BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

SEB Nordic Healthcare Seminar

January 18, 2022
Gunilla Osswald, PhD, CEO

BIOARCTIC

Disclaimer

- This presentation has been prepared and produced by BioArctic AB (publ) (“BioArctic”) solely for the benefit of investment analysis of BioArctic and may not be used for any other purpose. Unless otherwise stated, BioArctic is the source for all data contained in this presentation. Such data is provided as at the date of this presentation and is subject to change without notice.
- This presentation includes forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause BioArctic’s actual results, performance, achievements or industry results to be materially different from those expressed or implied by these forward-looking statements. Forward-looking statements speak only as of the date of this presentation and BioArctic expressly disclaims any obligation or undertaking to release any update of, or revisions to, any forward-looking statement in this presentation, as a result of any change in BioArctic’s expectations or any change in events, conditions or circumstances on which these forward-looking statements are based.
- This presentation does not constitute or form part of, and should not be construed as, an offer or invitation for the sale of or the subscription of, or a solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it or the fact of its distribution form, or be relied on in connection with, any offer, contract, commitment or investment decision relating thereto, nor does it constitute a recommendation regarding the securities of BioArctic.
- The information in this presentation has not been independently verified.
- No regulatory body in Sweden or elsewhere has examined, approved or registered this presentation.

BIOARCTIC

BioArctic – a unique Swedish biopharma company improving the lives of 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 pipeline 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

Industry leading partners and **valuable collaboration agreements** totaling BSEK 8.9[1] (BUSD ~1) plus royalties

Note: 1) FX as per September 30, 2021

BIOARCTIC

Rich and well-balanced pipeline with fully-financed partnered projects and cutting-edge proprietary projects

	Project	Partner	Discovery	Pre-clinical	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)]	Pre-clinical (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					

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
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

BIOARCTIC

Long-standing and successful partnerships – de-risking clinical development and optimizing commercialization

	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**

BIOARCTIC

Recent highlights

Alzheimer's disease – Lecanemab

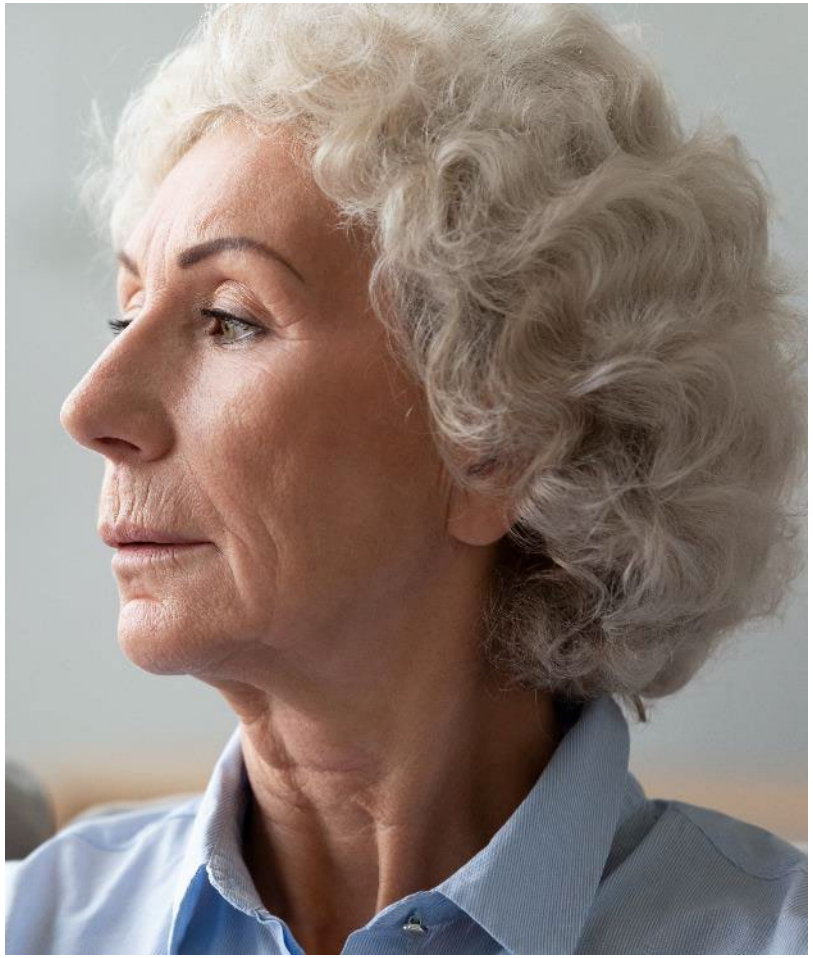
- Eisai has after agreement with FDA initiated a rolling BLA submission under the accelerated approval pathway which is expected to be completed during H1 2022
- Data presented at CTAD congress in November continue to further strengthen and differentiate lecanemab towards competitors
- Lecanemab selected for DIAN-TU clinical trial for dominantly inherited Alzheimer's disease
- In December 2021, the FDA granted lecanemab Fast Track designation

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

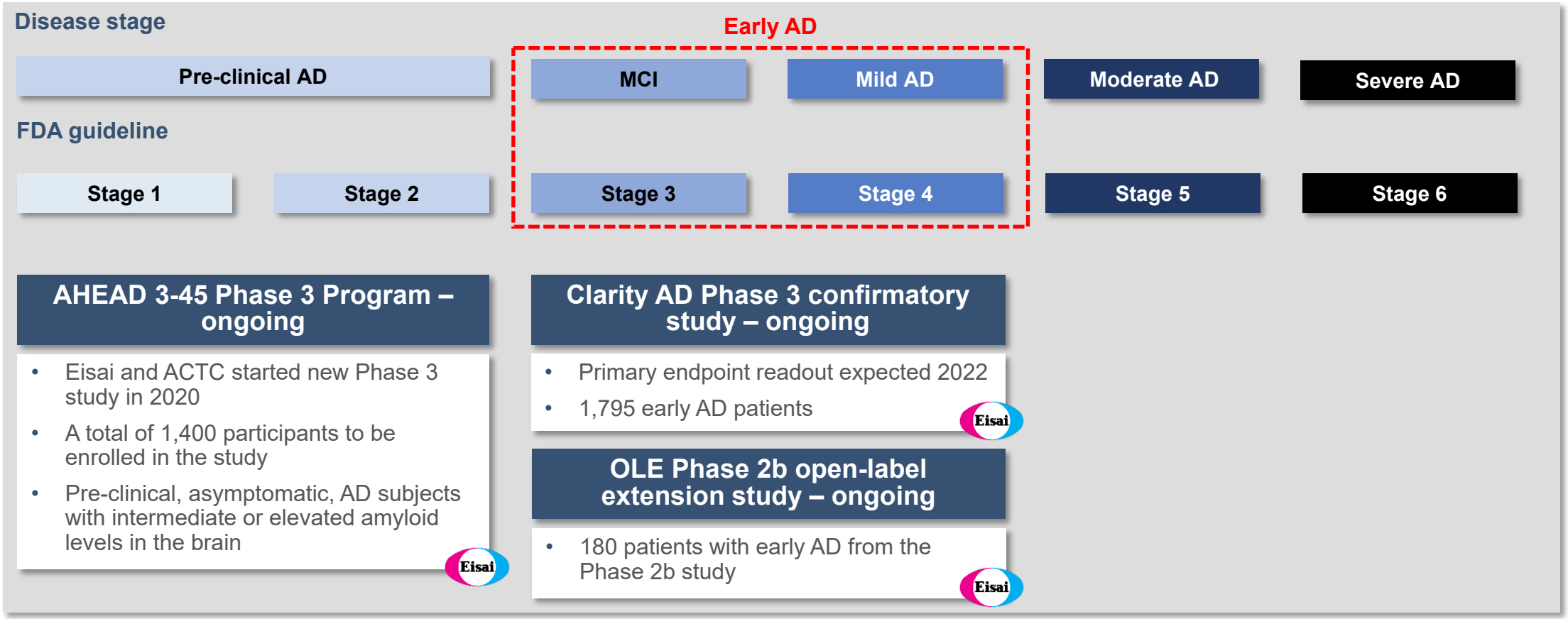
Other

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



BIOARCTIC

Lecanemab – broad late-stage clinical program

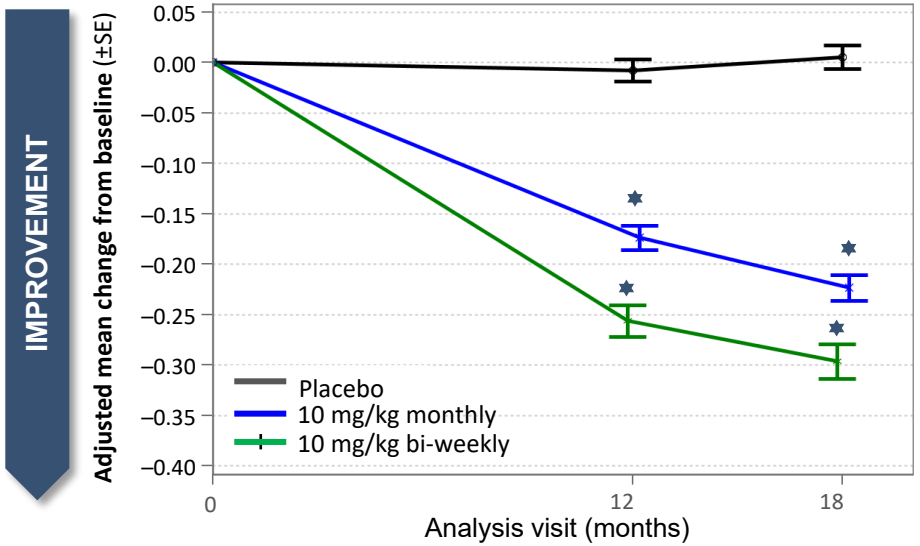


➢ *Selected for the DIAN-TU Tau NexGen study*

BIOARCTIC

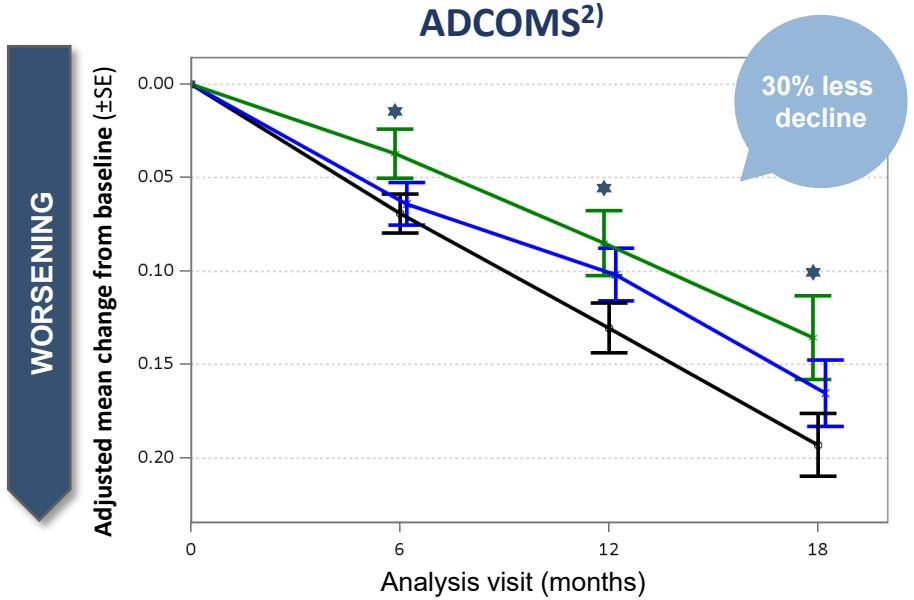
Lecanemab – potential disease modifying antibody with encouraging Phase 2b efficacy & safety profile

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

BIOARCTIC

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

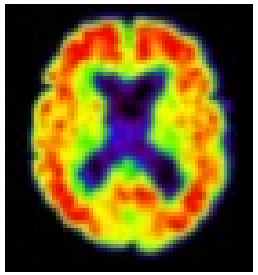
Phase 3 Study Design

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

BIOARCTIC

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

- → Accelerated approval pathway initiated - expected to be completed H1 2022
- → Submission for full approval 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
- → Expanded Alzheimer's disease populations:
  - → Selected for AHEAD in pre-symptomatic individuals
  - → Selected for DIAN-TU – dominantly inherited Alzheimer disease

BIOARCTIC

ABBV-0805 – potential disease modifying antibody in Parkinson's disease in preparation for Phase 2

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

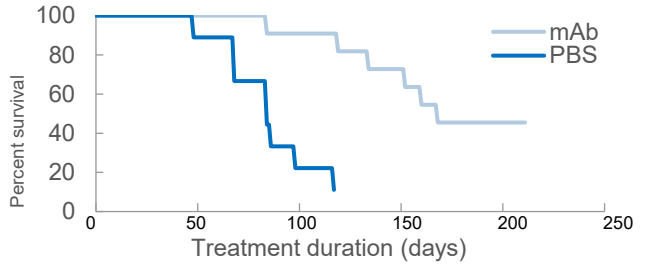
- Highly selective (>100.000) for pathological forms of misfolded alpha-synuclein (oligomers/protofibrils) vs physiological forms (monomers)

Built on genetic and pathology rationale

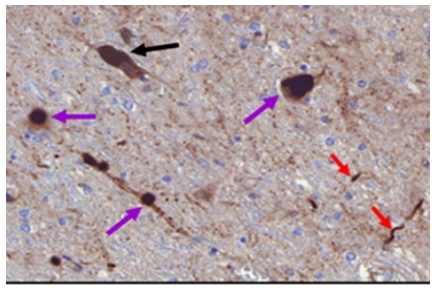
- Alpha-synuclein mutations lead to PD
- Alpha-synuclein oligomers/ protofibrils are elevated in PD

Pre-clinical proof of concept

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



Human target binding of 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.

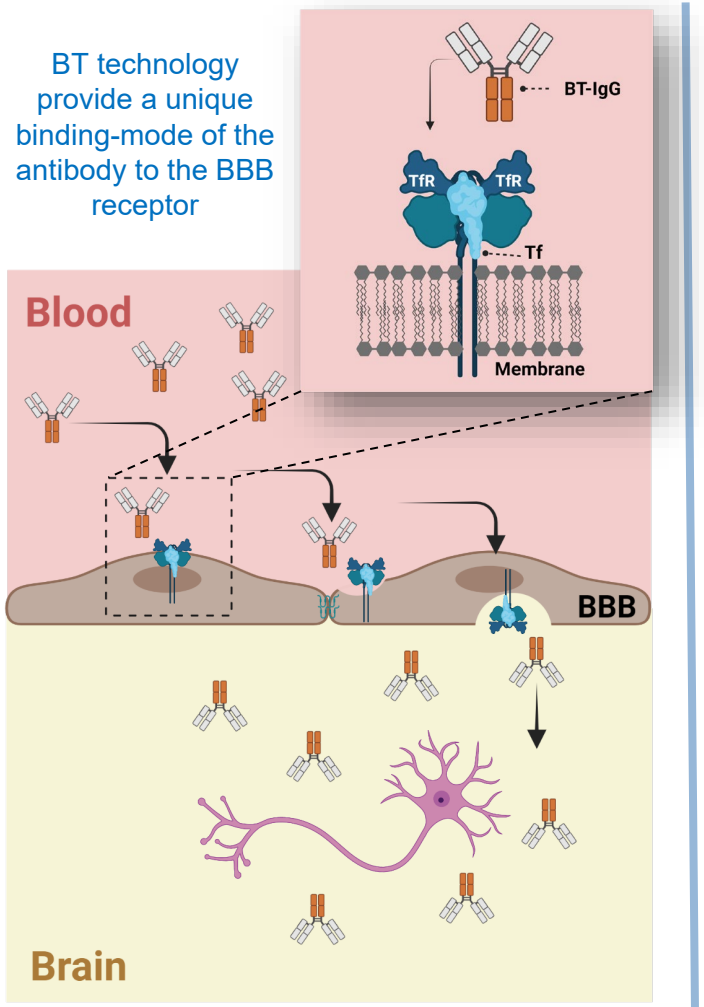
BIOARCTIC

Brain Transporter (BT) technology delivers biotherapeutics to the brain

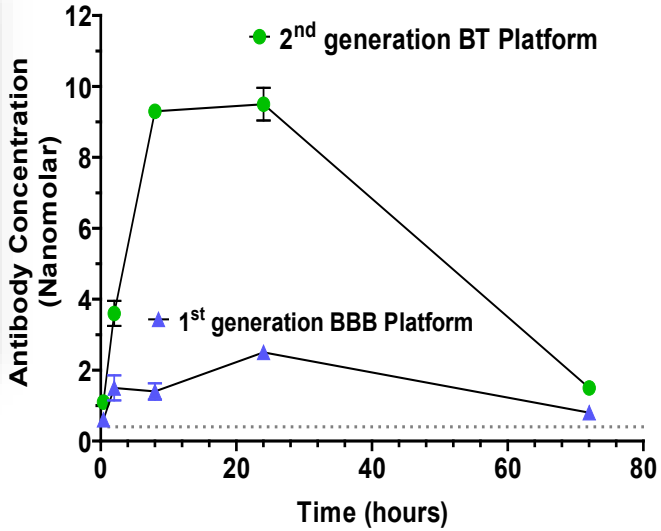
Novel platform achieves high exposure and broad brain distribution

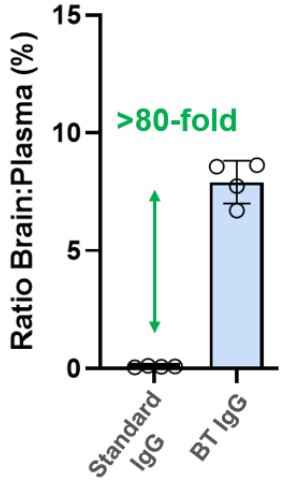
Brain Transporter technology mediate transport across the BBB

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



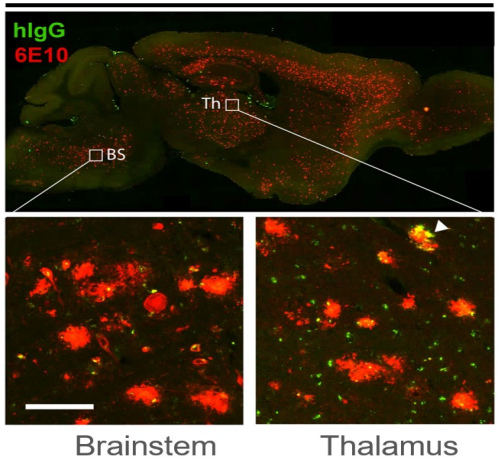
2nd – generation technology provide superior brain exposure



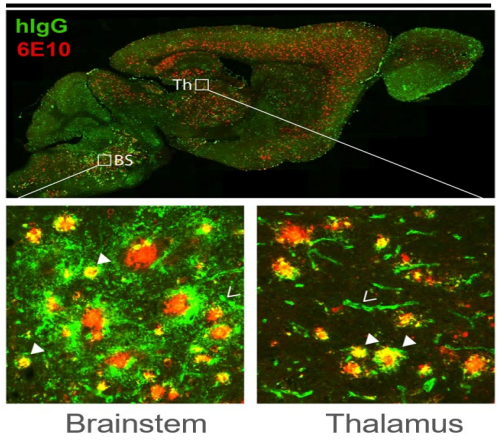


Rapid and global brain distribution

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

BIOARCTIC

TDP-43 – opportunity for ALS and other neurodegenerative disorders

Amyotrophic lateral sclerosis (ALS) – a debilitating rare disease

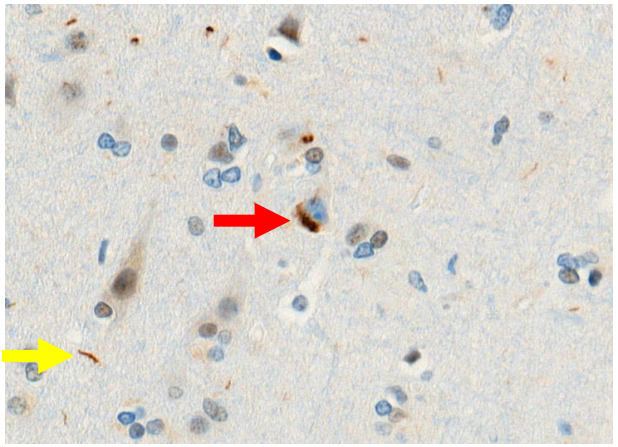
- Progressive neurodegenerative disease characterized by motor neuron degeneration

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

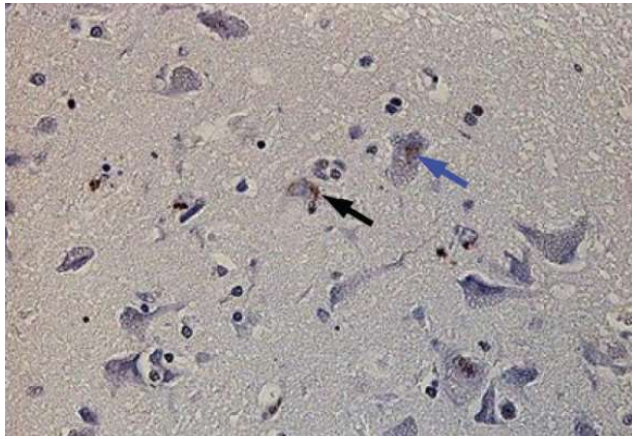
Several mutations in TARDBP (encoding TDP-43) are linked to familial ALS[1)] and FTD[2)]

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

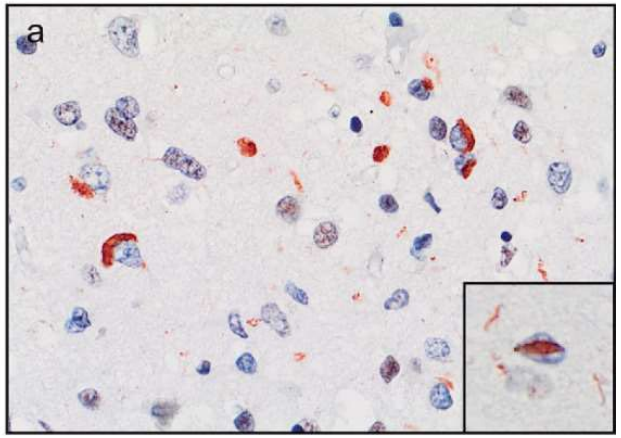
- 97% of **ALS[1)]** cases (orphan drug indication)
- 50% **AD[3)]** cases
- 45% **FTD[2)]** cases



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



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

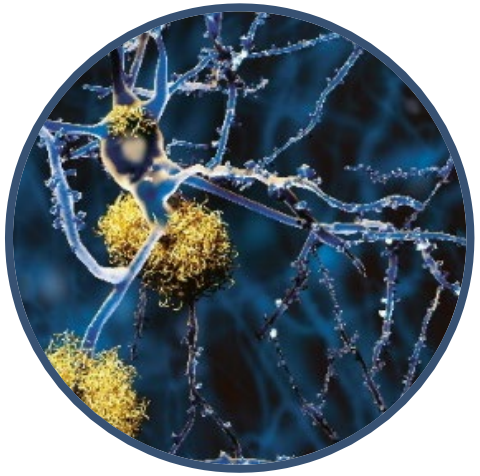


Abnormal TDP-43 immunoreactivity is common in **FTD[2)]**

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

Upcoming news flow

Alzheimer's disease



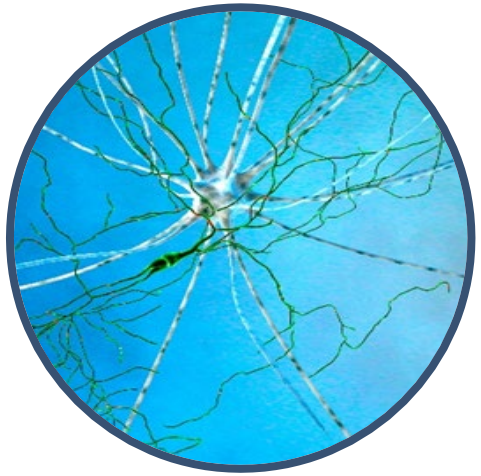
Lecanemab (Eisai)

- Rolling submission for accelerated approval in the US expected to be completed H1 2022
- Clarity AD topline data expected in September 2022
- Data to be disclosed at international congresses

Discovery stage programs

- Advancement of projects

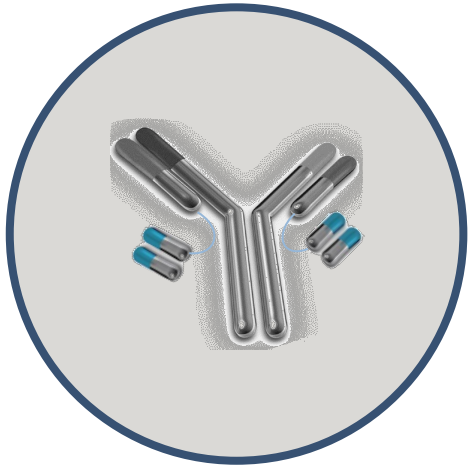
Parkinson's disease



ABBV-0805 (AbbVie)

- Start Phase 2
- Data presented at international congresses

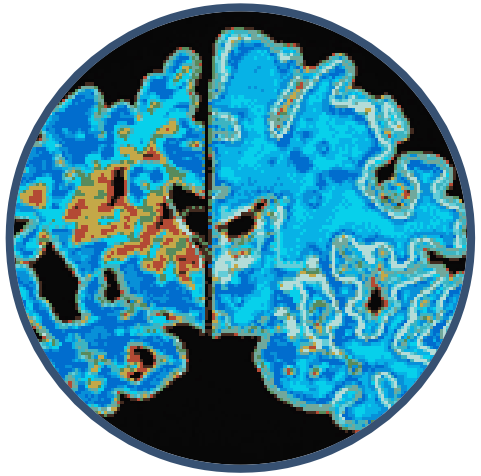
Blood-brain barrier



Brain Transporter (BT) technology platform

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

Other CNS disorders



Neurodegeneration

- Data to be disclosed at international congresses

BIOARCTIC

BioArctic – with patients in Mind

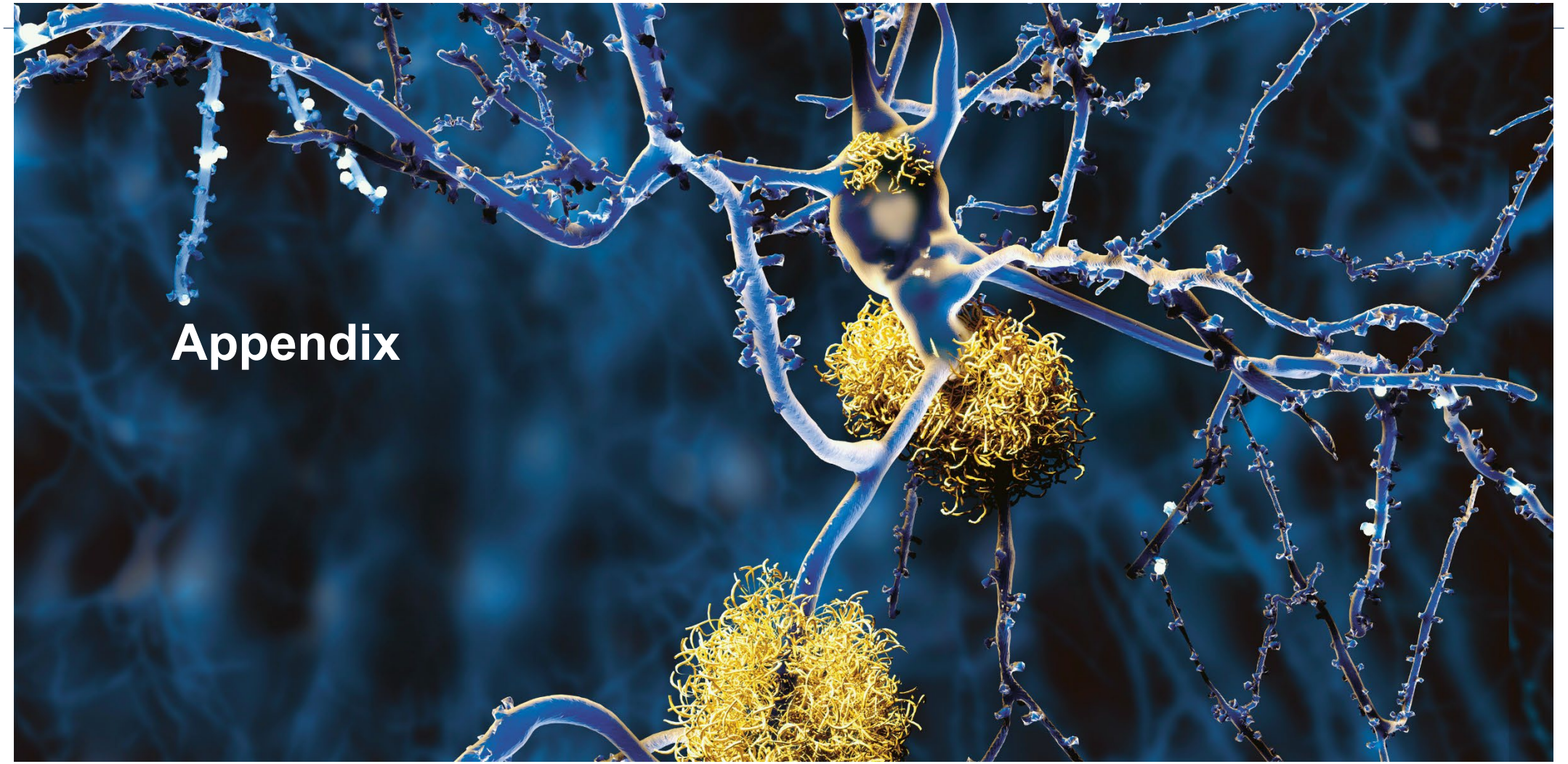
Great science

Great projects

Great partners

Great people

BIOARCTIC



Appendix

Lecanemab – favourable 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

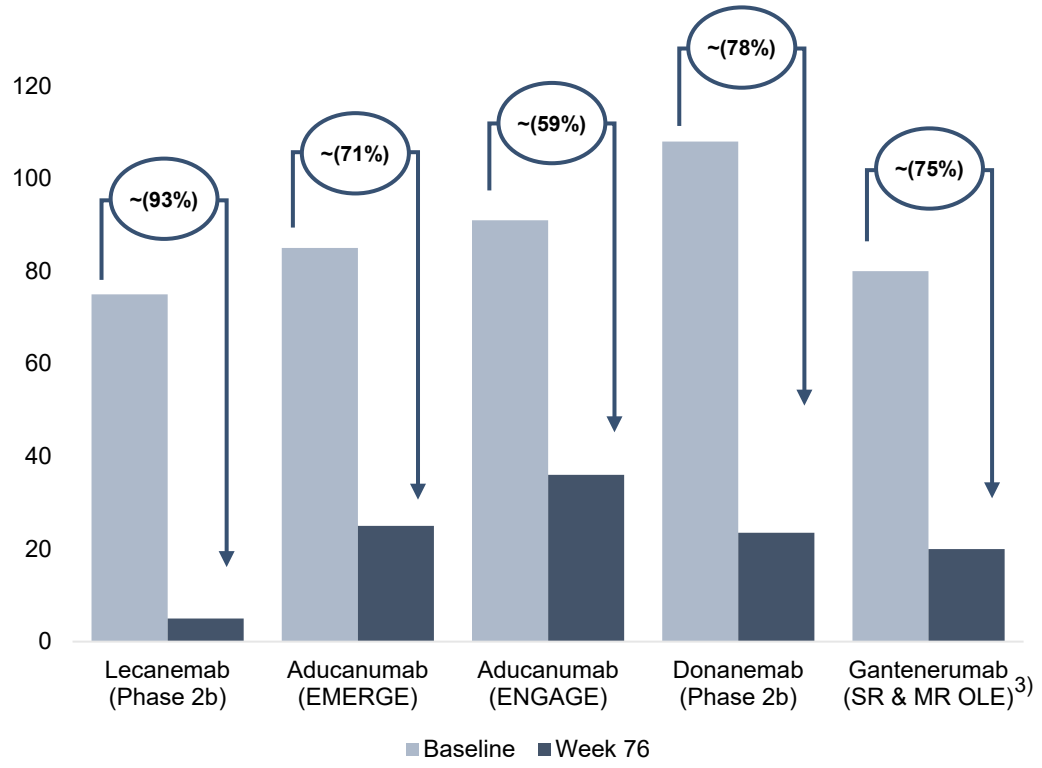
Opportunities for differentiation include; rapid clinical effect, better tolerability profile, no titration - full dose from day 1

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.

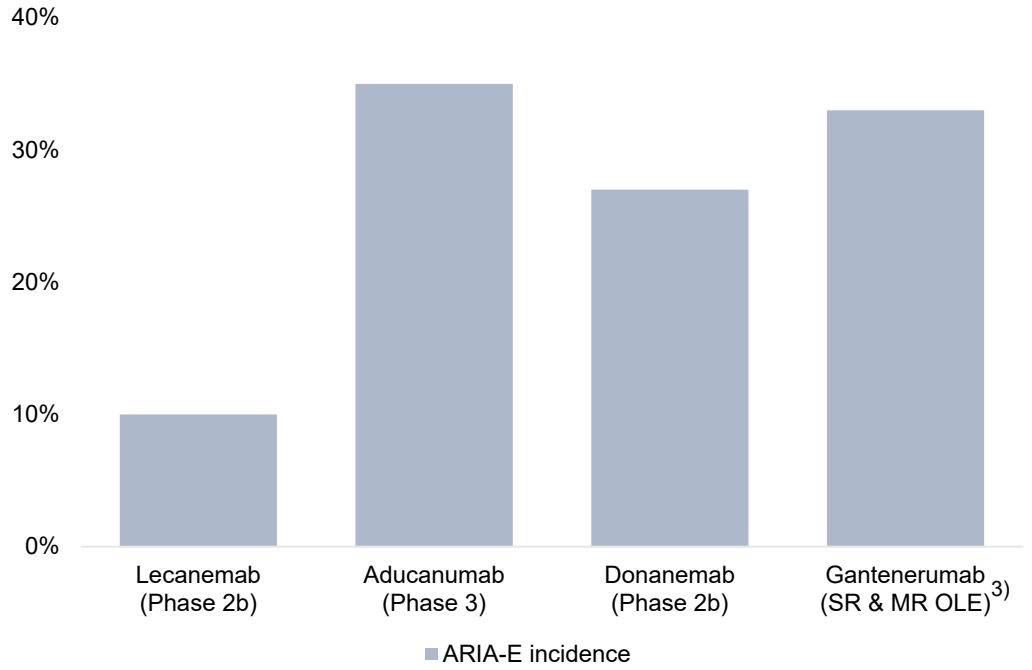
BIOARCTIC

Lecanemab – strongest reduction of brain amyloid and lowest ARIA-E incidence among competitors

PET[1] amyloid, centiloids



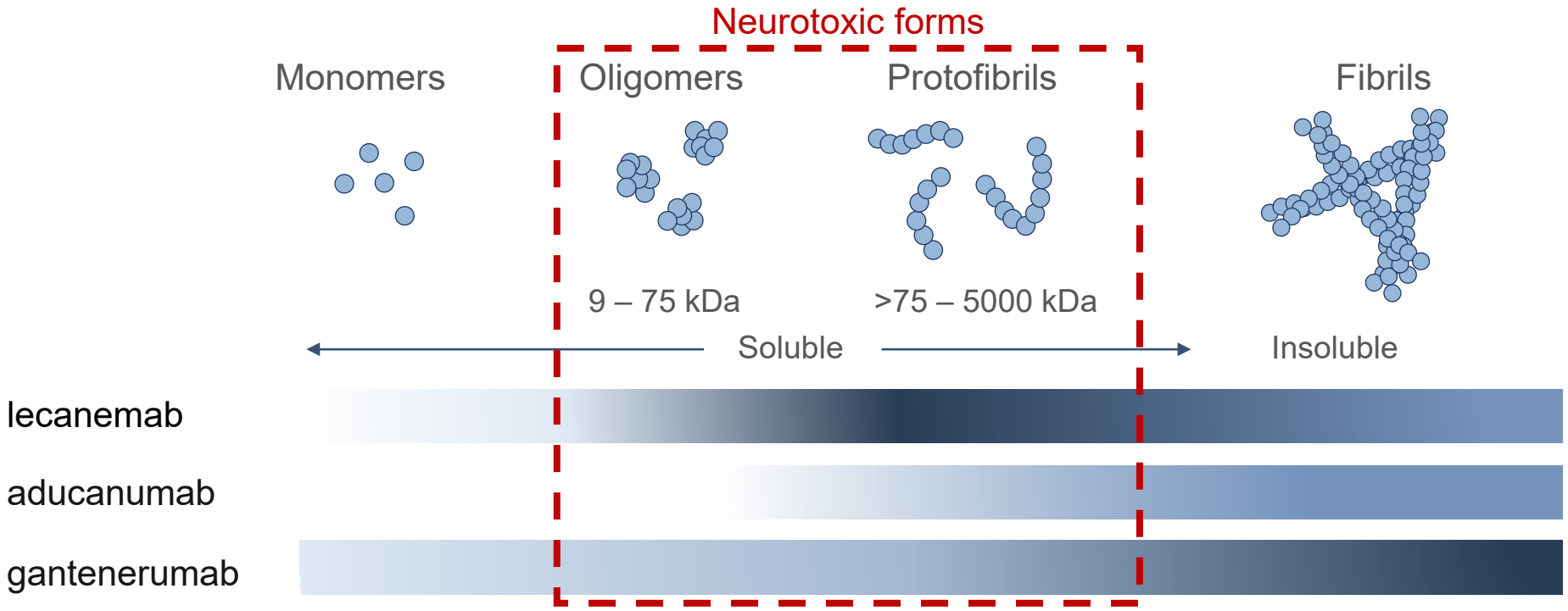
ARIA-E[2] incidence



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

BIOARCTIC

Lecanemab – unique selectivity towards toxic soluble species of Aβ

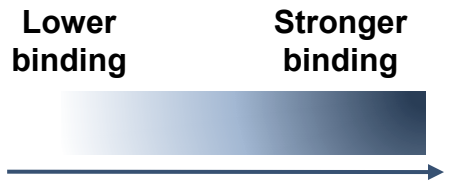


Lecanemab had the highest preference for soluble protofibrils/oligomers versus monomeric and fibrillar forms of Aβ

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

BIOARCTIC