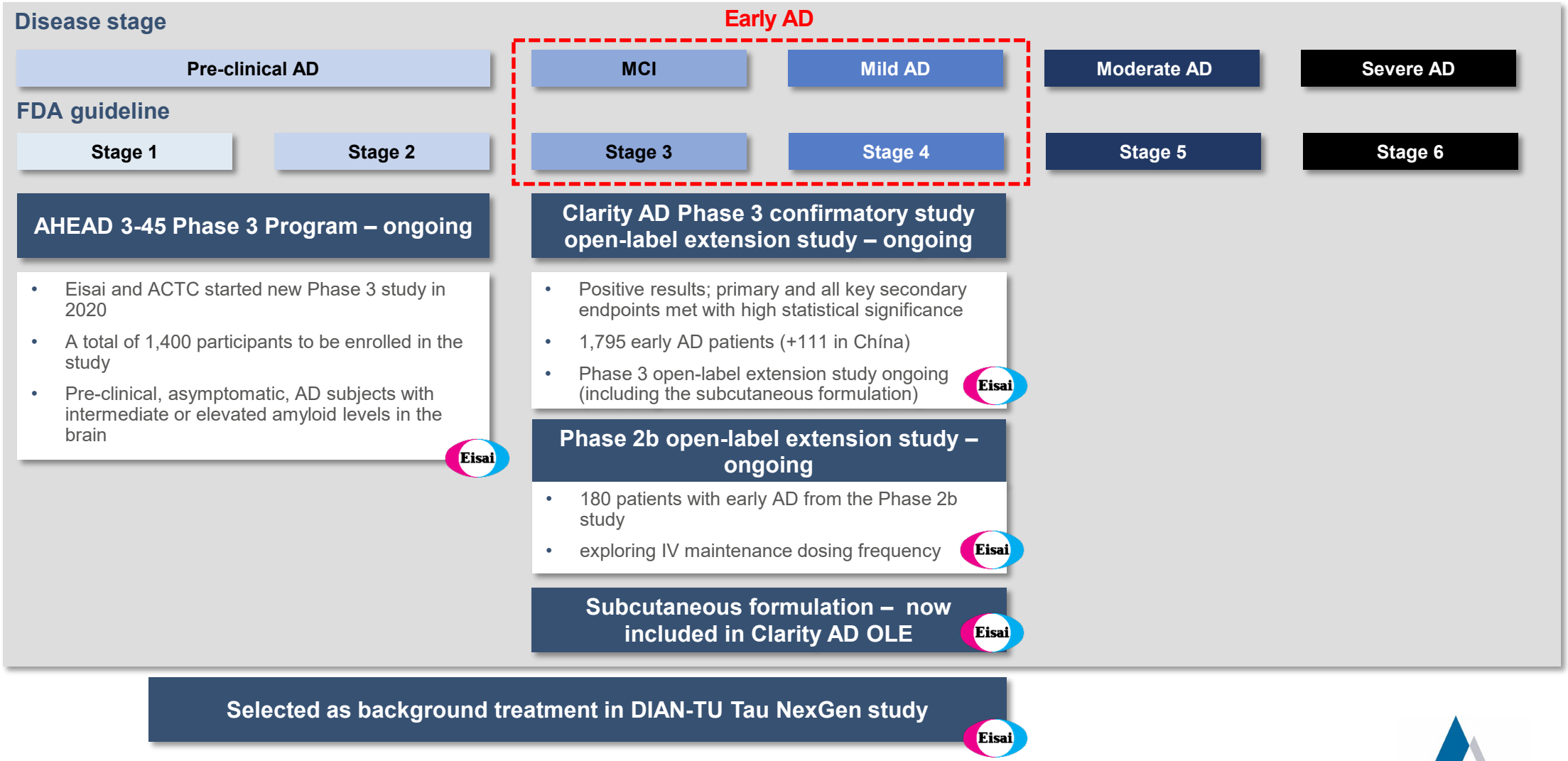
# Lecanemab – broad late-stage clinical program




**Selected as background treatment in DIAN-TU Tau NexGen study**

Eisai



MCI – Mild Cognitive Impairment
OLE – Open Label Extension
ACTC – Alzheimer's Clinical Trials Consortium
IV – Intravenous Infusion

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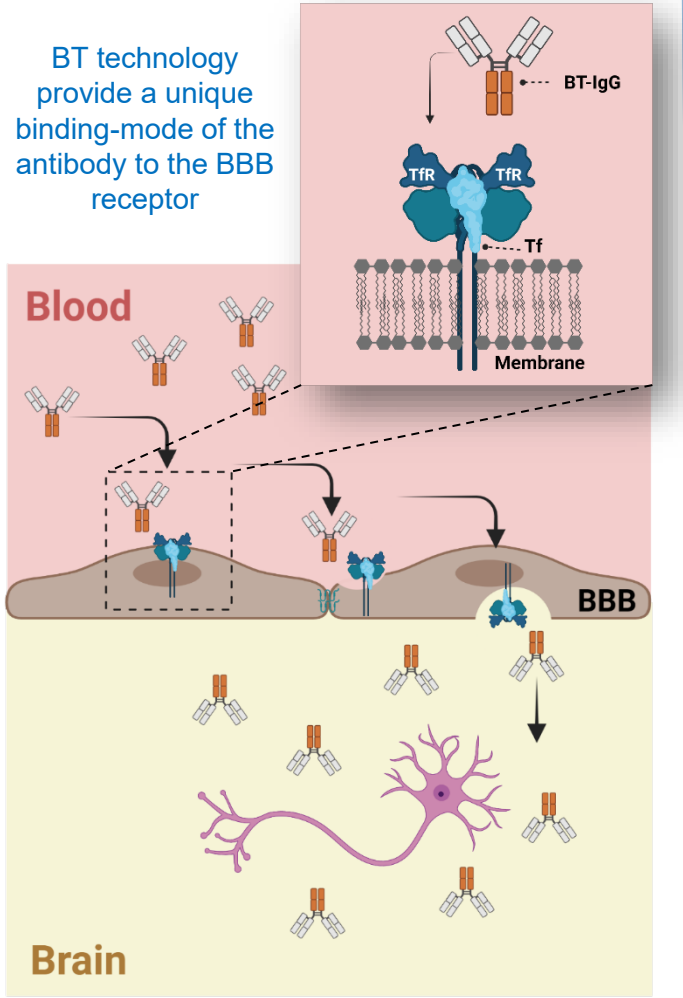
# Our view on current developments in the Alzheimer's disease field

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

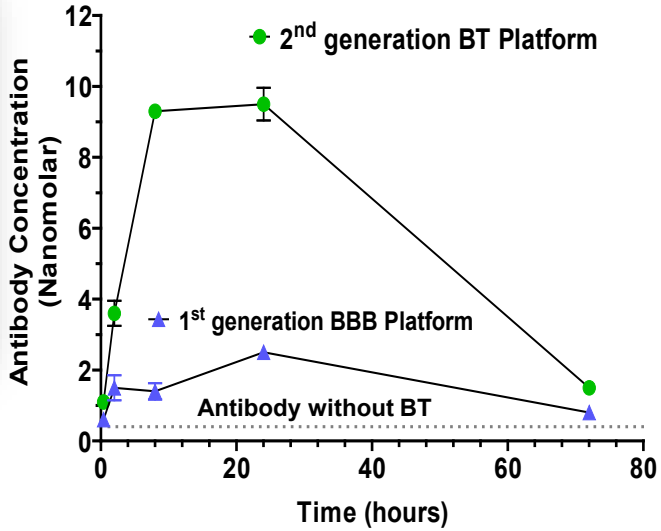
*Novel platform achieves high exposure and broad brain distribution*

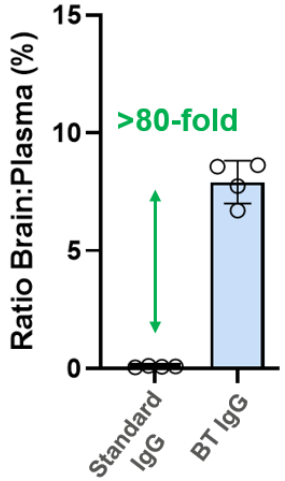
## Brain Transporter technology mediate transport across the BBB

BT technology provide a unique binding-mode of the antibody to the BBB receptor



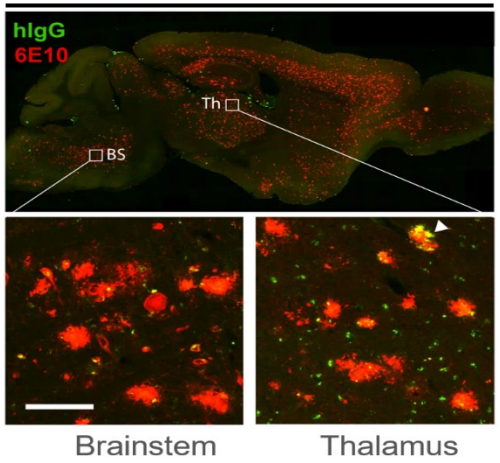

## 2nd – generation technology provide superior brain exposure



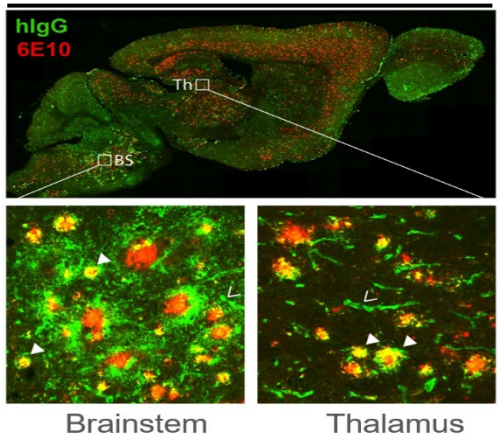




## Rapid and global brain distribution

**mAb158**




**BT-mAb158**




**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

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# TDP-43 – opportunity for ALS and other neurodegenerative disorders

## Amyotrophic lateral sclerosis (ALS) – a debilitating rare disease

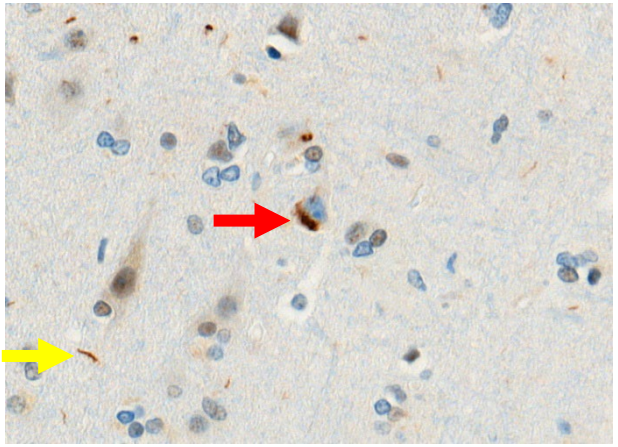
- Progressive neurodegenerative disease characterized by motor neuron degeneration

## TDP-43 a promising target for ALS – an orphan disease indication

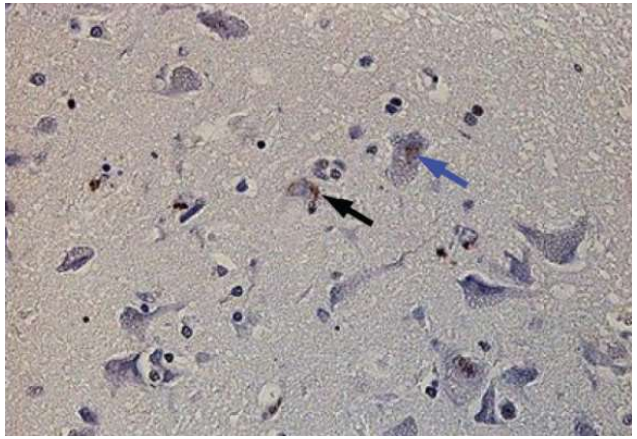
Several mutations in TARDBP (encoding TDP-43) are linked to familial ALS[1)] and FTD[2)]

Pathological aggregation of TDP-43 is found in multiple neurodegenerative diseases

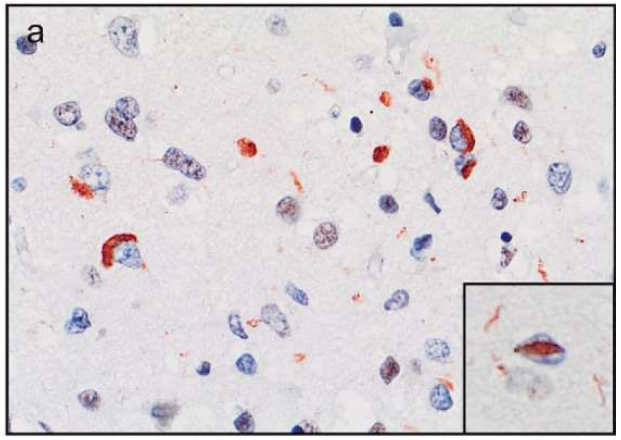
- 97% of **ALS[1)]** cases (orphan drug indication)
- 50% **AD[2)]** cases
- 45% **FTD[3)]** cases



TDP-43 pathology very common in **ALS[1)]**



Abnormal TDP-43 immunoreactivity is common in **AD[2)]**




Abnormal TDP-43 immunoreactivity is common in **FTD[3)]**

Source: Ling et. al. 2013
Note: 1) Amyotrophic lateral sclerosis, 2) Alzheimer's disease, 3) Fronto temporal dementia



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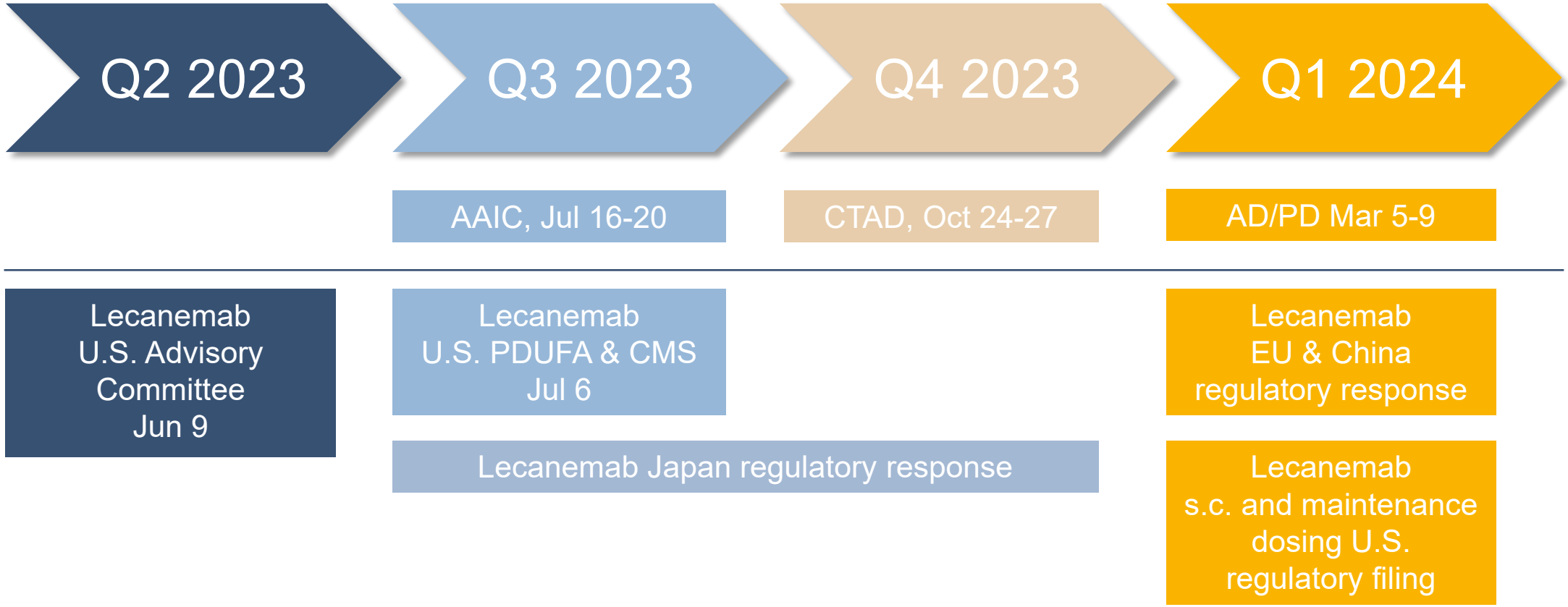
# Upcoming news flow




PDUFA – Prescription Drug User Fee Act
CMS – Centers for Medicare & Medicaid Services
s.c. – subcutaneous

# BioArctic: With Patients in Mind

Great science

Great projects

Great partners

Great people

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# IR team

| GUNILLA OSSWALD, CEO | ANDERS MARTIN-LÖF, CFO | OSKAR BOSSON, VP COMMUNICATIONS & IR | CECILIA LANNEBO, DIRECTOR IR |
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