BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

Pro Hearings

June 2, 2022

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BIOARCTIC

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BioArctic – a unique Swedish biopharma company
Improving life for patients with central nervous system disorders

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 and combination of both proprietary projects with substantial marketing and out-licensing potential and partnered projects generating income

Well-financed with close to MSEK 800 (MUSD ~86[1]) 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
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) *(Clarity AD)*	Eisai[1]	Early Alzheimer's disease[3]				
	Lecanemab (BAN2401) *(AHEAD 3-45)*	Eisai[1]	Preclinical (asymptomatic) Alzheimer's disease[4]				
	BAN2401 back-up	Eisai					
	AD1801 (ApoE)						
	AD1503 (Trunc Abeta)						
	AD-BT2802						
	AD-BT2803						
	AD2603						
PARKINSON'S DISEASE	BAN0805[2] (alpha-synuclein)						
	PD1601 (alpha-synuclein)						
	PD1602 (alpha-synuclein)						
OTHER CNS DISORDERS	Lecanemab (BAN2401)		Down's syndrome[5] Traumatic brain injury[5]				
	ND3014 (TDP-43/)		ALS				
	ND-BT3814 (TDP-43 with BT)		ALS				
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform						

as of March 31, 2022

1) Partnered with Eisai for lecanemab (BAN2401) for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding lecanemab (BAN2401) in 2014
2) AbbVie in-licensed BAN0805 in late 2018 and has developed the antibody with the designation ABBV-0805. On April 20, 2022, AbbVie informed BioArctic that it had taken a strategic business decision to terminate the collaboration regarding BioArctic's alpha-synuclein portfolio. We are currently working with AbbVie to transfer the projects back with the aim of finding a new committed partner
3) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease
4) Normal cognitive function with intermediate or elevated levels of amyloid in the brain
5) 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	Parkinson's disease
Partner track record	Eisai: Discovered and developed world's best-selling medicine for symptoms in Alzheimer's Industry-leading pipeline in dementia area Aricept donepezil HCl tablet: Used to treat confusion (dementia) related to Alzheimer's disease	abbvie: World's all-time best-selling medicine (BUSD 20) Duopa carbidopa/levodopa: Approved product for symptoms associated with Parkinson's disease HUMIRA adalimumab: 10 different indications in immunology
Collaboration and license	Milestones of up to **MEUR 151** remains to be received Royalties High single digit % **BioArctic retains rights to lecanemab in other indications and option to market in the Nordics**	Milestones of **MUSD 130** received, out of MUSD 755 Project transfer ongoing **AbbVie has global rights to alpha-synuclein portfolio for all indications**

AbbVie has taken a strategic business decision to end its collaboration with BioArctic regarding its alpha-synuclein portfolio. BioArctic will now, in accordance with the license agreement, take back the project and prepare for future partnering.

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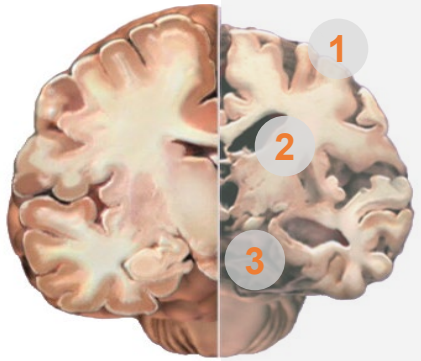
Alzheimer’s disease – high unmet medical need

Alzheimer’s Disease

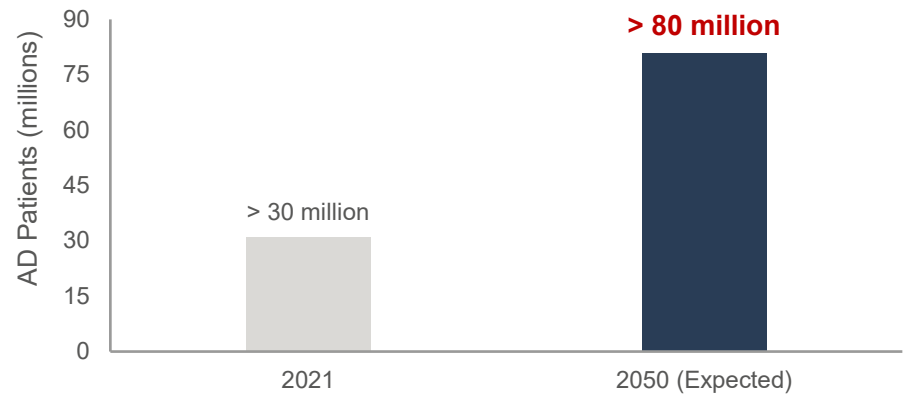
- Alzheimer’s disease (AD) is a devastating condition where neurons (nerve cells) in the brain die from exposure to toxic aggregates of a protein called amyloid beta (Aβ)
- The disease can commence up to 15 to 20 years before the patient shows clinical symptoms. The brain can shrink by almost 30 percent during the disease progression before the patient eventually dies
- AD leads to a progressive decline in memory and cognitive abilities, such as thinking, language, and learning capacity

Alzheimer’s progressively degenerates critical brain regions resulting in functional compromise

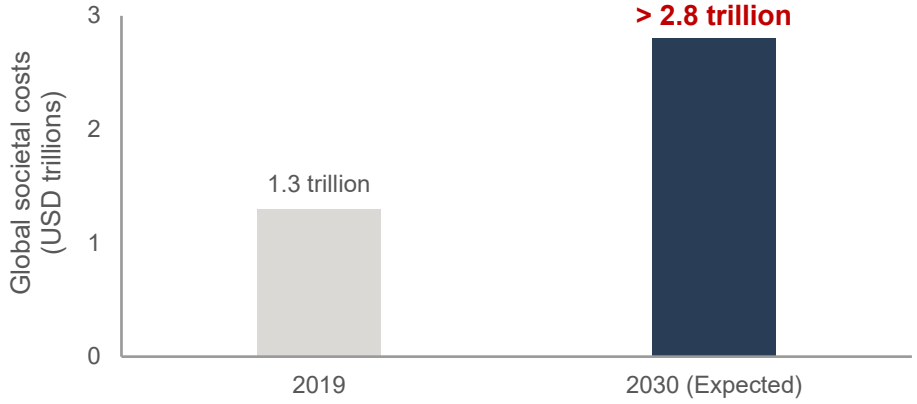


1. Cerebral cortex shrinks
   - Involved in memory, planning, thinking, language and more
2. Ventricles enlarged
   - Liquid-filled cavities. Indicate loss of surrounding regions
3. Hippocampus shrinks
   - Responsible for memory formation

High unmet medical need



High cost to society



Source: WHO

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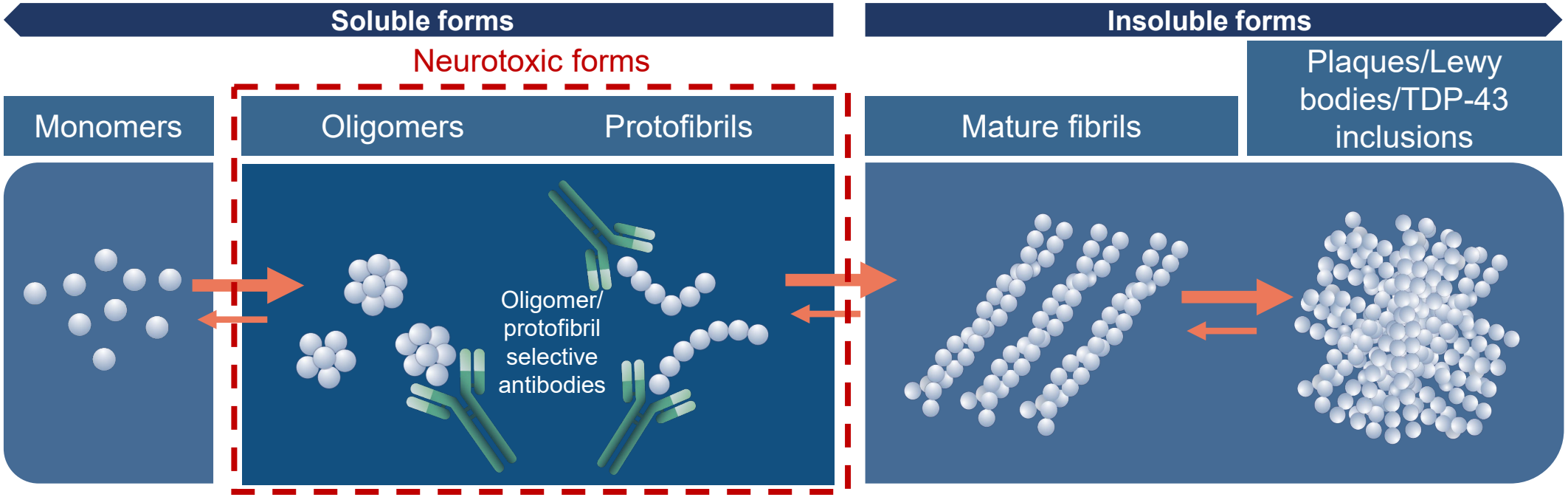
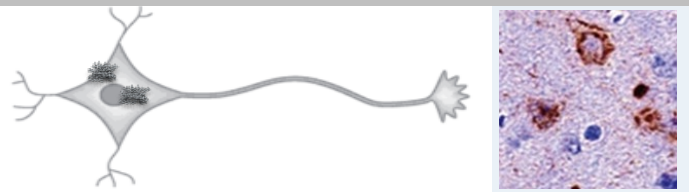
Neurotoxic forms of aggregated misfolded proteins – a promising target for disease modifying treatments in CNS disorders



Alzheimer's disease: misfolded amyloid beta results in amyloid plaques

Parkinson's disease: misfolded alpha-synuclein results in Lewy Bodies

ALS: misfolded TDP-43 results in TDP-43 inclusions



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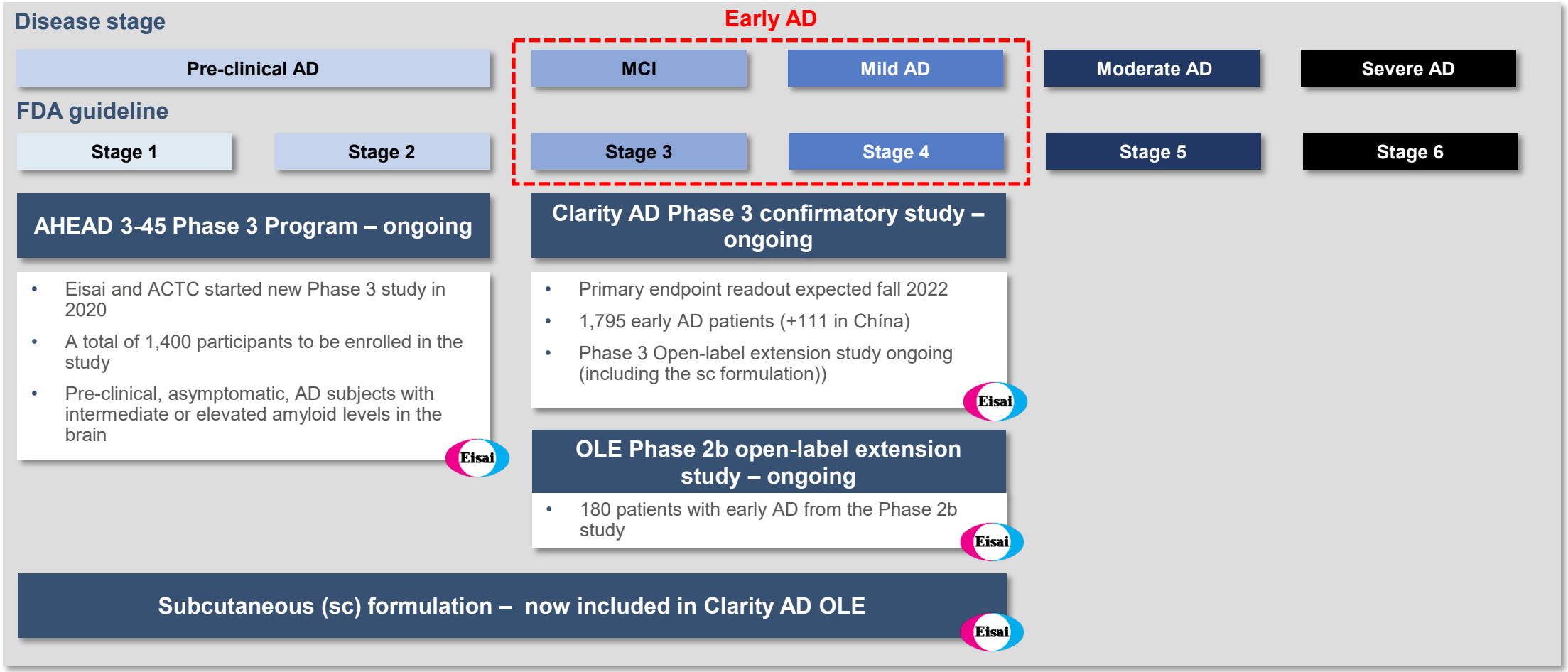
Lecanemab – broad late-stage clinical program



Selected as background treatment in DIAN-TU Tau NexGen study – first patient enrolled in January 2022

Eisai

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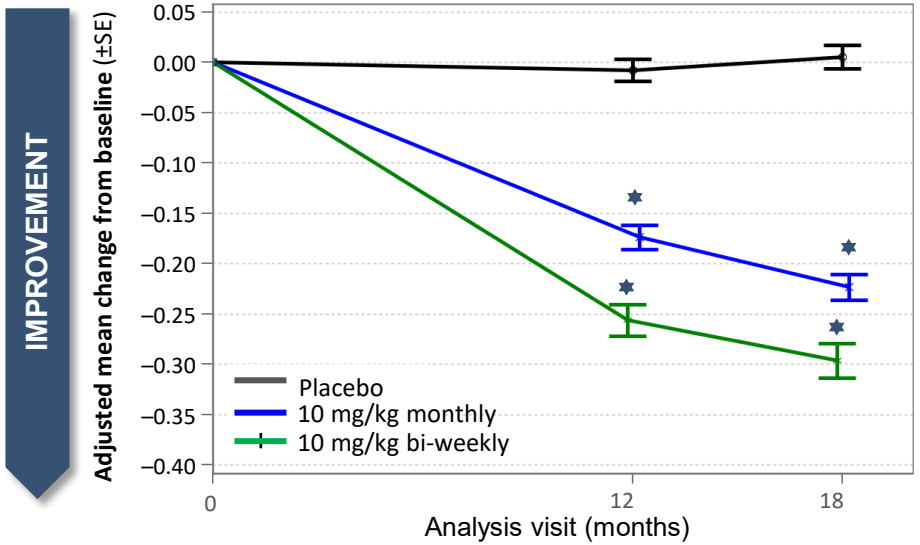
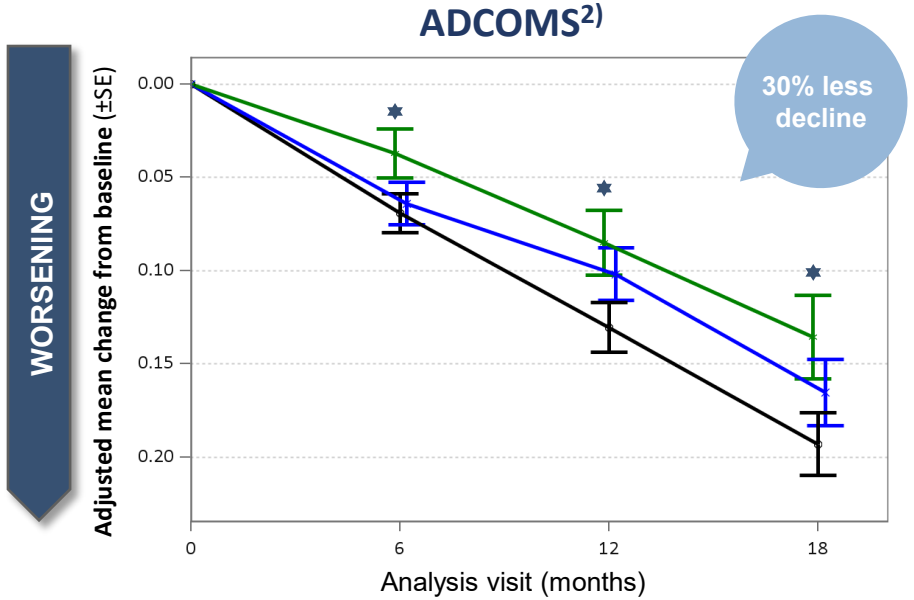
Lecanemab – potential disease modifying antibody with encouraging Phase 2b efficacy & safety profile

Amyloid PET[1)] SUVr



0.30 reduction in PET[1)] SUVr
>90% of patients negative amyloid PET[1)]

ADCOMS[2)]



Similar results for CDR-SB and ADAS-cog

Lecanemab has positive Phase 2b results

- **Large trial –** 856 early Alzheimer's patients
- **Consistent effects** on clinical outcomes, imaging and neurodegenerative biomarkers
- **Rapid onset** of clinical effect
- **Effect increases over time**
- **Good safety profile –** no titration required due to low frequency of ARIA–E (<10%)

* *Statistically significant*

Source: Presented at the Clinical Trials on Alzheimer's Disease Conference 2018; Barcelona, Spain. October 25, 2018, Alzheimer's Research & Therapy volume 13, Article number: 80 (2021). Note: 1) PET: positron emission tomography, 2) Alzheimer's disease composite score

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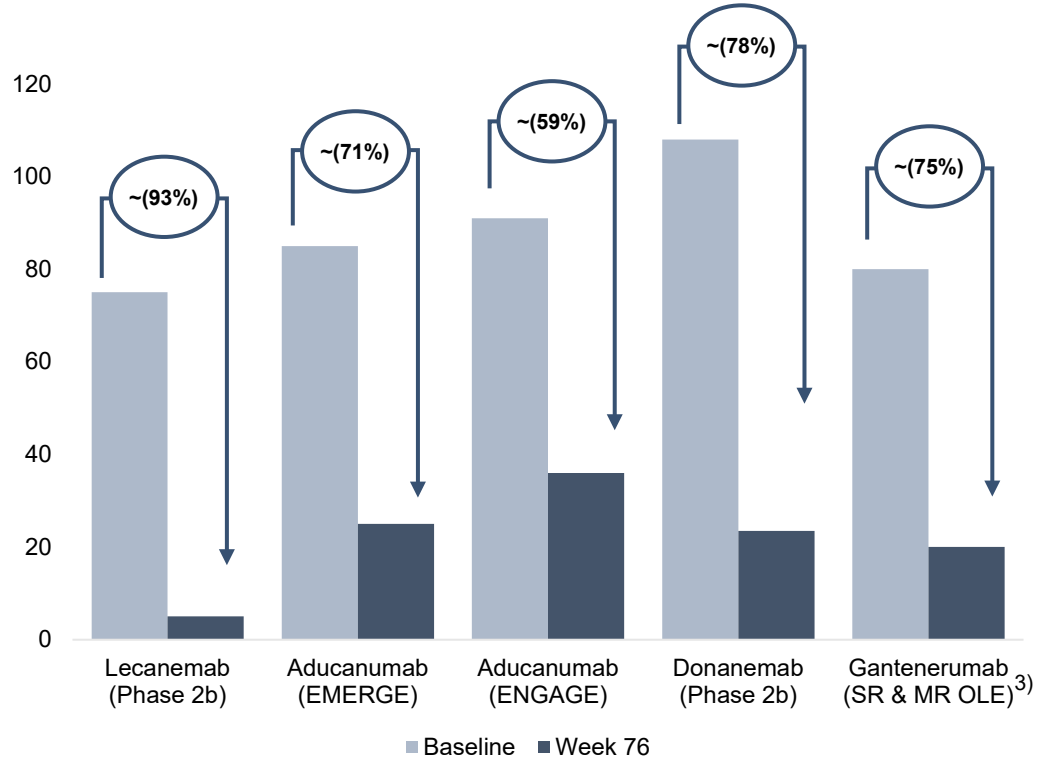
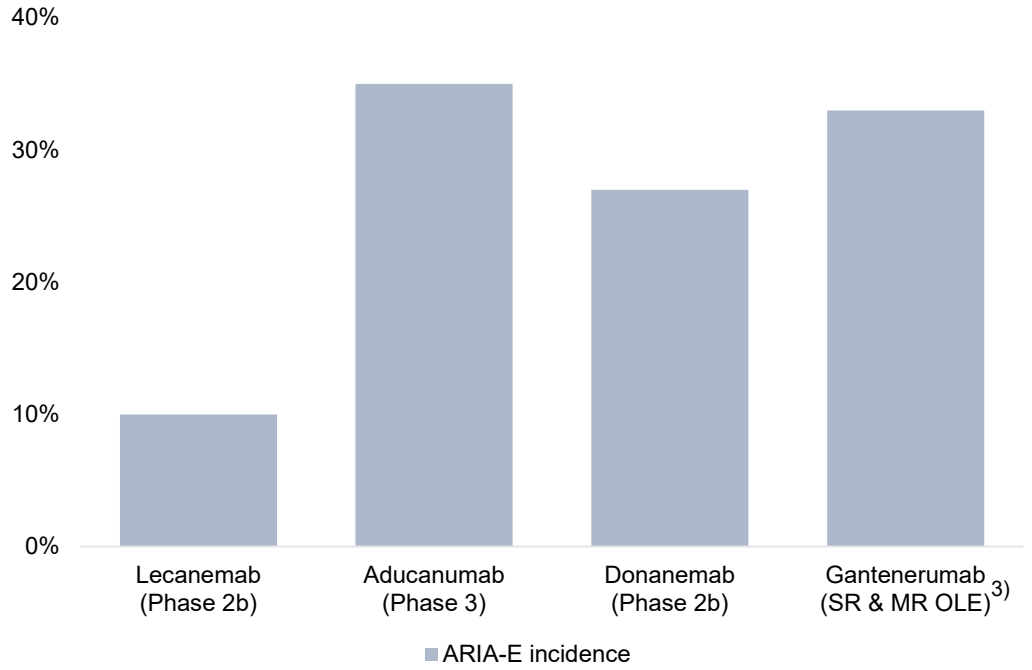
Lecanemab – strong reduction of brain amyloid and low ARIA-E incidence

PET[1] amyloid, centiloids



ARIA-E[2] incidence



Note: 1) PET: positron emission tomography, 2) Amyloid related imaging abnormalities edema, 3) Week 104
Curtesy Carnegie research

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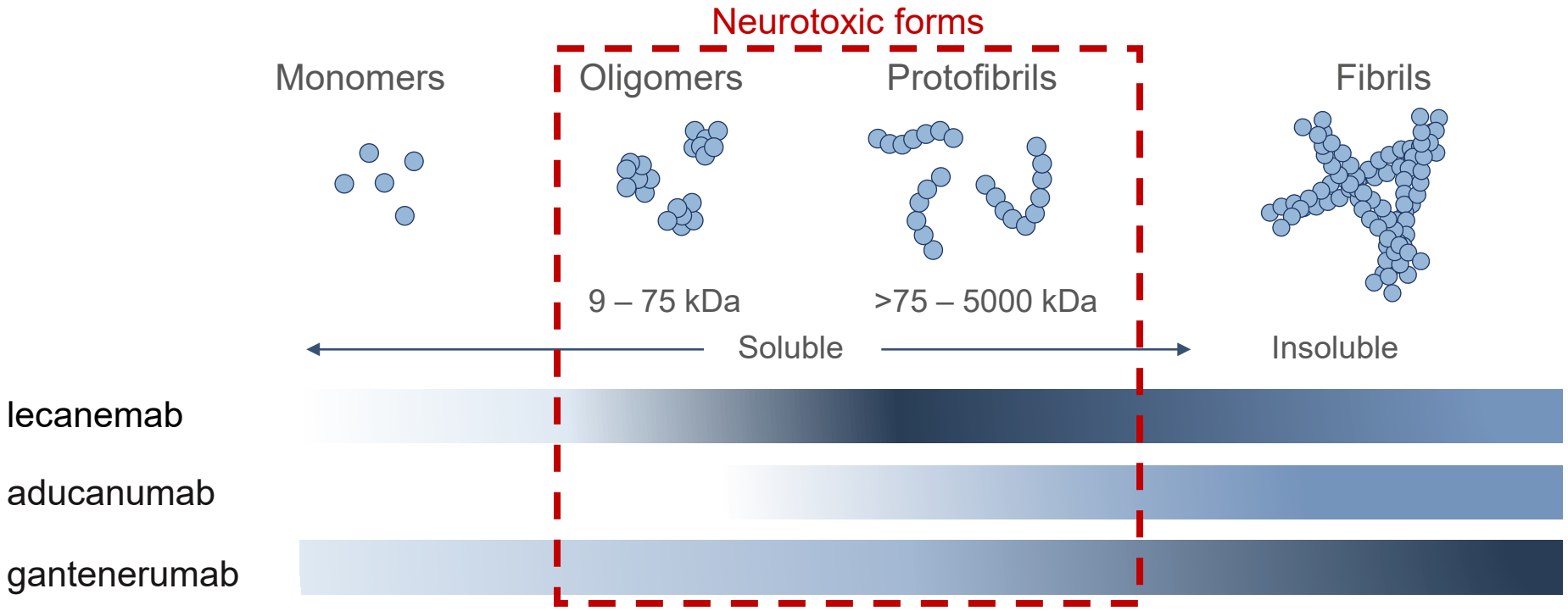
Lecanemab – unique selectivity towards toxic soluble species of Aβ

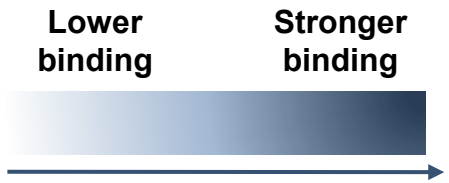


Lecanemab had the highest preference for soluble protofibrils/oligomers versus monomeric and fibrillar forms of Aβ

Aducanumab and gantenerumab had a preferences for the insoluble fibrils

Aducanumab showed a lower binding to all Aβ species

Gantenerumab had somewhat higher binding to monomers and prefers fibrils



Source: Presented at CTAD 2021. Note: Illustration is based on data from Biacore, inhibition ELISA and immunoprecipitation

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Lecanemab – favorable safety profile and encouraging efficacy data as key differentiators

	Lecanemab	Aducanumab	Donanemab	Gantenerumab
Companies	BioArctic/Eisai/Biogen	Neurimmune/Biogen/Eisai	Eli Lilly	Morphosys/Roche
Primary target	Aβ oligomers/protofibrils	Aβ fibrils	pGlu3-Aβ	Aβ fibrils
Epitope	N-terminus 2-8	N-terminus 3-7	Aβ p3	N-term + mid 3-11, 18-27
Strong reduction of brain amyloid measured by PET	✓	✓	✓	✓
Clinical effect signal on ADAS-cog, CDR-SB	✓	✓	✓	TBD
ARIA-E, brain edema	10%	35%	27%	30%
Need for titration	No	6 months	3 months	9 months

Opportunities for differentiation include; rapid clinical effect, better tolerability profile, no titration - full dose from day 1

Sources: M. Tolar Alzheimer's Research & Therapy 2020 ; Int J Mol Sci 2021; Aduhelm FDA label, Klein et al. Alzheimer's Research & Therapy (2019) 11:101, Swanson C et. al.Alzheimers Dement. 2018;14(Suppl):1668.

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Clarity AD – pivotal Phase 3 study to confirm positive Phase 2b results

Important parameters

- Right target
- Right patient population
- Right dose & exposure
- Right measurements
- Right safety

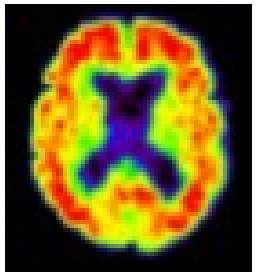
Phase 3 Study Design

Patient inclusion

Global recruitment:
- US, EU and Asia

Inclusion criteria:
- MCI due to AD or mild AD
- Positive amyloid PET/CSF

1,795
Early Alzheimer patients



Treatment 18 months

Randomized, double-blind, placebo controlled, parallel-group study

Lecanemab
10 mg/kg twice a month

Placebo

Primary analysis:
- Change from baseline in CDR-SB

Key analyses:
- Change from baseline in ADCOMS, ADAS-cog
- Change from baseline in brain amyloid PET SUVr
- Biomarkers: amyloid PET positive to negative conversion, tau PET, blood and CSF biomarkers incl. Aβ, p-tau, t-tau, neurogranin, Neurofilament light
- Safety and tolerability

Open-label extension (OLE)

Lecanemab
10 mg/kg twice a month

Once a week subcutaneous to be explored

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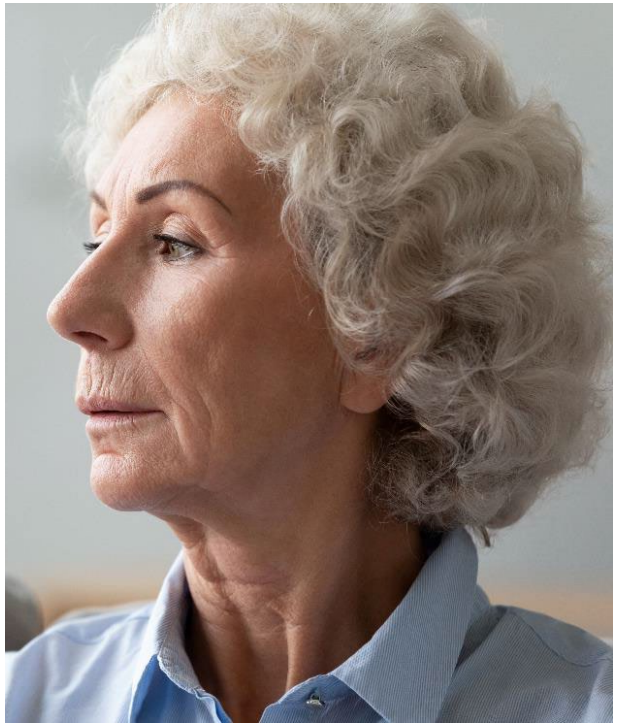
Recent news – Alzheimer’s disease

Alzheimer’s disease – Lecanemab

- Eisai has **completed the rolling submission** to the FDA of lecanemab for early Alzheimer’s disease under the accelerated approval pathway – awaiting FDAs acceptance of file and PDUFA date. BioArctic entitled to a milestone of MEUR 15 at acceptance
- Lecanemab was granted **Fast Track designation** by the FDA in December 2021 and **prior assessment review** by PMDA in March 2022
- Data presented at AD/PD congress in March continue to **further strengthen and differentiate lecanemab** towards competitors
- An article in Neurology and Therapy based on disease modeling suggests that **lecanemab could delay the progression** to Alzheimer's dementia by several years
- **Build-up of commercial organization** initiated



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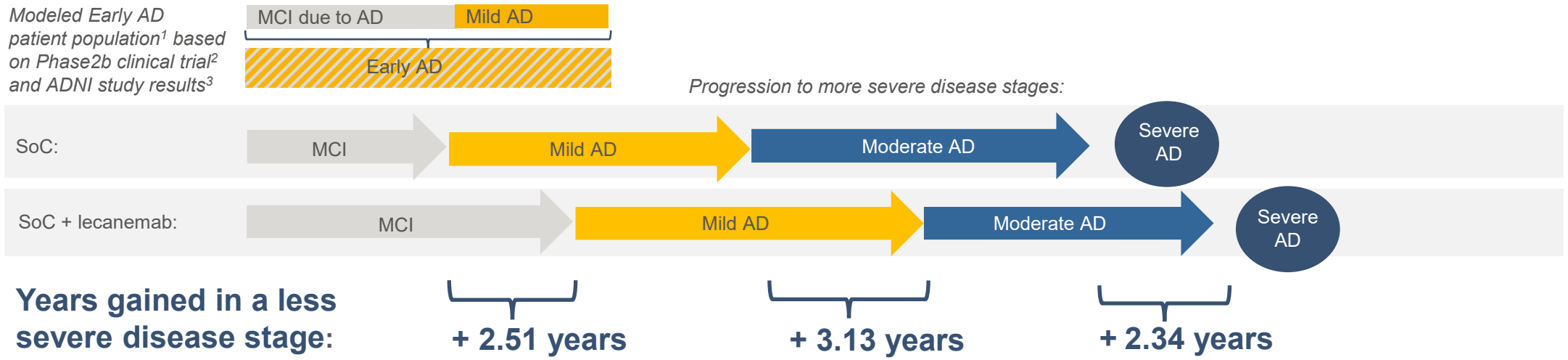
Disease modeling suggests that lecanemab could delay progression to Alzheimer´s dementia by several years

Simulated mean time advancing to mild, moderate, and severe Alzheimer's disease (AD) dementia was longer for patients in the lecanemab-treated group than for patients in the standard of care group



The results from the modeling show the potential clinical value of lecanemab for patients with early AD and how it can slow the rate of disease progression, delay progression to AD dementia with several years and 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-Aβ protofibril antibody". Alzheimer's Res Ther. 2021.*
3. *ADNI (Alzheimer's Disease Neuroimaging Initiative) study*

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Lecanemab – potential to lead the paradigm shift in the treatment of Alzheimer's disease

Increased likelihood for lecanemab success

- → Positive and consistent Phase 2b results
- → Phase 2b OLE further strengthens the Phase 2b results
- → Phase 3 study "Clarity AD" designed to confirm the positive Phase 2b results

✓

Opportunity to be first with full approval in US, Japan and EU

- → Accelerated approval path way ongoing in the US and rolling submission completed May 2022
- → Submission for full approval in the US, EU and Japan planned by Q1 2023, pending topline Phase 3 data expected fall 2022

✓

Opportunity to differentiate

- → Unique binding profile
- → Rapid and profound brain amyloid clearance
- → Early onset of clinical effect in slowing cognitive decline
- → Good tolerability profile
- → Full dose from day one

✓

Further development programs

- → Subcutaneous injection
- → Blood biomarkers utilized to explore reduced dosing frequency for maintenance treatment
- → Expanded Alzheimer's disease populations:
  - → Selected for AHEAD in pre-symptomatic individuals
  - → Selected as background treatment for DIAN-TU NexGen study – dominantly inherited Alzheimer disease

✓

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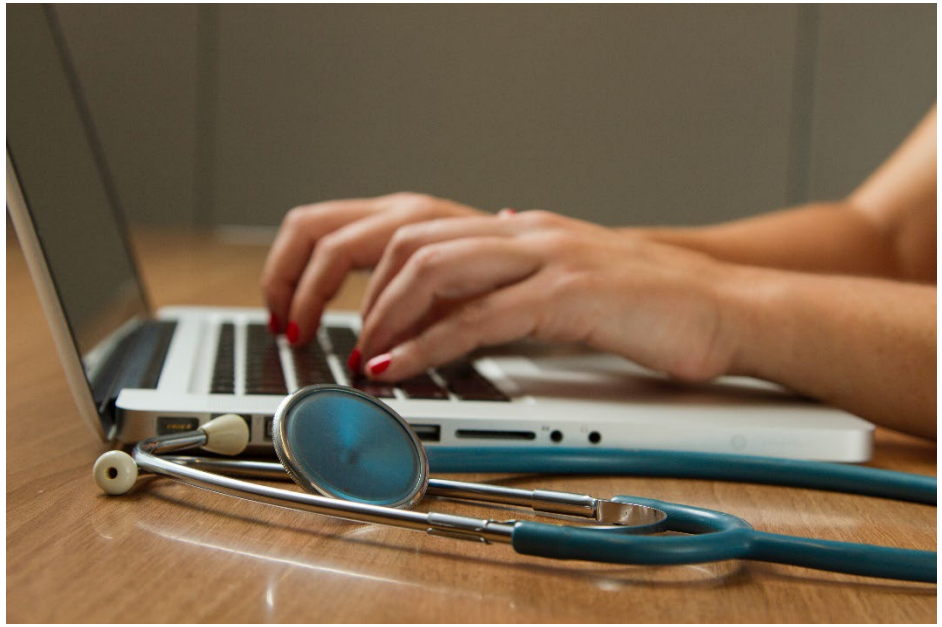
The next step on a transformational journey for BioArctic

Establish commercial organization in the Nordic countries, with stepwise and timely recruitment, including support functions and IT infrastructure

- Increase awareness about;
  - early Alzheimer's disease,
  - current and future diagnostics incl blood-based biomarkers,
  - the possibility of future paradigm-shifting disease modifying treatments
- Build and prepare pricing and market access strategies to demonstrate value of potential products
- Build a solid case for the positioning of potential products in a competitive market
- Prepare patient centric infrastructure to support launch based on the patient journey and digital education initiatives
- Prepare for Life Cycle Management (subcutaneous formulation, indication expansions)



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Significant progress and expansion of the pipeline

Parkinson's disease

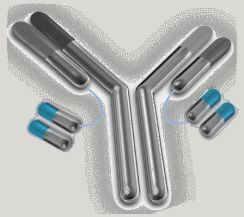
BAN0805

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

Discovery stage projects

- Pre-clinical stage alpha-synuclein projects

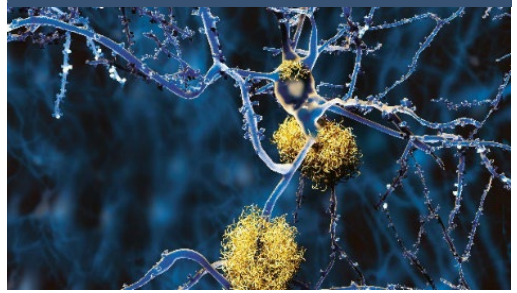
Blood-brain barrier



Brain Transporter (BT)

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

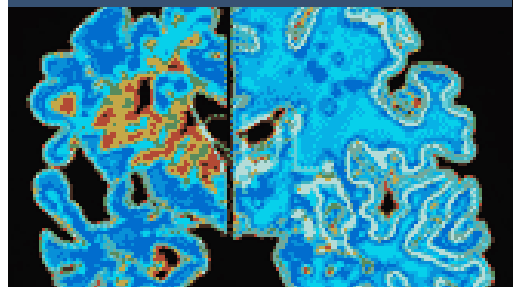
Alzheimer's disease



Discovery stage programs

- Expanded early-stage portfolio with two new AD+BT projects
- Five internal disease modifying antibody projects in Alzheimer's disease

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[1)] now also combined with the BT-technology

Note: 1) Amyotrophic lateral sclerosis

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BAN0805 – potential disease modifying antibody in Parkinson's disease with positive Phase 1 results

BAN0805

High unmet medical need

No existing disease-modifying treatment

Younger patient group, still at working age

TODAY

>6 million[1]
people with Parkinson's

Unique profile

Unique and targeted binding profile

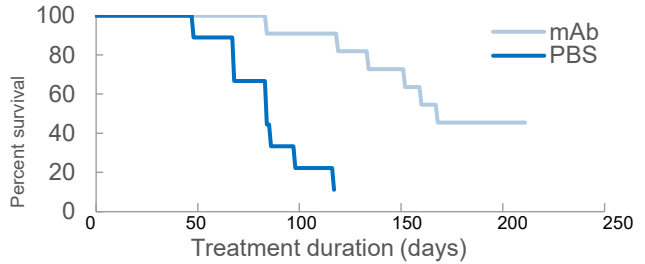
- Highly selective (>100,000) for pathological forms of misfolded alpha-synuclein (oligomers/protofibrils) vs physiological forms (monomers)

Built on genetic and pathology rationale

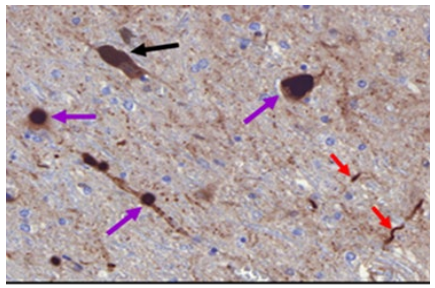
- Alpha-synuclein mutations lead to PD
- Alpha-synuclein oligomers/ protofibrils are elevated in PD

Pre-clinical proof of concept

- Reduction of neurotoxic alpha-synuclein oligomers/protofibrils
- Delays disease progression and increases lifespan



Human target binding of BAN0805 in PD brain



Black: neuromelanin ,Purple: Lewy bodies, Red:Lewy neurites

Phase 1 results presented at MDS congress in Sept 2021 support Phase 2 development with dosing once a month

Source: 1) Dorsey and Bloem, JAMA Neurology 2018;75:9-10
Data presented at the International Congress of Parkinson's disease and movement disorders® (MDS), held virtually September 17 to 22, 2021, and published in Neurobiology of Disease in November 2021.

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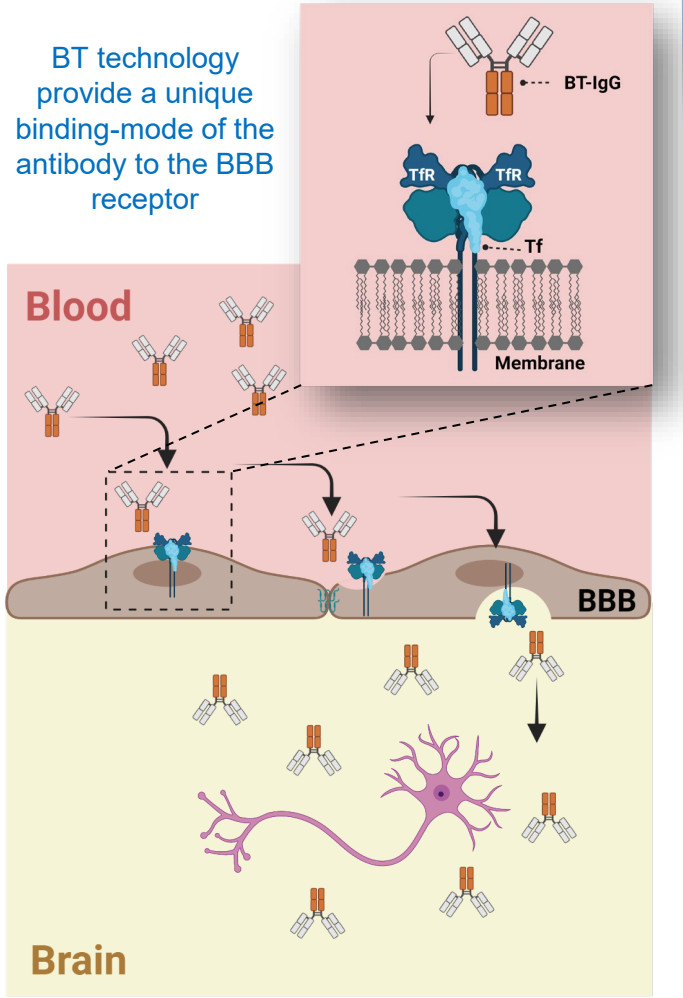
Brain Transporter (BT) technology delivers biotherapeutics to the brain

Novel platform achieves high exposure and broad brain distribution

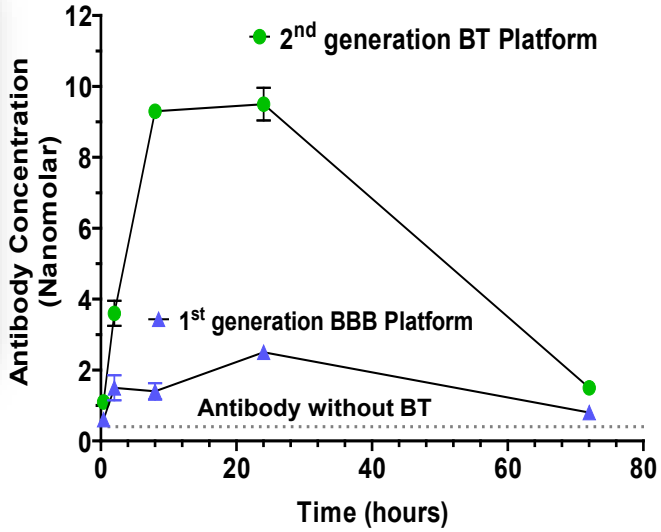
BT

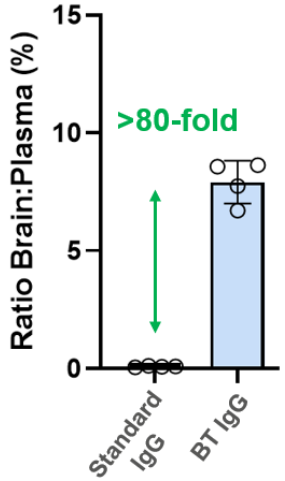
Brain Transporter technology mediate transport across the BBB

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



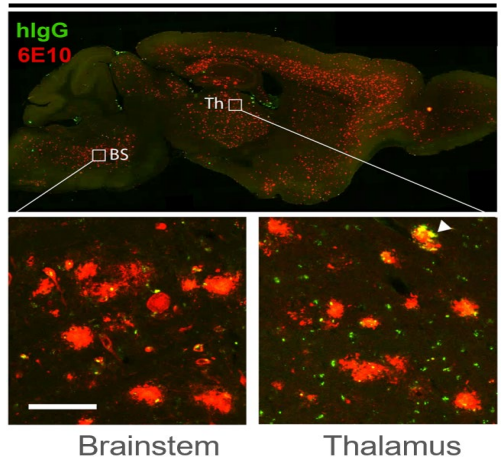
2nd – generation technology provide superior brain exposure



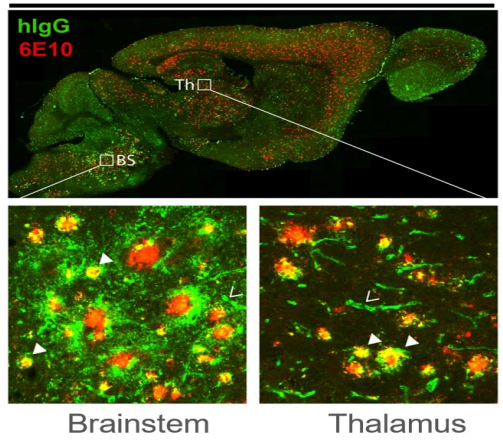


Rapid and global brain distribution

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 three portfolio projects (AD-BT2802, AD-BT2803, ND-BT3814)

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

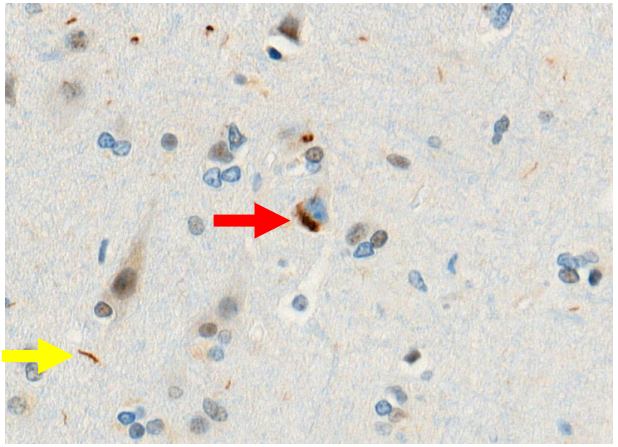
- Progressive neurodegenerative disease characterized by motor neuron degeneration

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

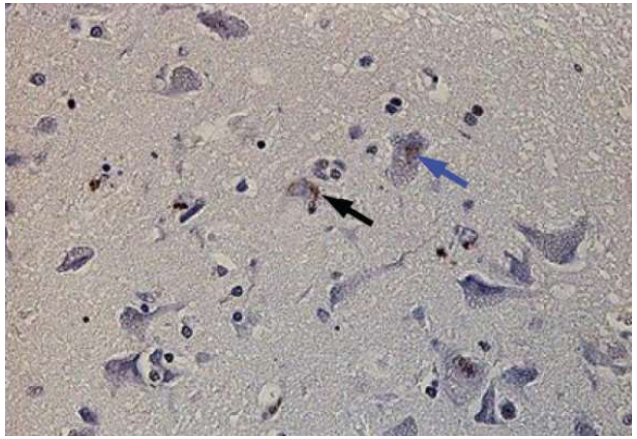
Several mutations in TARDBP (encoding TDP-43) are linked to familial ALS[1)] and FTD[2)]

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

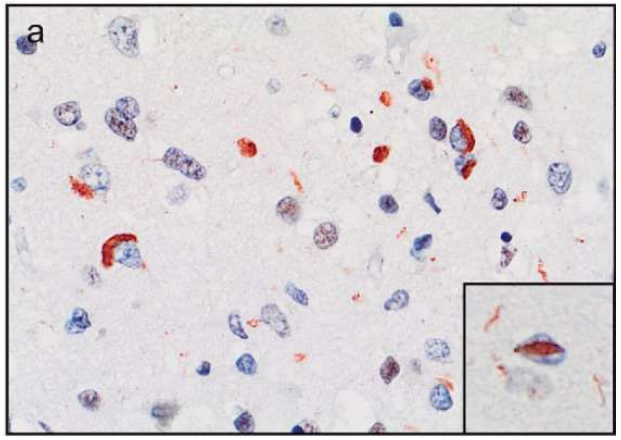
- 97% of **ALS[1)]** cases (orphan drug indication)
- 50% **AD[2)]** cases
- 45% **FTD[3)]** cases



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)]**

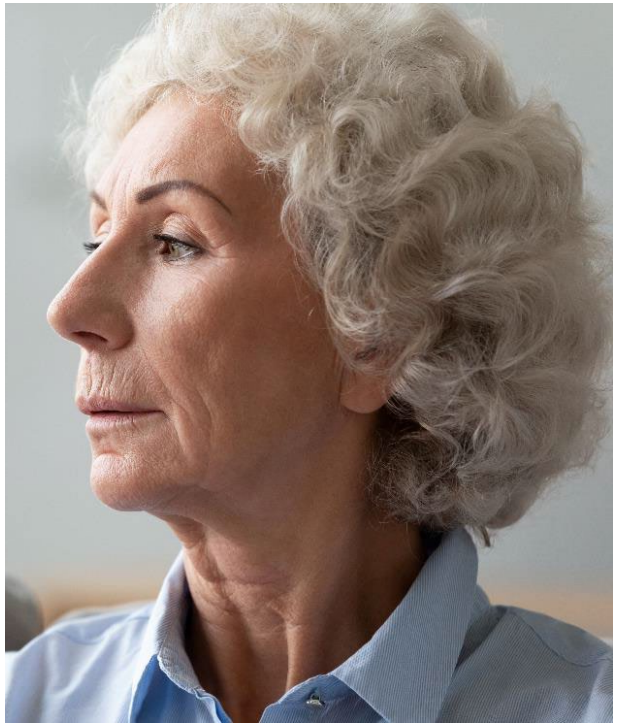
Source: Ling et. al. 2013
Note: 1) Amyotrophic lateral sclerosis, 2) Alzheimer's disease, 3) Fronto temporal dementia

BIOARCTIC

Recent news – rest of portfolio

Parkinson's disease – BAN0805

- BioArctic has received a **new drug substance patent** in the US for BAN0805 against Parkinson's disease valid until 2041, with the possibility of a patent term extension up until 2046
- Encouraging pre-clinical data and Phase 1 results were presented at MDS congress in September 2021 and at the 4D meeting in May. The Phase 1 study **results support continued development** of the antibody into Phase 2 with dosing once a month
- On April 20, 2022, AbbVie informed BioArctic that they have made a strategic business decision to terminate the license agreement regarding BioArctic's alpha-synuclein portfolio. BioArctic will now, in accordance with the license agreement, **take back the project and prepare for future partnering**

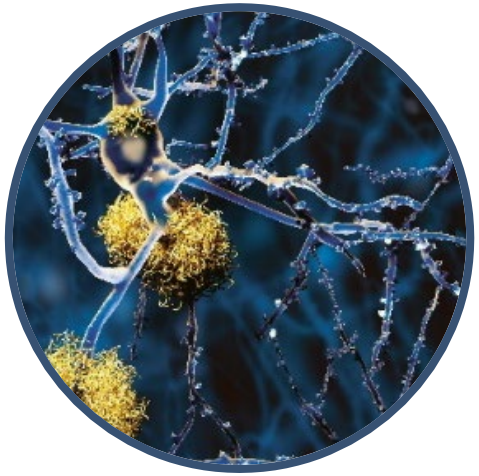


Other

- **Expanding into ALS** as a new indication with a treatment targeting (TDP-43)
- **Expanding project portfolio** with BT technology combined with TDP-43 antibody

Upcoming news flow

Alzheimer's disease



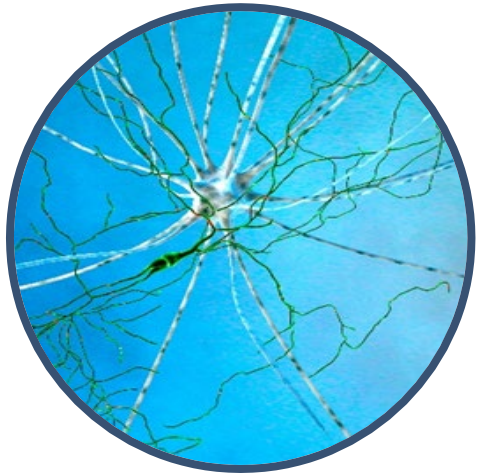
Lecanemab (Eisai)

- Rolling submission for accelerated approval in the US completed in May 2022
- Clarity AD topline data expected fall 2022
- Data to be disclosed at international congresses

Discovery stage programs

- Advancement of projects

Parkinson's disease

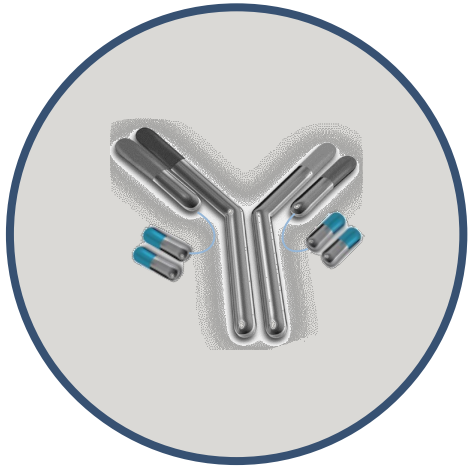


BAN0805

Data presented at international congresses

AbbVie has taken a strategic business decision to end its collaboration with BioArctic regarding its alpha-synuclein portfolio. BioArctic will now, in accordance with the license agreement, take back the project and prepare for future partnering.

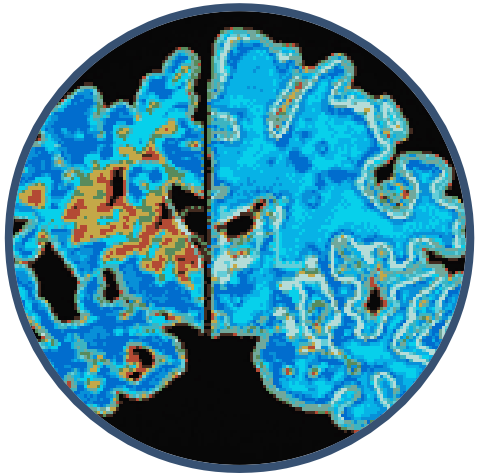
Blood-brain barrier



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

BioArctic: With Patients in Mind

Great science

Great projects

Great partners

Great people

BIOARCTIC

GUNILLA OSSWALD, CEO

JAN MATTSSON, CFO

OSKAR BOSSON, VP COMMUNICATIONS & IR

NEXT REPORT & IR CONTACT

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  Q2 Jan-Jun 2022
  on July 12, 2022
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