BIOARCTIC AB (PUBL)
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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 850 (MUSD ~94[1]) in cash and **valuable collaboration agreements**

1) FX as per December 31, 2021
2) FX as per December 31, 2021

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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						
	AD1502						
	AD1503						
	AD-BT2802						
	AD-BT2803						
	AD2603						
PARKINSON'S DISEASE	ABBV-0805[2]	AbbVie					
	PD1601	AbbVie					
	PD1602	AbbVie					
OTHER CNS DISORDERS	Lecanemab (BAN2401)		Down's syndrome[5] Traumatic brain injury[5]				
	ND3014		ALS				
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform						
DIAGNOSTICS	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

as of December 31, 2021

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 develops the antibody with the designation ABBV-0805. On April 20, 2022 , AbbVie informed BioArctic that they have made a strategic business decision to terminate the collaboration agreement
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	**MEUR 222** *Total value agreements* **MEUR 66** RECEIVED **Royalties High single digit %** **BioArctic retains rights to lecanemab in other indications and option to market in the Nordics**	**MUSD 755** *Total value agreements* **MUSD 130** RECEIVED **Royalties Tiered %** **AbbVie has global rights to alpha-synuclein portfolio for all indications**

On April 20, 2022, AbbVie informed BioArctic that they have made a strategic business decision to terminate the collaboration agreement

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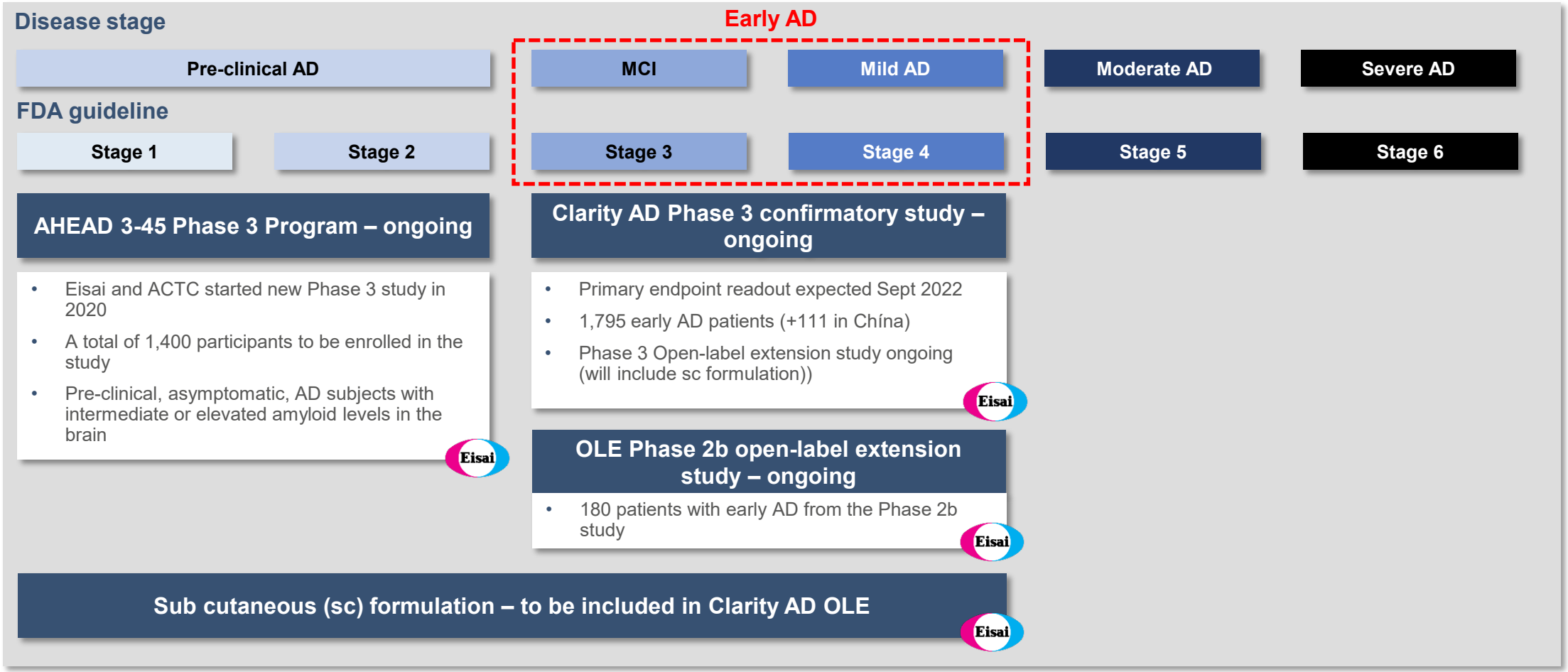
Lecanemab – broad late-stage clinical program



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

Eisai

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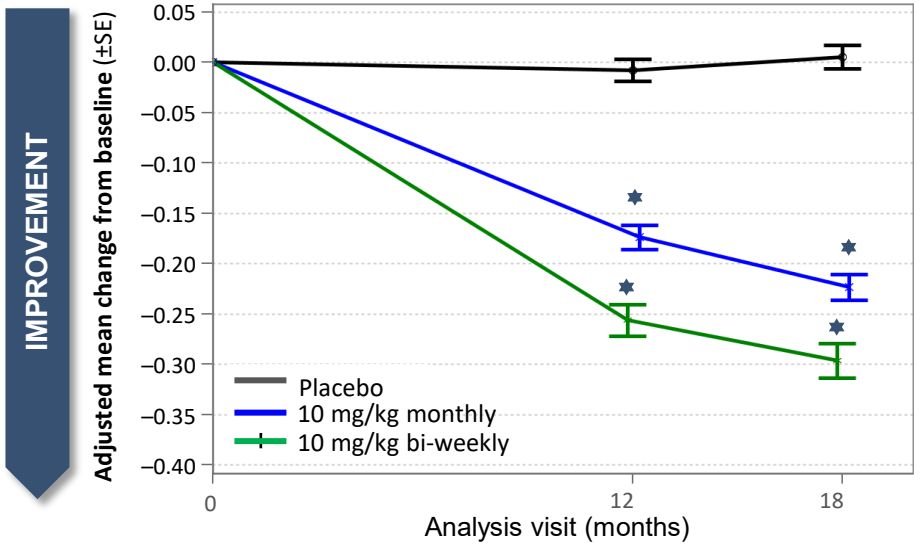
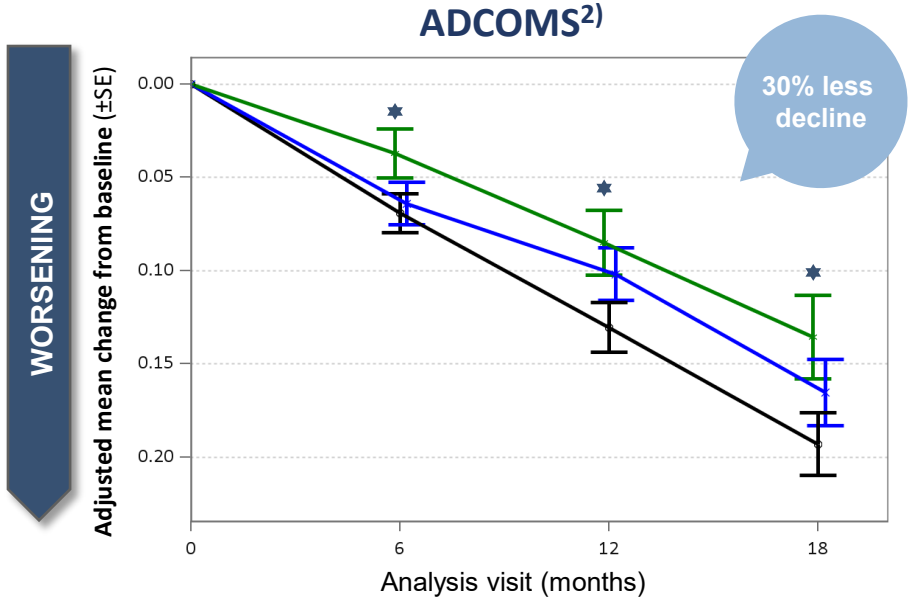
Lecanemab – potential disease modifying antibody with encouraging Phase 2b efficacy & safety profile in early Alzheimer's disease

Amyloid PET[1] SUVr



93% reduction in PET[1] centiloid
>90% of patients negative amyloid PET[1] SUVr

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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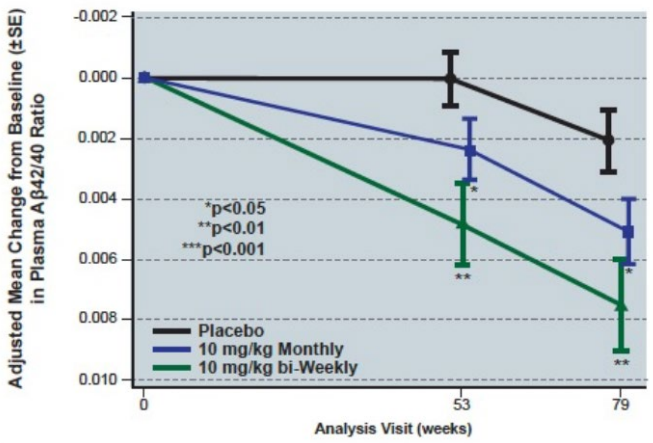
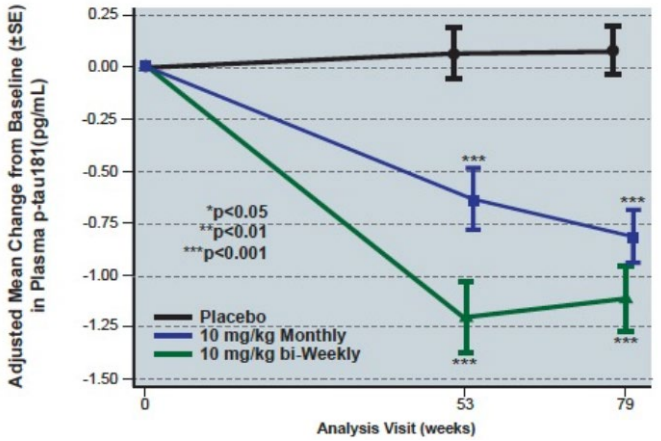
New data presented at AD/PD 2022 continues to strengthen lecanemab Robust effect on blood biomarkers in Phase 2b (Aβ 42/40 and p-tau 181)

"the AD/PD conference 2022 showcases the great achievements being done within the field and there is excitement towards the key results coming later this year"





Blood biomarker Aβ42/40 ratio

Robust effect on plasma Aβ42/40 ratio by lecanemab

Plasma Aβ42/40 ratio correlates with brain amyloid PET clearance

Blood biomarker p-tau 181

Robust effect on plasma p-tau181 by lecanemab

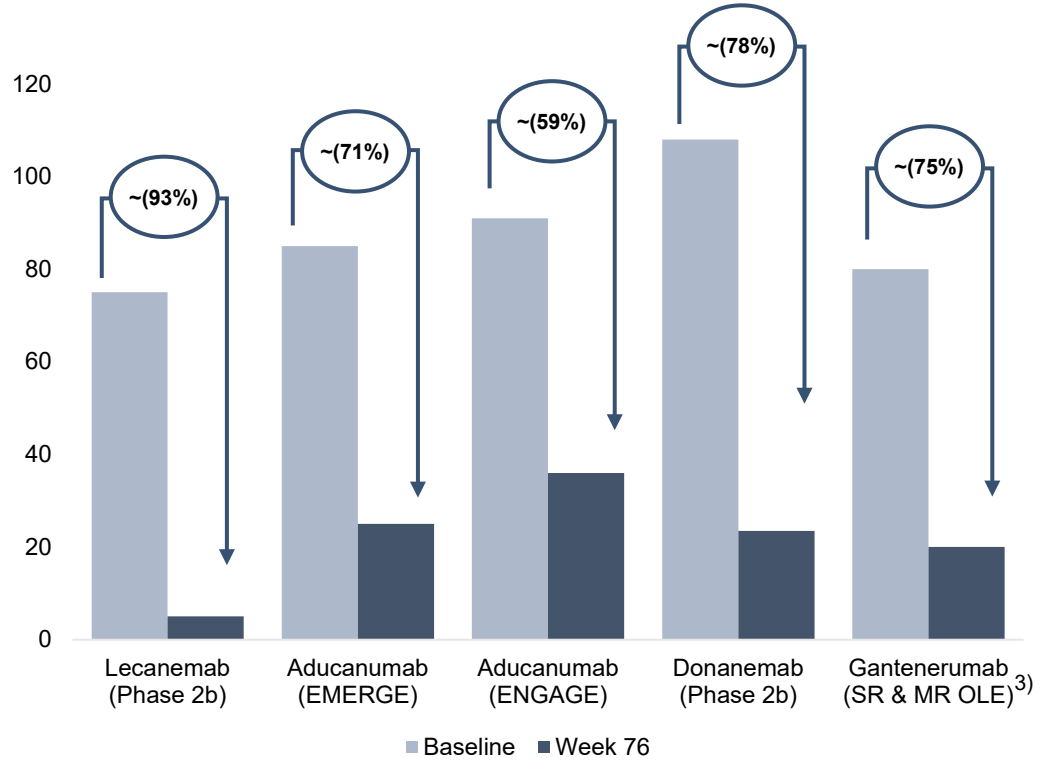
Targeting amyloid influence the downstream tau-related processes

Y-axis was inverted for plasma Aβ42/40 Ratio. Increase in plasma Aβ42/40 Ratio reflects decrease in brain amyloid levels for this inverted figure.

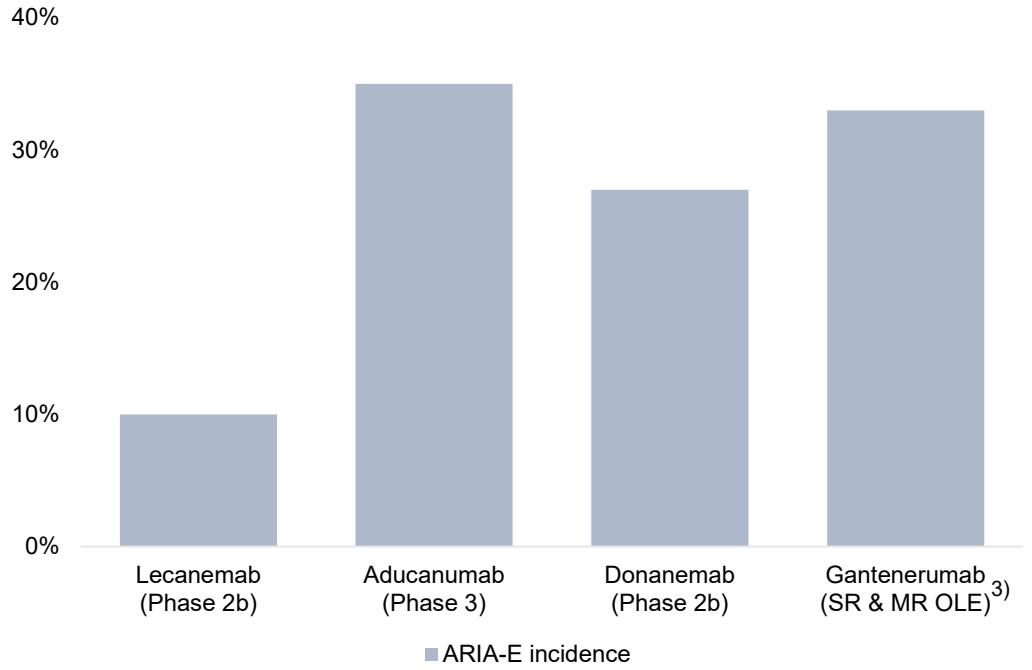
Source: Data presented at AD/PD 2022 by BioArctic and Eisai

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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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

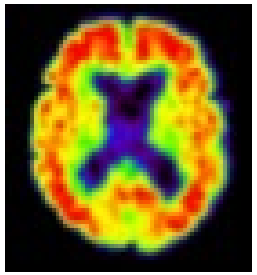
Phase 3 Study Design

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

Less frequent IV dosing to be explored

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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 and EU

- → Accelerated approval pathway ongoing in the US and submission is expected to be completed Q2 2022
- → Submission for full approval in the US, EU and Japan planned by Q1 2023, pending topline Phase 3 data expected Sept 2022

✓

Opportunity to differentiate

- → Rapid and profound brain amyloid clearance
- → Early onset of clinical effect in slowing cognitive decline
- → Better tolerability profile than competition
- → 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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Recent news

Alzheimer's disease – Lecanemab

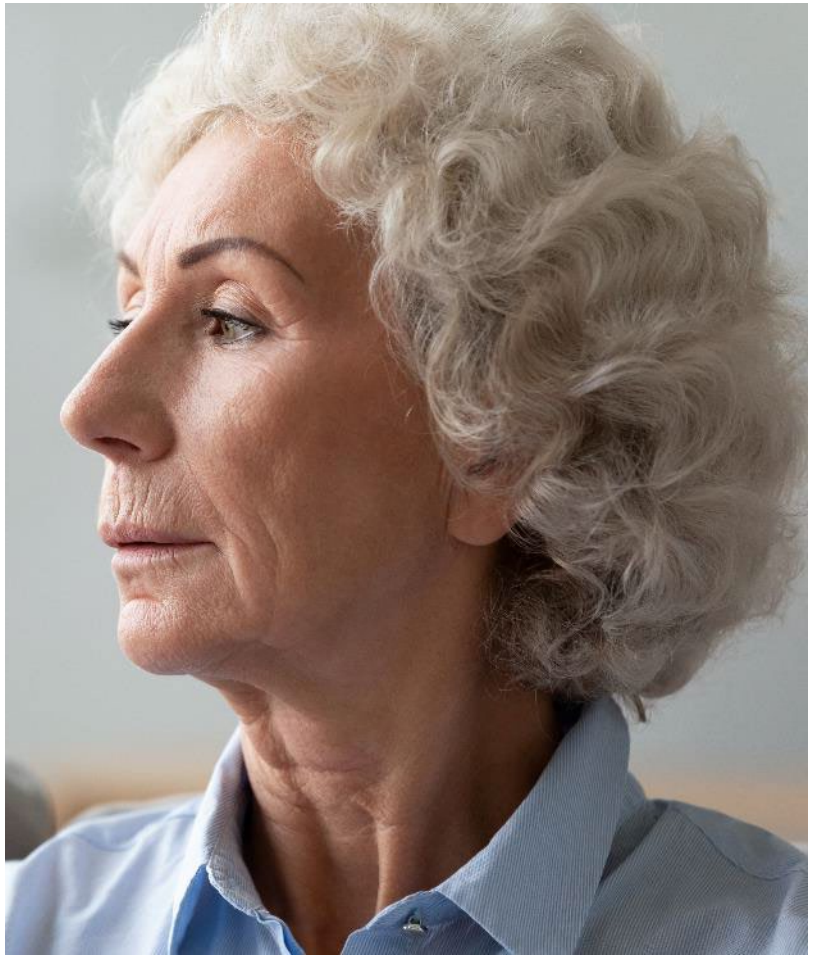
- Eisai has after agreement with FDA initiated a rolling BLA submission under the accelerated approval pathway. Two of three parts have been submitted and the submission is expected to be completed during Q2 2022
- Data presented at AD/PD congress in March continue to further strengthen and differentiate lecanemab towards competitors
- Lecanemab selected by DIAN-TU as background anti-amyloid therapy in combination with tau therapies in the NexGen study in dominantly inherited Alzheimer's disease, first patient enrolled in January 2022
- Lecanemab was granted Fast Track designation by the FDA in December 2021 and was granted prior assessment review by PMDA in March 2022

Parkinson's disease – ABBV-0805

- Encouraging pre-clinical data presented at the MDS congress in September and published in Neurobiology of Disease in November
- Phase 1 results presented by AbbVie at the MDS congress in September support Phase 2 development with dosing once a month
- On April 20, 2022, AbbVie informed BioArctic that they have made a strategic business decision to terminate the collaboration agreement

Other

- Build-up of commercial organization initiated
- Expanding into new indications and treatment target (TDP-43)



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ABBV-0805 – potential disease modifying antibody in Parkinson's disease

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

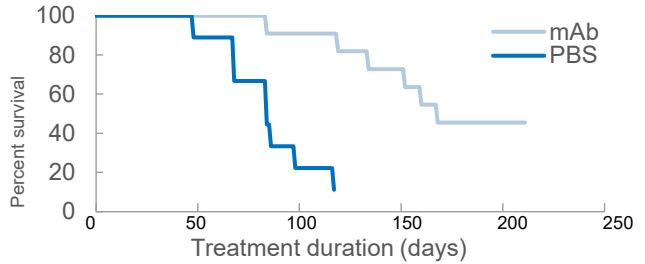
- Highly selective (>100,000) for pathological forms of aggregated alpha-synuclein (oligomers/protofibrils) vs physiological forms (monomers)

Built on genetic and pathology rationale

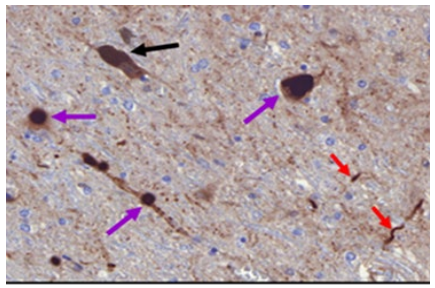
- Alpha-synuclein mutations lead to PD
- Alpha-synuclein oligomers/ protofibrils are elevated in PD

Pre-clinical proof of concept

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



Human target binding of ABBV-0805 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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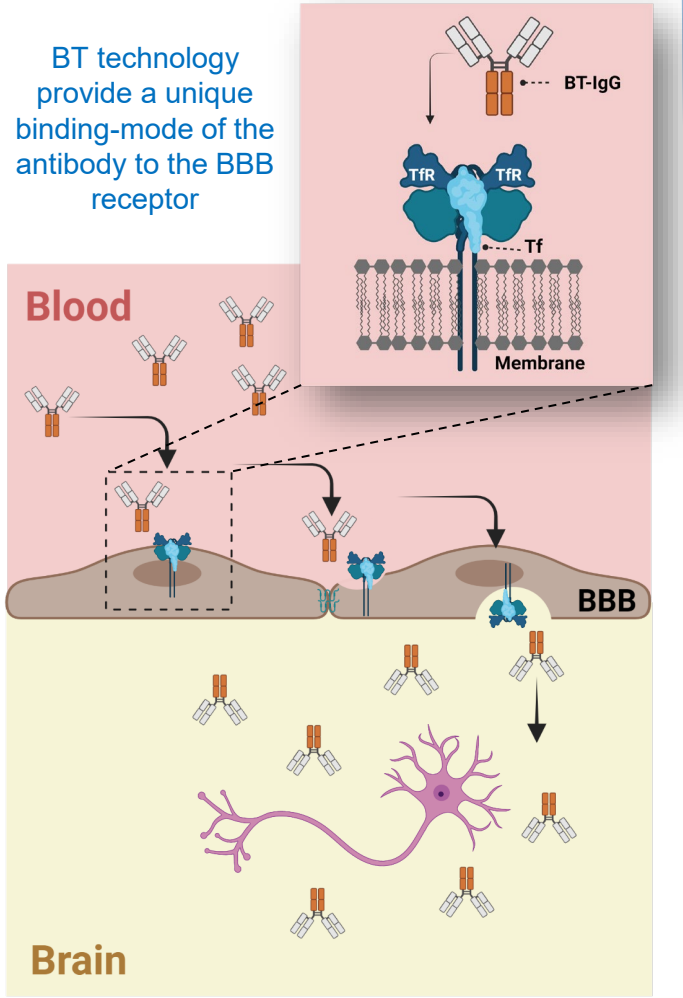
Brain Transporter (BT) technology delivers biotherapeutics to the brain

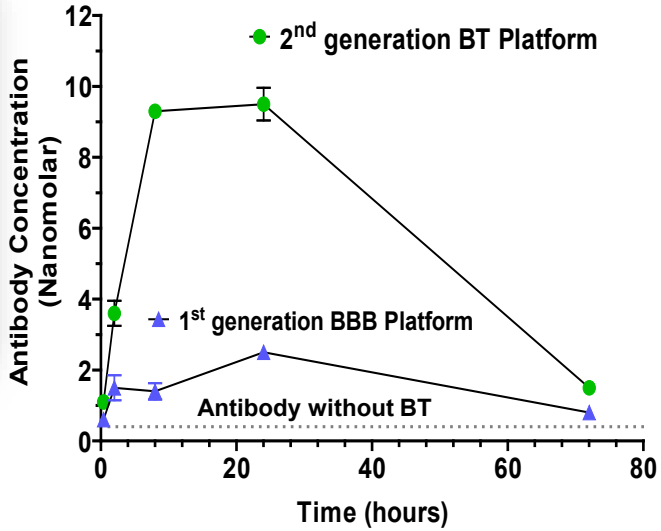
Novel platform achieves high exposure and broad brain distribution

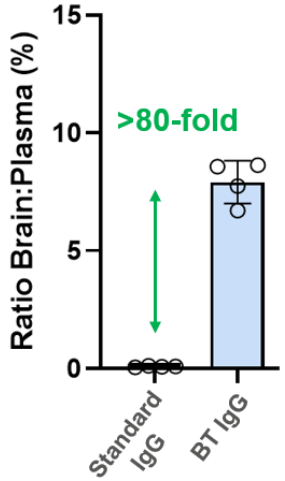
Brain Transporter technology mediate transport across the BBB

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



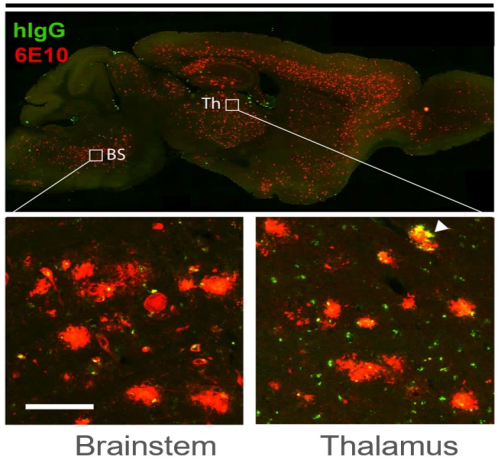
2nd – generation technology provide superior brain exposure



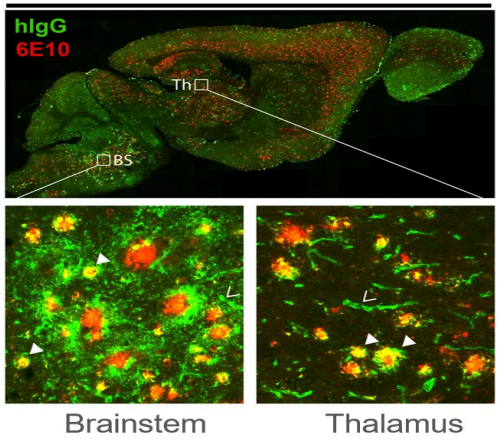


Rapid and global brain distribution

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 two portfolio projects (AD-BT2802, AD-BT2803)

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

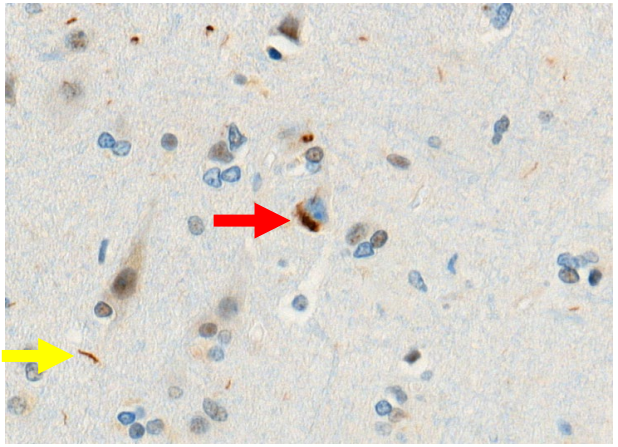
- Progressive neurodegenerative disease characterized by motor neuron degeneration

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

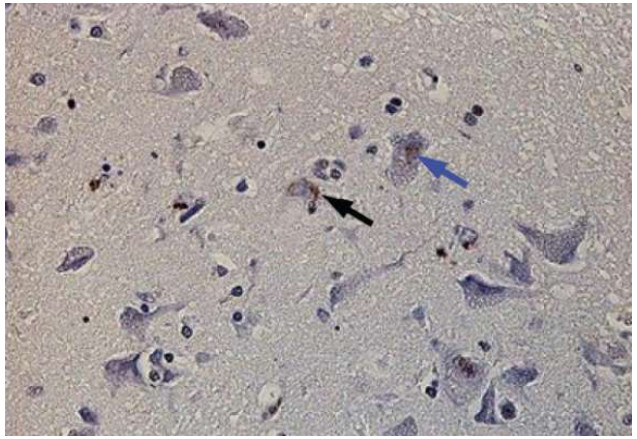
Several mutations in TARDBP (encoding TDP-43) are linked to familial ALS[1)] and FTD[2)]

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

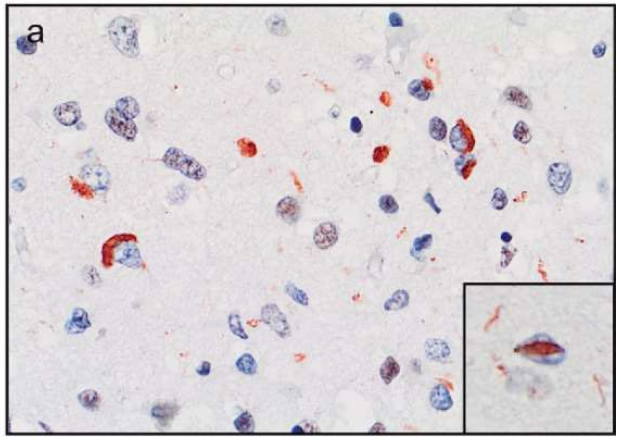
- 97% of **ALS[1)]** cases (orphan drug indication)
- 50% **AD[2)]** cases
- 45% **FTD[3)]** cases



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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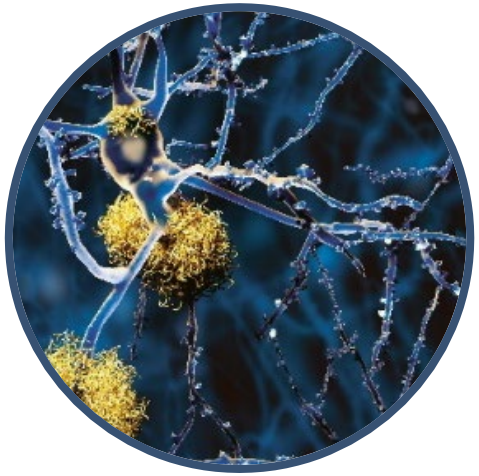
Upcoming news flow

Alzheimer's disease



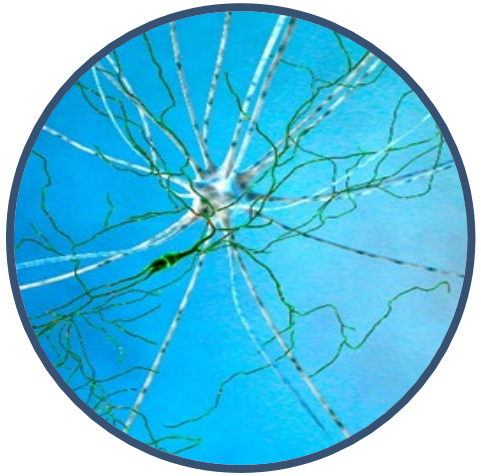
Lecanemab (Eisai)

- Rolling submission for accelerated approval in the US expected to be completed Q2 2022
- Clarity AD topline data expected in September 2022
- Data to be disclosed at international congresses

Discovery stage programs

- Advancement of projects

Parkinson's disease

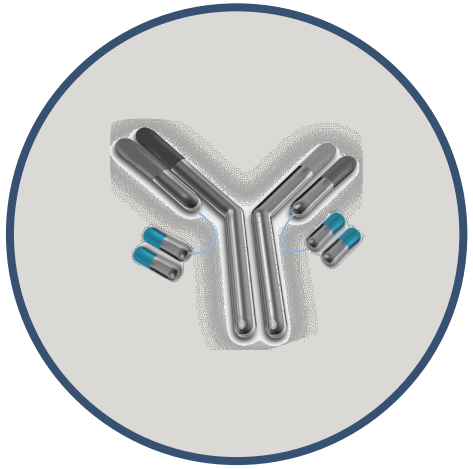


ABBV-0805 (AbbVie*)

- Data presented at international congresses

*On April 20, 2022, AbbVie informed BioArctic that they have made a strategic business decision to terminate the collaboration agreement

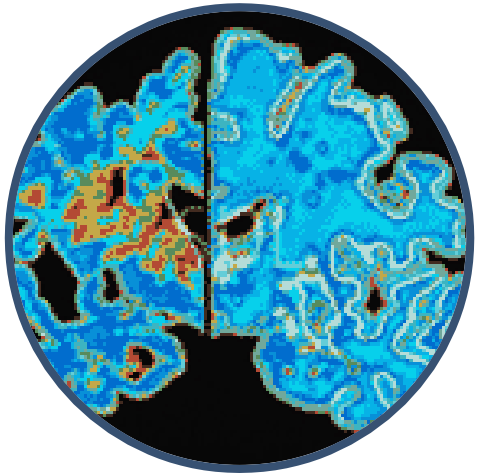
Blood-brain barrier



Brain Transporter (BT) technology platform

- Further development of the technology platform
- Data to be disclosed at international congresses

Other CNS disorders



Neurodegeneration

- Data to be disclosed at international congresses

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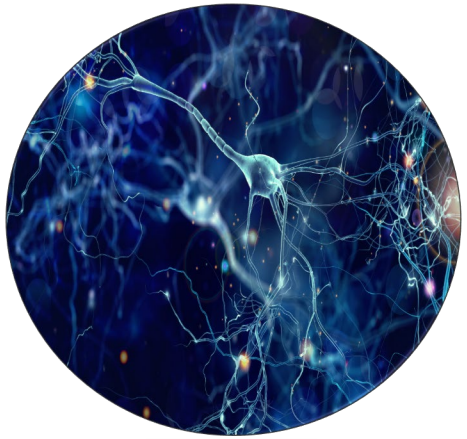
BioArctic: With Patients in Mind

Great science



Great projects

Great partners

Great people

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GUNILLA OSSWALD, CEO

OSKAR BOSSON, VP COMMUNICATIONS & IR

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