

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

# Carnegie Healthcare Seminar

Stockholm, March 15, 2022

---

*Gunilla Osswald, PhD, CEO*



# 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.
- Investigational uses of an agent in development included in this presentation are not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.
- 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 – 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<sup>1</sup>) in cash and **valuable collaboration agreements** totaling BSEK 9.1<sup>2</sup> (BUSD ~1) plus royalties

# Attractive and well-balanced project portfolio combines fully-financed partner projects and cutting-edge proprietary projects







	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
<b>ALZHEIMER'S DISEASE</b>	Lecanemab (BAN2401) ( <i>Clarity AD</i> )	Eisai <sup>1</sup>	Early Alzheimer's disease <sup>3</sup>				
	Lecanemab (BAN2401) ( <i>AHEAD 3-45</i> )	Eisai <sup>1</sup>	Preclinical (asymptomatic) Alzheimer's disease <sup>4</sup>				
	BAN2401 back-up	Eisai					
	AD1801						
	AD1502						
	AD1503						
	AD-BT2802						
	AD-BT2803						
	AD2603						
<b>PARKINSON'S DISEASE</b>	ABBV-0805 <sup>2</sup>	AbbVie					
	PD1601	AbbVie					
	PD1602	AbbVie					
<b>OTHER CNS DISORDERS</b>	Lecanemab (BAN2401)		Down's syndrome <sup>5</sup> Traumatic brain injury <sup>5</sup>				
	ND3014		ALS				
<b>BLOOD BRAIN BARRIER</b>	Brain Transporter (BT) technology platform						
<b>DIAGNOSTICS</b>	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

as of December 31, 2021

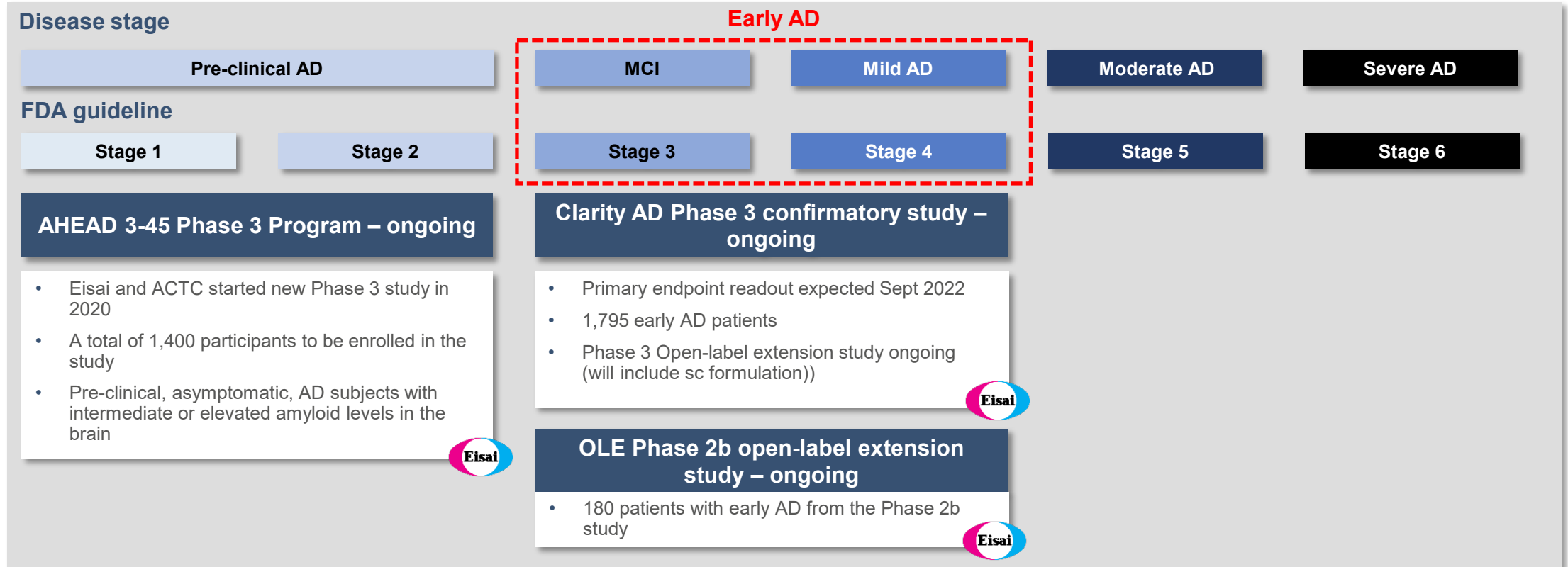
- 1) Partnered with Eisai for lecanemab (BAN2401) for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding lecanemab (BAN2401) in 2014
- 2) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805
- 3) Mild cognitive impairment due 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



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

	Alzheimer's disease 	Parkinson's disease 
Partner track record	 <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>
Collaboration and license	 <p><b>MEUR 222</b> Total value agreements</p> <p><b>MEUR 66</b> RECEIVED</p> <p>Royalties High single digit %</p> <p>BioArctic retains rights to lecanemab in other indications and option to market in the Nordics</p>	 <p><b>MUSD 755</b> Total value agreements</p> <p><b>MUSD 130</b> RECEIVED</p> <p>Royalties Tiered %</p> <p>AbbVie has global rights to alpha-synuclein portfolio for all indications</p>

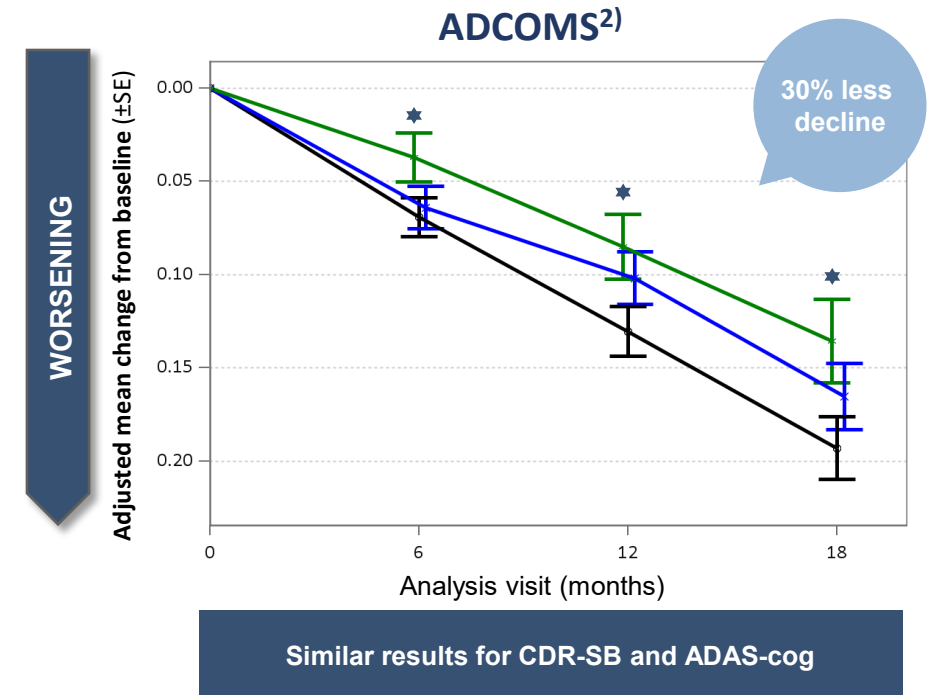
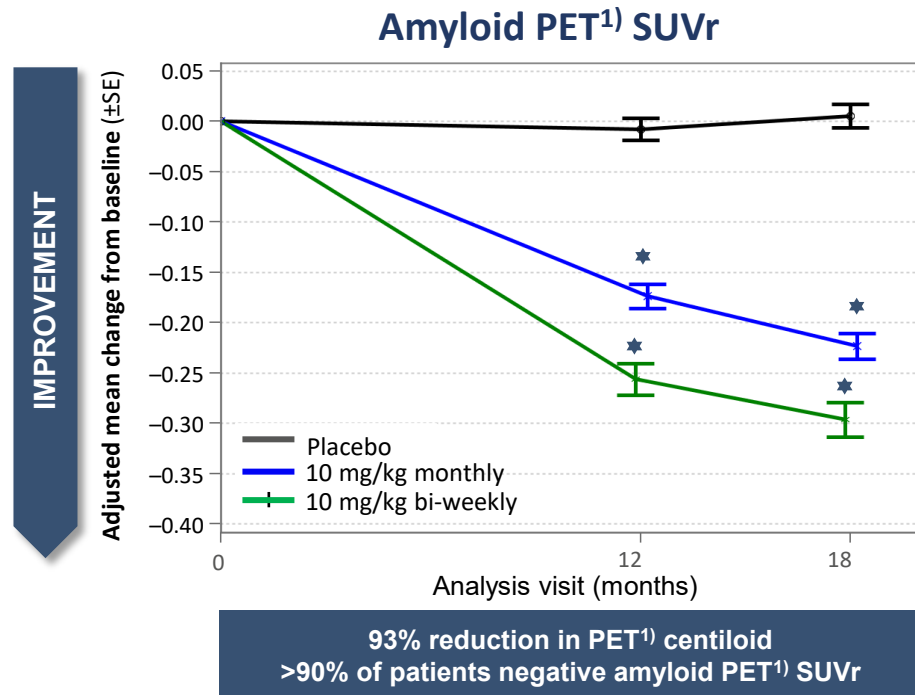
# Lecanemab – broad late-stage clinical program in Alzheimer’s disease



**Sub cutaneous (sc) formulation – Phase 1 study – select optimal dose for OLE Q1 2022**

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

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



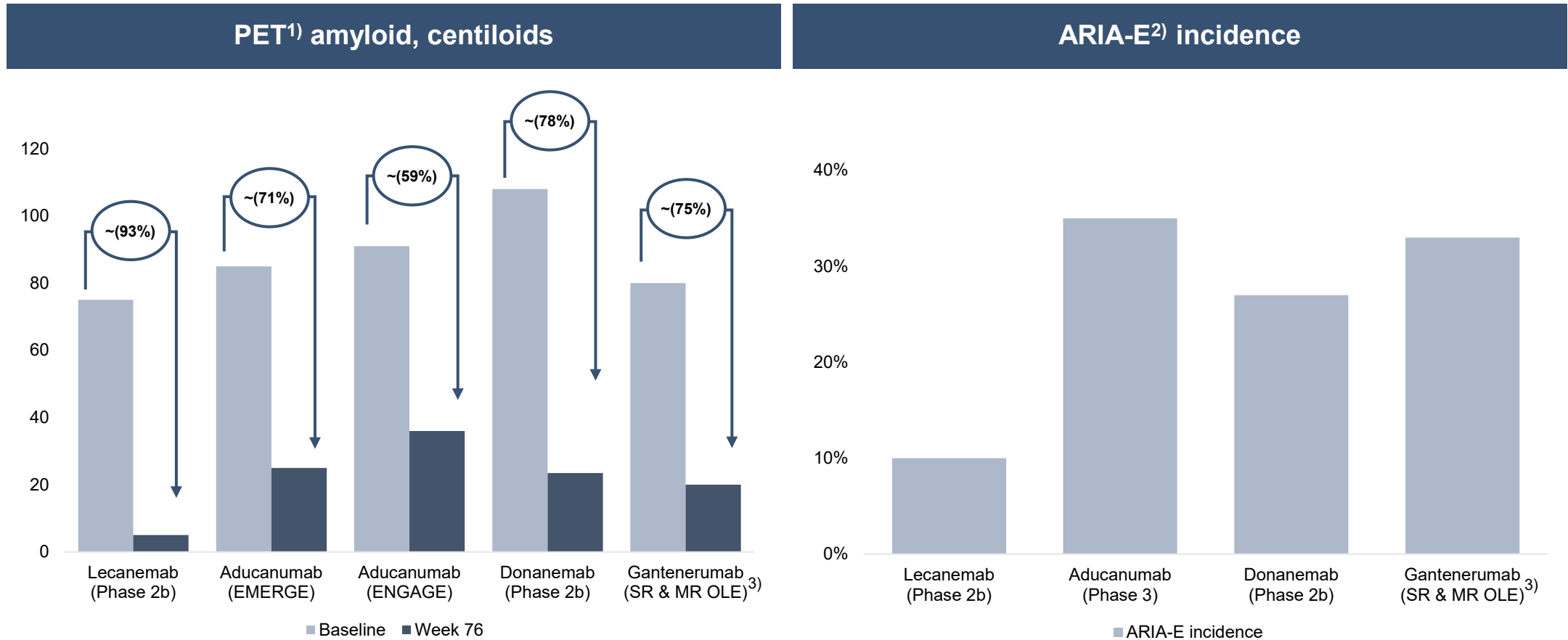
Lecanemab has positive Phase 2b results

- 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

# Lecanemab – strongest reduction of brain amyloid in Alzheimer patients and lowest ARIA-E incidence among late-stage competitors



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



# 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 and 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



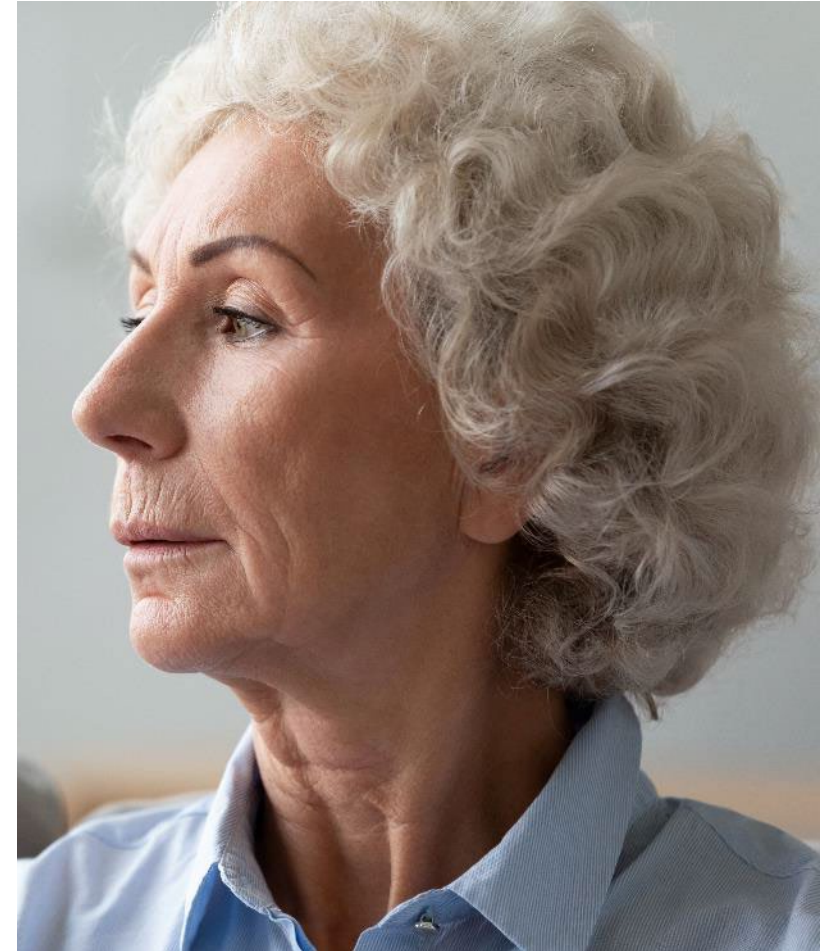
# Recent highlights

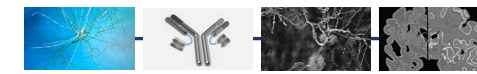
## Alzheimer's disease – Lecanemab

- Eisai initiated a rolling BLA submission under the accelerated approval pathway in September 2021.
  - In December, the second of three parts of the file was submitted
  - The submission is expected to be completed during Q2 2022
- Lecanemab was granted Fast Track designation by the FDA in December 2021
- Lecanemab granted “prior assessment consultation” in Japan and Eisai initiated submission of data in March 2022
- Lecanemab selected by DIAN-TU as backbone anti-amyloid therapy in combination with tau therapies in the NexGen study in dominantly inherited Alzheimer's disease
  - First patient enrolled in January 2022


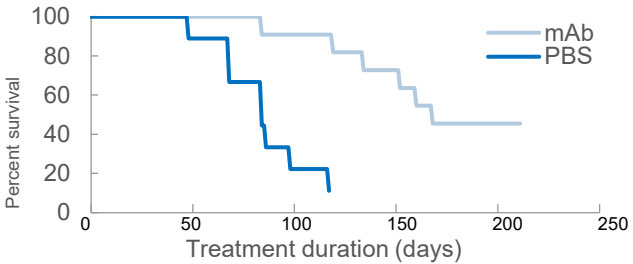
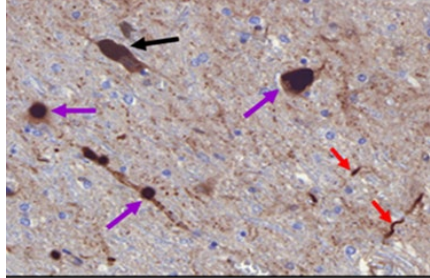
## Other

- Expanding into new indications and treatment target (TDP-43)
- Continuing to build Nordic commercial organization
  - four new recruits with vast industry experience

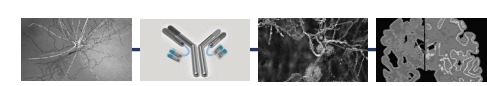




# ABBV-0805 – potential disease modifying antibody in Parkinson’s disease in preparation for Phase 2

High unmet medical need	Unique profile	Pre-clinical proof of concept
<p><b>No existing disease-modifying treatment</b></p>  <p><b>Younger patient group, still at working age</b></p> <p><b>TODAY</b> &gt;6 million<sup>1</sup> people with Parkinson’s</p>	<p><b>Unique and targeted binding profile</b></p> <ul style="list-style-type: none"> <li>Highly selective (&gt;100,000) for pathological forms of misfolded alpha-synuclein (oligomers/protofibrils) vs physiological forms (monomers)</li> </ul> <p><b>Built on genetic and pathology rationale</b></p> <ul style="list-style-type: none"> <li>Alpha-synuclein mutations lead to PD</li> <li>Alpha-synuclein oligomers/protofibrils are elevated in PD</li> </ul>	<ul style="list-style-type: none"> <li>Reduction of neurotoxic alpha-synuclein oligomers/protofibrils</li> <li>Delays disease progression and increases lifespan</li> </ul>  <p><b>Human target binding of ABBV-0805 in PD brain</b></p>  <p><i>Black: neuromelanin ,Purple: Lewy bodies, Red:Lewy neurites</i></p>
<p><b>Phase 1 results presented at MDS congress in Sept 2021 support Phase 2 development with dosing once a month</b></p>		

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.



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

*Novel platform achieves high exposure and broad brain distribution*

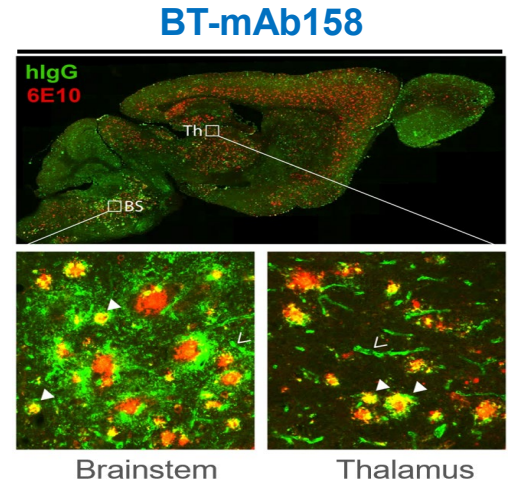
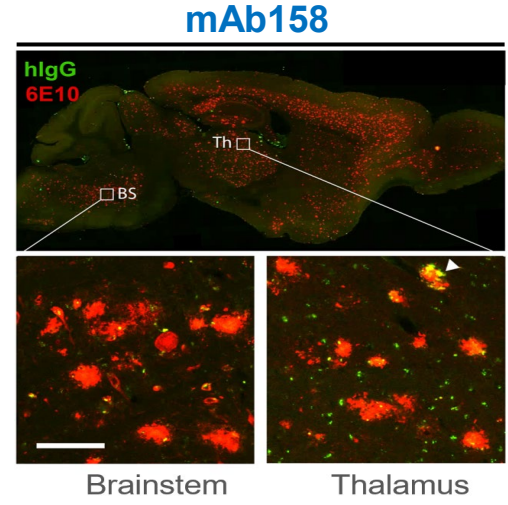
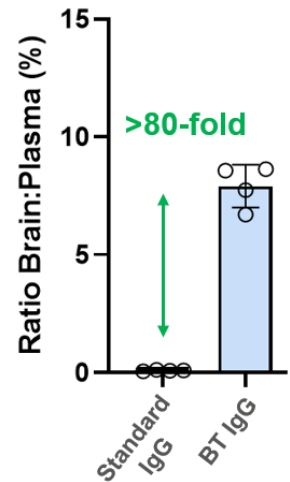
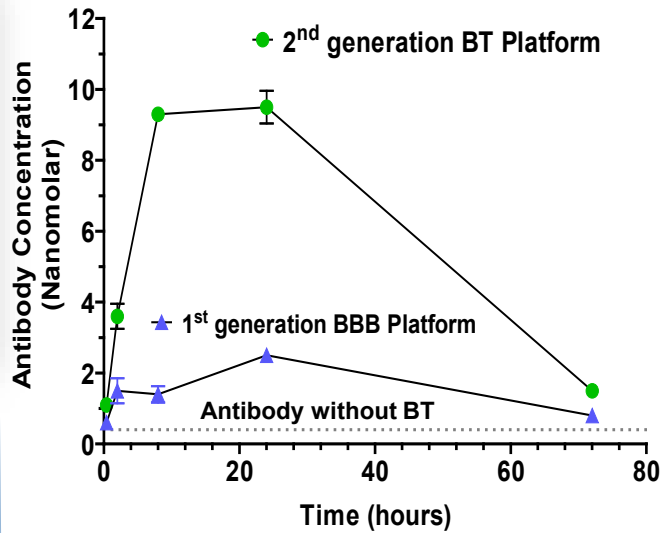
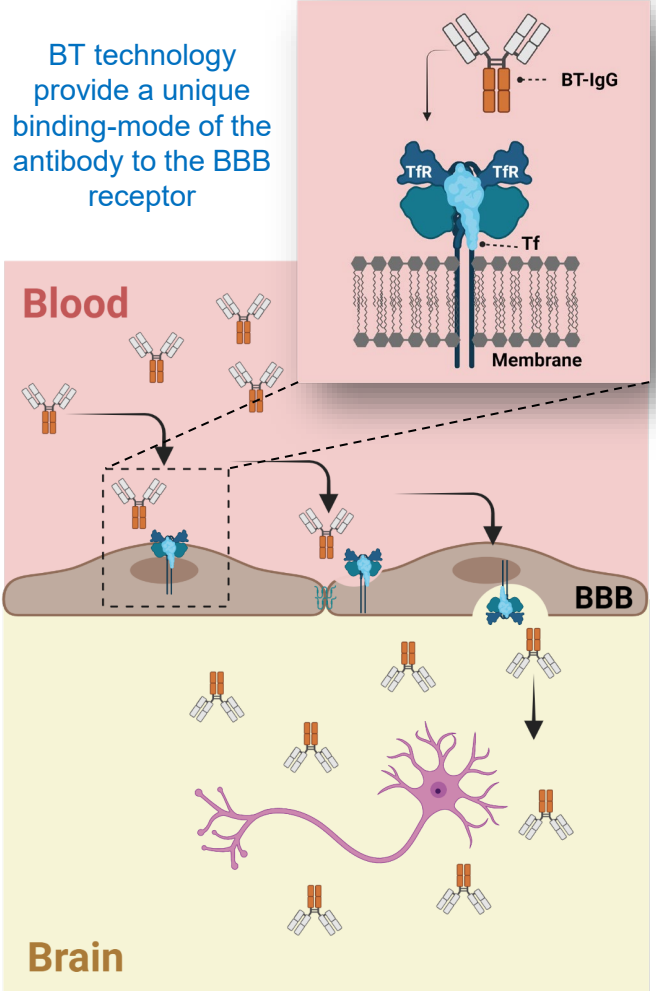
**BT**

Brain Transporter technology mediate transport across the BBB

2nd – generation technology provide superior brain exposure

Rapid and global brain distribution

**Short summary**



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

- 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





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

Amyotrophic lateral sclerosis (ALS) – a debilitating rare disease

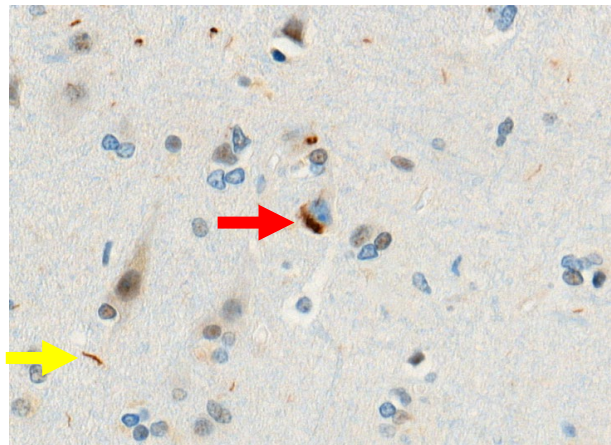
- Progressive neurodegenerative disease characterized by motor neuron degeneration

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

Several mutations in TARDBP (encoding TDP-43) are linked to familial ALS<sup>1)</sup> and FTD<sup>2)</sup>

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

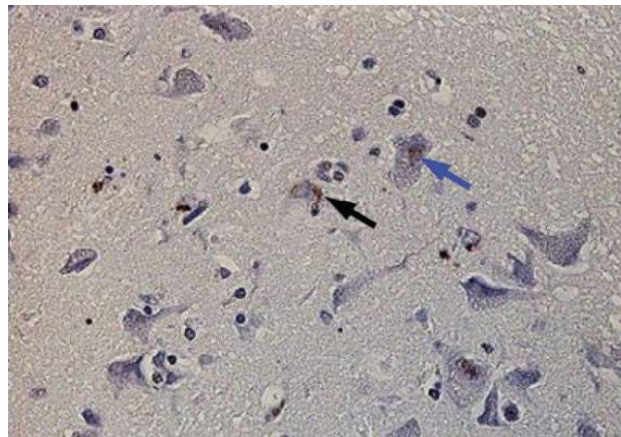
- 97% of **ALS**<sup>1)</sup> cases (orphan drug indication)
- 50% **AD**<sup>2)</sup> cases
- 45% **FTD**<sup>3)</sup> cases



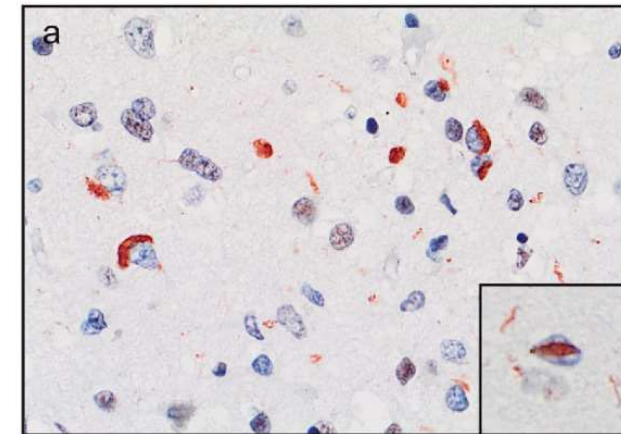
TDP-43 pathology very common in **ALS**<sup>1)</sup>

Source: Ling et. al. 2013

Note: 1) Amyotrophic lateral sclerosis, 2) Alzheimer's disease, 3) Fronto temporal dementia



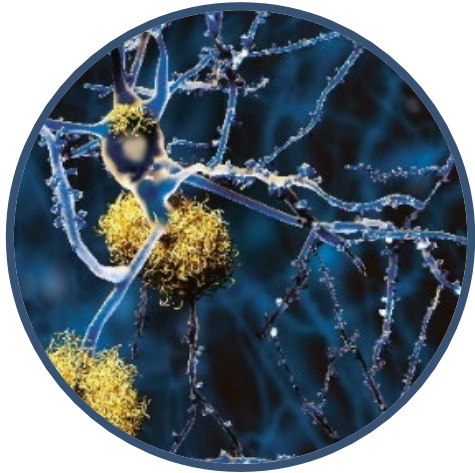
Abnormal TDP-43 immunoreactivity is common in **AD**<sup>2)</sup>



Abnormal TDP-43 immunoreactivity is common in **FTD**<sup>3)</sup>

# Upcoming news flow

## Alzheimer's disease



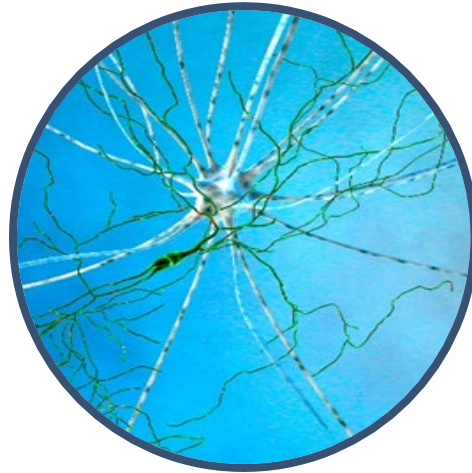
### Lecanemab (Eisai)

- 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

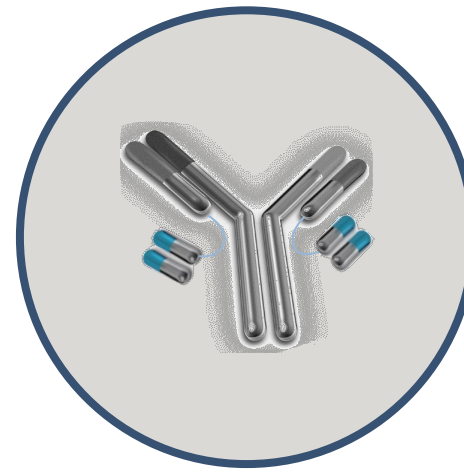
## Parkinson's disease



### ABBV-0805 (AbbVie)

- Start Phase 2
- Data presented at international congresses

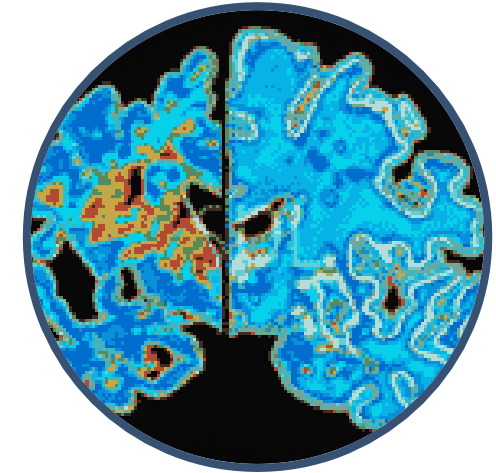
## Blood-brain barrier



### Brain Transporter (BT) technology platform

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

## Other CNS disorders



### Neurodegeneration

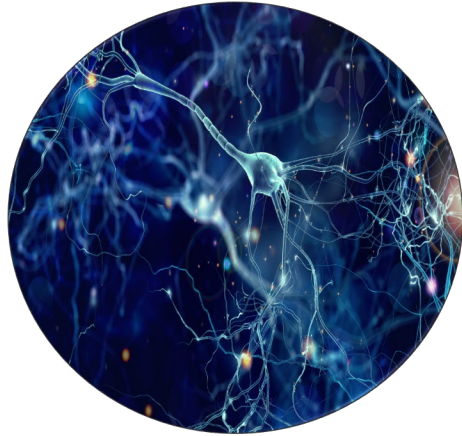
- Data to be disclosed at international congresses



# BioArctic: With Patients in Mind

---

Great science



Great projects



Great partners



Great people



**GUNILLA OSSWALD, CEO**



**OSKAR BOSSON, VP  
COMMUNICATIONS & IR**

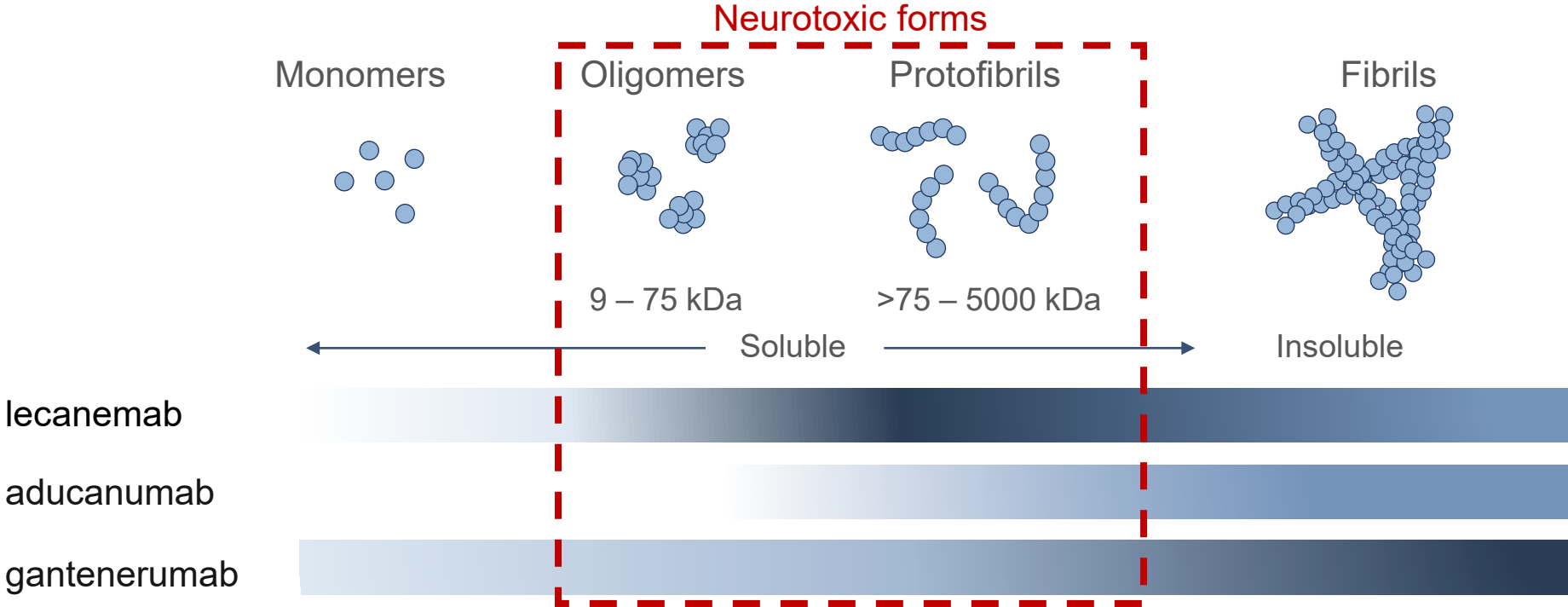


**NEXT REPORT & IR  
CONTACT**

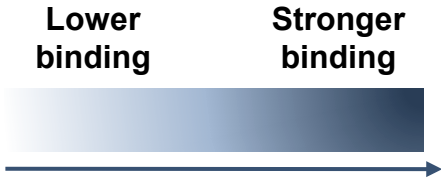
- **Next Report:**  
Q1 Jan-Mar 2022  
on April 28, 2022
- **Contact:**  
Oskar Bosson,  
VP Communications & IR  
+46 704 10 71 80  
[ir@bioarctic.se](mailto:ir@bioarctic.se)

To subscribe to financial reports/press releases and for more information, please visit [www.bioarctic.com](http://www.bioarctic.com)

# 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