ØU LIFE SCIENCE INVESTOR CONFERENCE

BioArctic – a global leader in neurodegenerative diseases

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BioArctic – a global leader in neurodegenerative diseases

Focus on neurodegenerative disorders

- Disorders with very large unmet needs and large patient populations

World-class R&D organization leveraging strong collaborations

- BioArctic behind Leqembi®, the world's first fully approved* disease modifying therapy for Alzheimer's disease

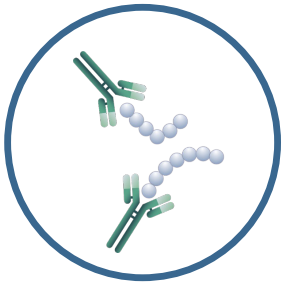
Broad project portfolio building on two technology platforms

- Several projects in Alzheimer's disease, Parkinson's disease, ALS end enzyme replacements

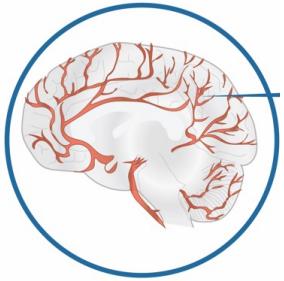
Well-financed from milestones and royalties from lead product

- 9% royalty on global Leqembi® sales plus milestones from partner Eisai
- 2023 operating profit of SEK 253 M, Cash position ~SEK 0.8 B

Highly selective antibodies targeting aggregated forms of toxic proteins



BrainTransporter™ technology delivers biotherapeutics to the brain



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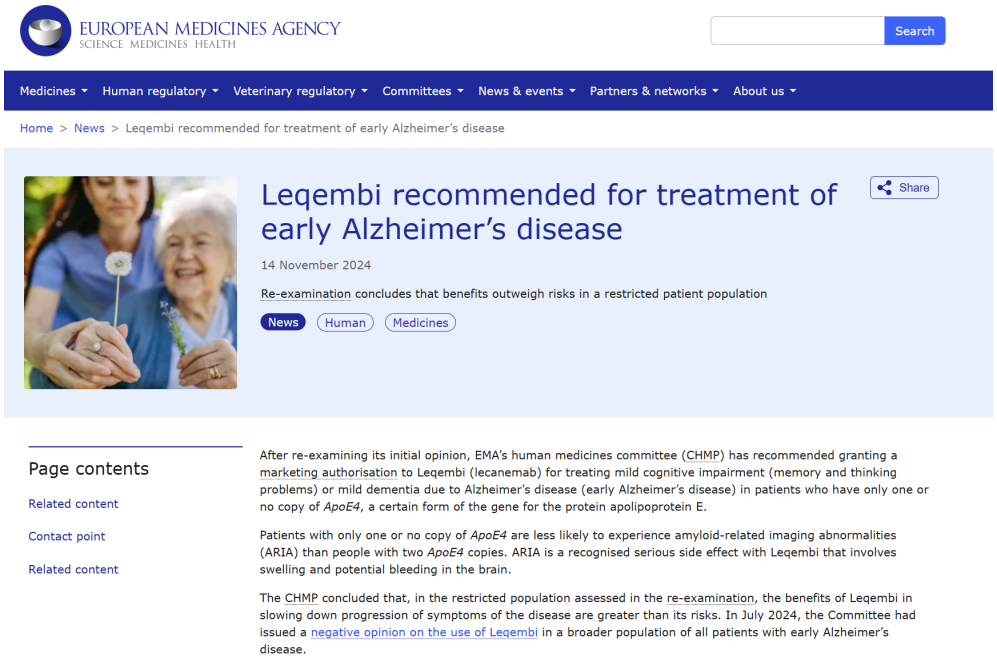
- Leqembi is fully approved in the US, Japan, China, South Korea, Great Britain and several other markets and pending approval in other markets

Leqembi receives positive opinion in the EU

- **Positive EU recommendation for Leqembi**
  - EMA's Committee for Medicinal Products for Human Use (CHMP) recommended granting a market authorization on November 14 after re-examination
  - Decision from the European Commission expected within 67 days (latest Feb 2025).

- **For treatment of mild cognitive impairment (MCI) and mild dementia caused by Alzheimer's disease**
  - In adult patients who are heterozygotes (carry one copy) or are non-carriers of the Apolipoprotein E ε4 (ApoE ε4) gene.



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Leqembi recommended for treatment of early Alzheimer's disease

14 November 2024

Re-examination concludes that benefits outweigh risks in a restricted patient population

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After re-examining its initial opinion, EMA's human medicines committee (CHMP) has recommended granting a marketing authorisation to Leqembi (lecanemab) for treating mild cognitive impairment (memory and thinking problems) or mild dementia due to Alzheimer's disease (early Alzheimer's disease) in patients who have only one or no copy of *ApoE4*, a certain form of the gene for the protein apolipoprotein E.

Patients with only one or no copy of *ApoE4* are less likely to experience amyloid-related imaging abnormalities (ARIA) than people with two *ApoE4* copies. ARIA is a recognised serious side effect with Leqembi that involves swelling and potential bleeding in the brain.

The CHMP concluded that, in the restricted population assessed in the re-examination, the benefits of Leqembi in slowing down progression of symptoms of the disease are greater than its risks. In July 2024, the Committee had issued a negative opinion on the use of Leqembi in a broader population of all patients with early Alzheimer's disease.

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Leqembi is the first AD disease-modifying treatment to receive full approval globally, establishing new standard of care

USA ✓

Approved
July 2023

IV maintenance therapy submitted Q1 2024, PDUFA 25 Jan 2025

Rolling submission for subcutaneous autoinjector maintenance dosing completed October 2024

Preparing for filing of subcutaneous induction treatment

Japan ✓

Approved
September 2023

Launched
December 2023

EU ✓

Positive CHMP opinion
November 2024

EU Commission decision for Market authorization by February 2025

China ✓

Approved
January 2024

Launched
June 2024

Rest of World ✓

Approved in
South Korea, Israel, Hong Kong, United Arab Emirates, Great Britain

Applications submitted:
Australia (reconsideration)
Canada, Switzerland, Taiwan, Singapore, Brazil, Russia, Saudi Arabia, India, South Africa, The Philippines, Thailand, Vietnam, Malaysia, Mexico, Indonesia

FDA – Food & Drug Administration
CMS – Centers for Medicare & Medicaid Services
PMDA – Pharmaceuticals and Medical Devices Agency
EMA – European Medicines Agency
S.C. – subcutaneous
A.I. – Auto-injector

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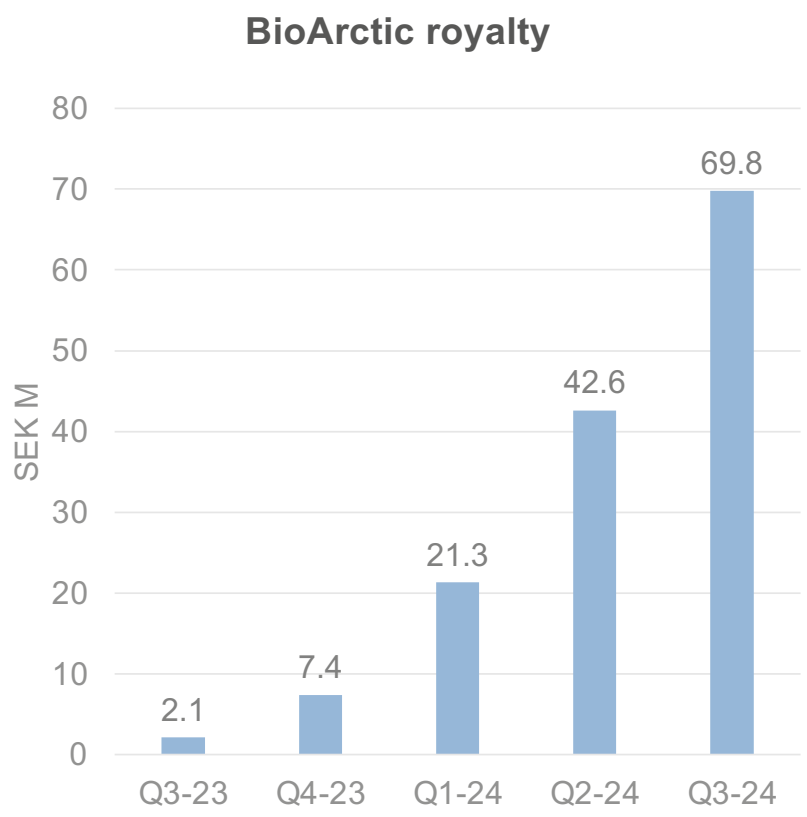
Leqembi US sales lower than expected, offset by strong development in Japan and China – Eisai revises forecast



- Global sales Q3-24 were ¥ 10 B (~67 MUSD), ~66% increase from Q2-24
  - Royalties increased by 64% to SEK 69.8 M
- US expansion slower than expected
  - ~ ¥ 5.9 B in Q3 (~39 MUSD), ~30% growth from Q2
  - Strong demand but bottleneck in infusion capacity, ~6,000 patients waiting for treatment
  - Infusion capacity will increase during q4 and q1 by 80-90%
- Continued strong development in Japan
  - ~ ¥ 2.7 B in Q3 (~18 MUSD), ~80% growth from Q2
  - ~800 facilities treating ~5.000 patients
  - TV DTC campaign starting Nov. 15 to raise awareness about MCI and promote early diagnosis
- Strong start in China after launch in end of June
  - ~ ¥ 1.2 B in Q3 (~8 MUSD)
  - ~240 hospitals treating ~3.000 patients
  - Self-pay market using blood-based biomarkers and digital platform
- Eisai adjusted FY 2024 (q2-24 - q1-25) forecast of ¥ 56.5 B (~370 MUSD) to ¥ 42.5 B (~280 MUSD)
  - Mid- and long-term forecasts unchanged

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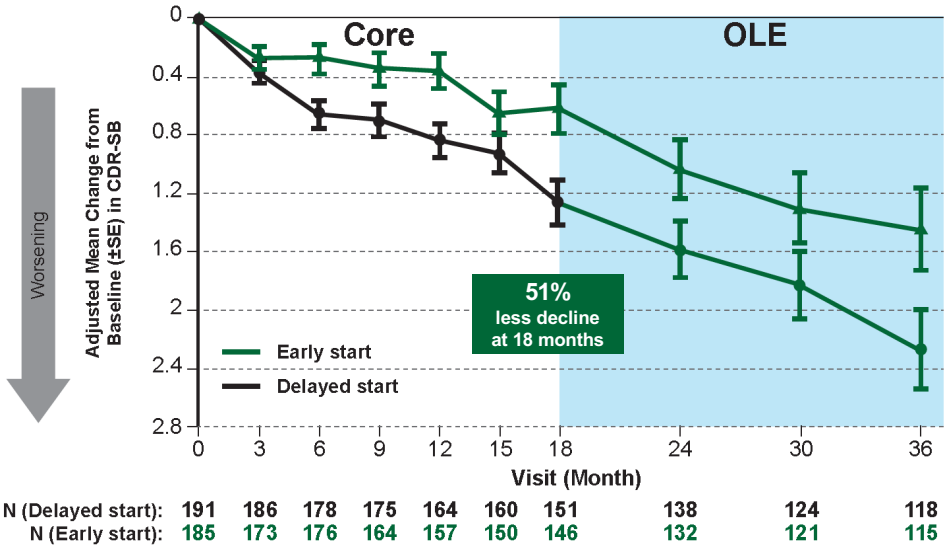
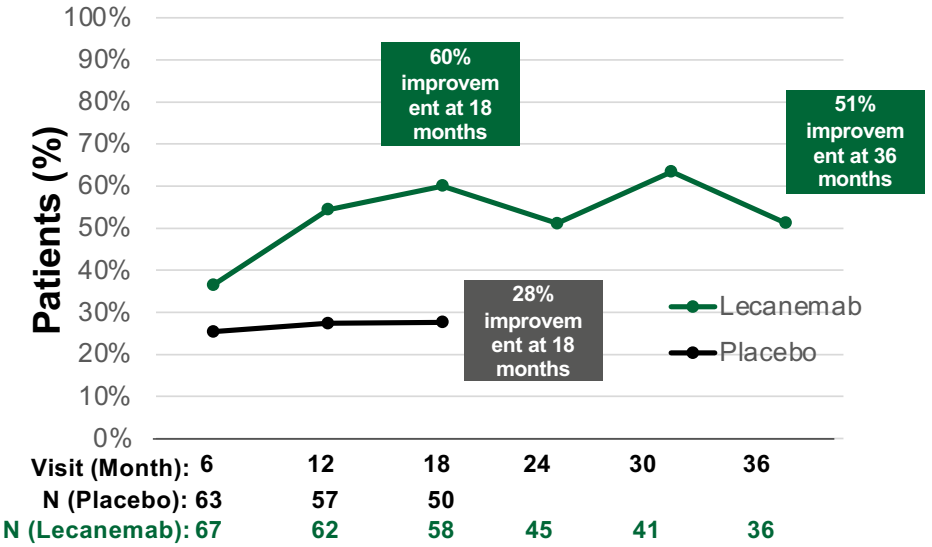
New data underline the importance of starting treatment early

More than 50% slowing of decline in patients with low Aβ (<60 CL)



More than 50% of patients with no or low tau improved over 3 years



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Simplified diagnosis and continued development of Leqembi could increase patient population and convenience

Convenient Administration

Approved (8 geographies)	Submitted (US)	Rolling submission finalized (US)	To be submitted
Intravenous treatment 10 mg/kg bi-weekly	Intravenous maintenance 10 mg/kg monthly	Subcutaneous maintenance 360 mg weekly	Subcutaneous initial treatment weekly

Simplified Diagnosis

Simplified diagnosis with blood-based biomarkers
Screening & confirmational

Broadened Indication

Potential approval for pre-symptomatic Alzheimer's

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A broad project portfolio with a focus on neurodegenerative diseases

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory & Market
ALZHEIMER'S DISEASE	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 (PyroGlu Aβ)							
	BAN2802	Eisai						
	BAN2803 (PyroGlu Aβ Ab with BT)							
PARKINSON'S DISEASE	Exidavnemab (BAN0805) (alpha-synuclein)							
	PD1601 (alpha-synuclein)							
	PD1602 (alpha-synuclein)							
	PD-BT2238 (alpha-synuclein with BT)							
OTHER CNS DISORDERS	Lecanemab[4] (BAN2401)							
	ND3014 (TDP-43) ALS							
	ND-BT3814 (TDP-43 with BT) ALS							
	GD-BT6822 (GCase with BT) Gaucher disease							
BLOOD BRAIN BARRIER	BrainTransporter (BT) technology platform							

as of September 30, 2024

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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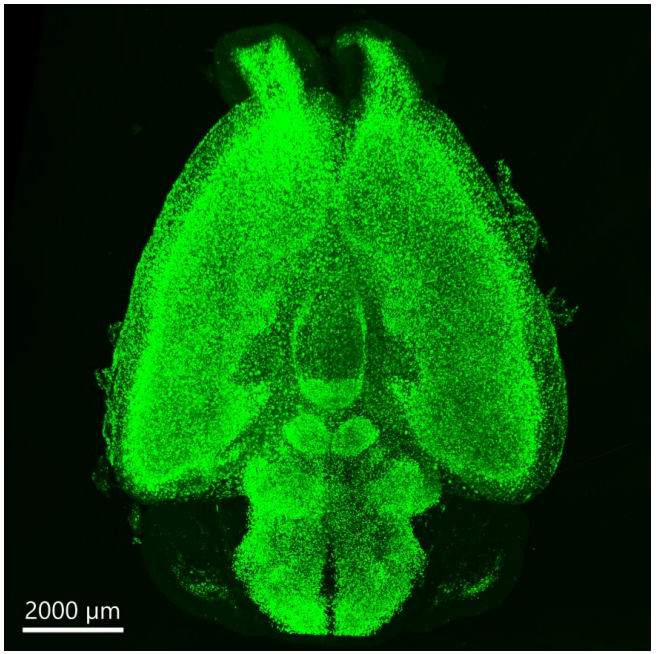
Pipeline progressing well, with strong new data validating the BrainTransporter platform presented

BioArctic BrainTransporter

- Presented validation at PEGS conference, demonstrating rapid, broad and deep brain distribution of BT-anti amyloid Ab

Exidavnemab

- Phase 2a study initiated in Parkinson's disease, exploring to also include patients with Multiple System Atrophy



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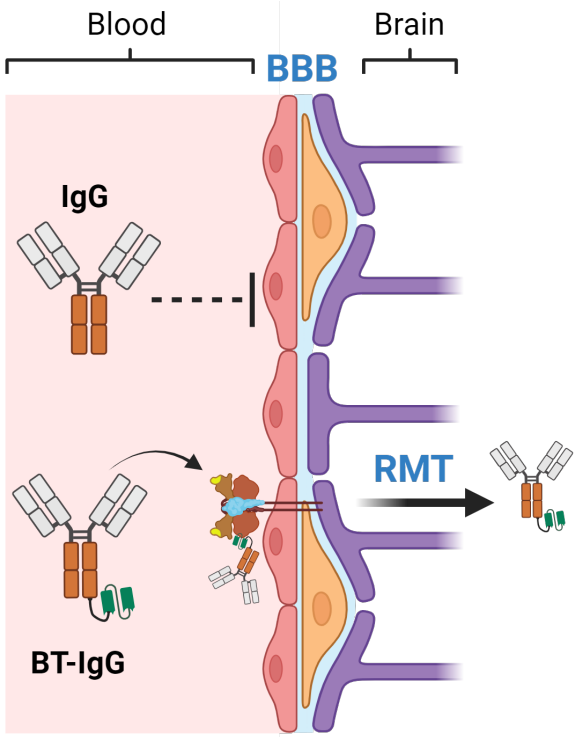
BrainTransporter dramatically improves antibody delivery to the brain using active transport across the blood brain barrier

Overcoming the BBB obstacle through receptor-mediated transport



BBB: Blood brain barrier
RMT: Receptor-mediated transport

Offers several opportunities to further enhance antibodies and other modalities in clinic

Opportunities	Note
Increased brain exposure	Promotes **active transport** across the BBB
Broader brain distribution	Access **deeper brain structures** using the brain capillary network
Faster efficacy	Promotes **rapid brain exposure** due fast BBB transport
Stronger efficacy	**Complete access to the target population** by increased exposure and broader brain distribution
Convenience – lower dose	**Reduced volume** and **number of injections** required for clinical effect
Safety – lower dose/different distribution	**Reduce the total drug load** required for clinical effect

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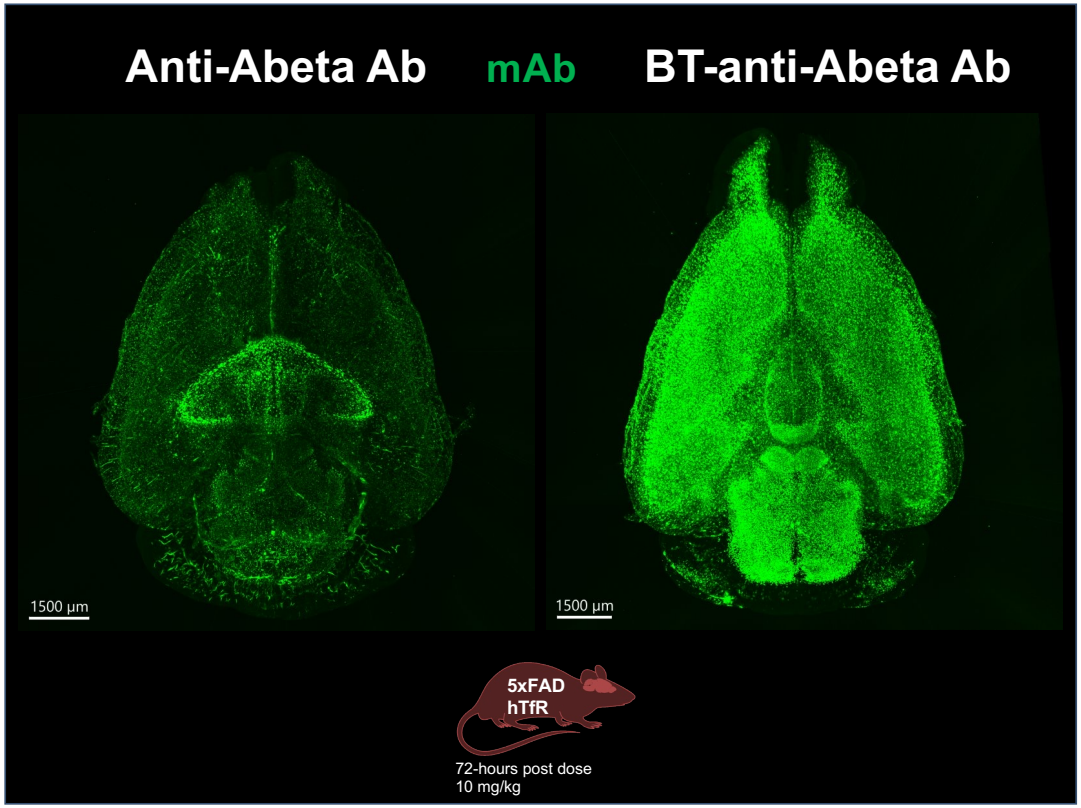
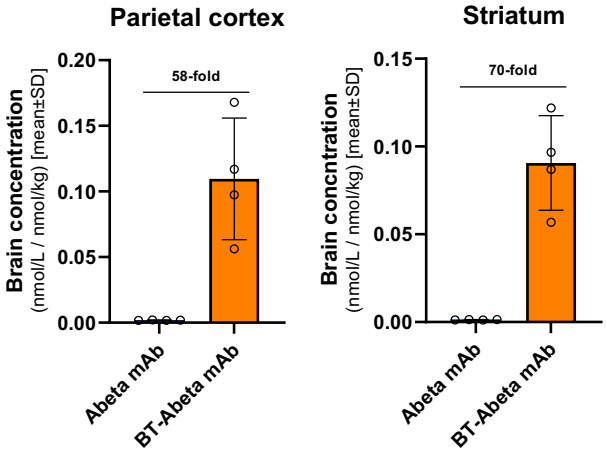
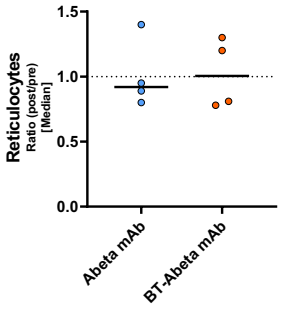
Stronger, deeper and broader brain distribution with the BrainTransporter approach without affecting hematology



BT substantially increases brain exposure in non-human primates



BT-Abeta mAb does not induce reticulocyte loss



Applied in all parts of BioArctic's project portfolio
Opportunities also in other therapeutic areas

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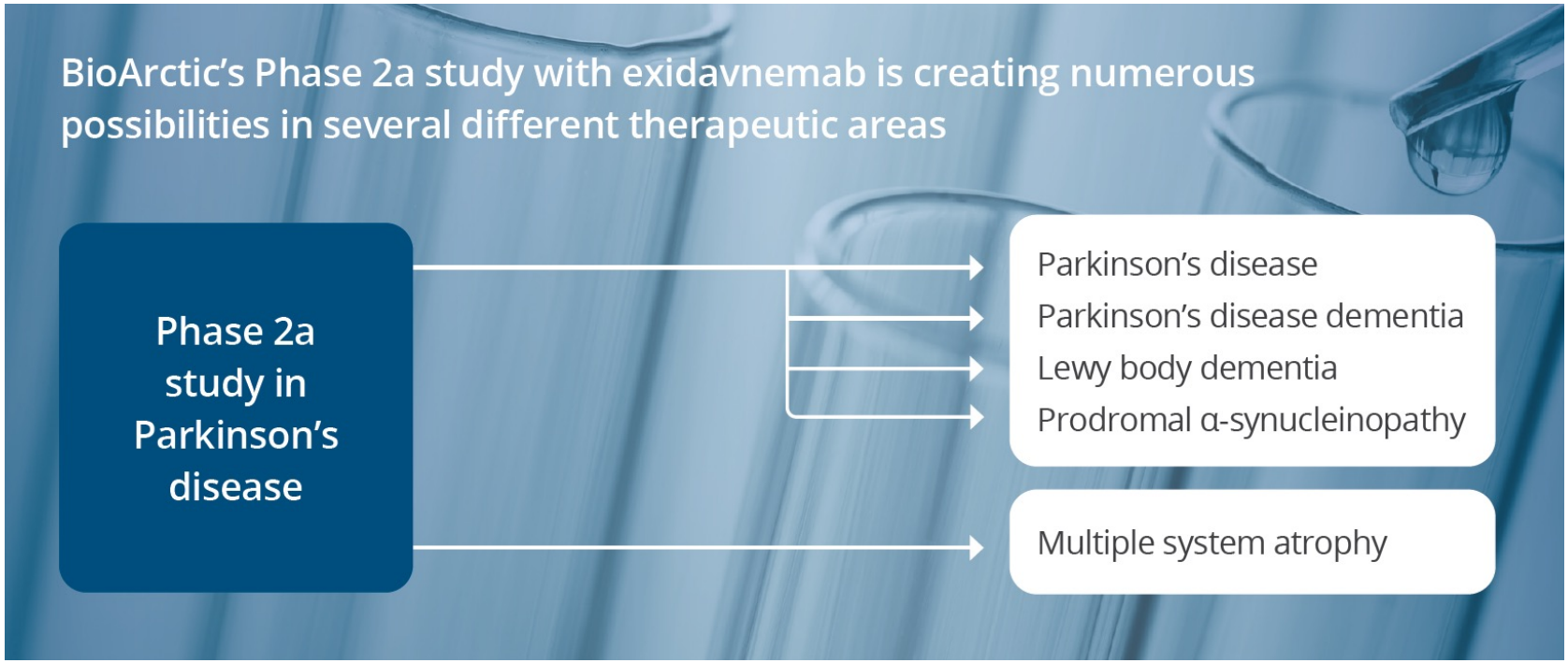
Screening for exidavnemab Phase 2a study ongoing

Offers opportunities in several neuronal synucleinopathies (NSD)



Biomarkers available to identify patients with pathological α-syn

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Exidavnemab Phase 2a study “EXIST” in Parkinson's disease
Exploring to add a MSA cohort

EXIST PHASE 2A STUDY DESIGN

Patient inclusion

Patients with Mild to Moderate Parkinson's Disease (PD)

Inclusion criteria:

- Idiopathic PD with confirmed dopamine transporter deficit
- Stable symptomatic PD medication
- Cognition inconsistent with dementia
- Hyposmia as shown by positive smell test

Stratification:

α-synuclein SAA* positive

No of subjects:

24

Treatment 3 months

Randomized, double-blind, placebo-controlled trial

Exidavnemab low dose	Exidavnemab high dose
Placebo	Placebo

2H 2024 Initiation

Mid 2025 Safety review

1H 2026 Results

Read-outs

Primary endpoints:

Safety & tolerability

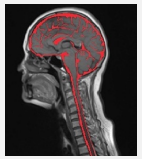
Key secondary endpoints:

PK & Immunogenicity

Exploratory:

Biomarkers

Plasma & CSF



Digital -motor -cognition

* SAA = Seeding amplification assay

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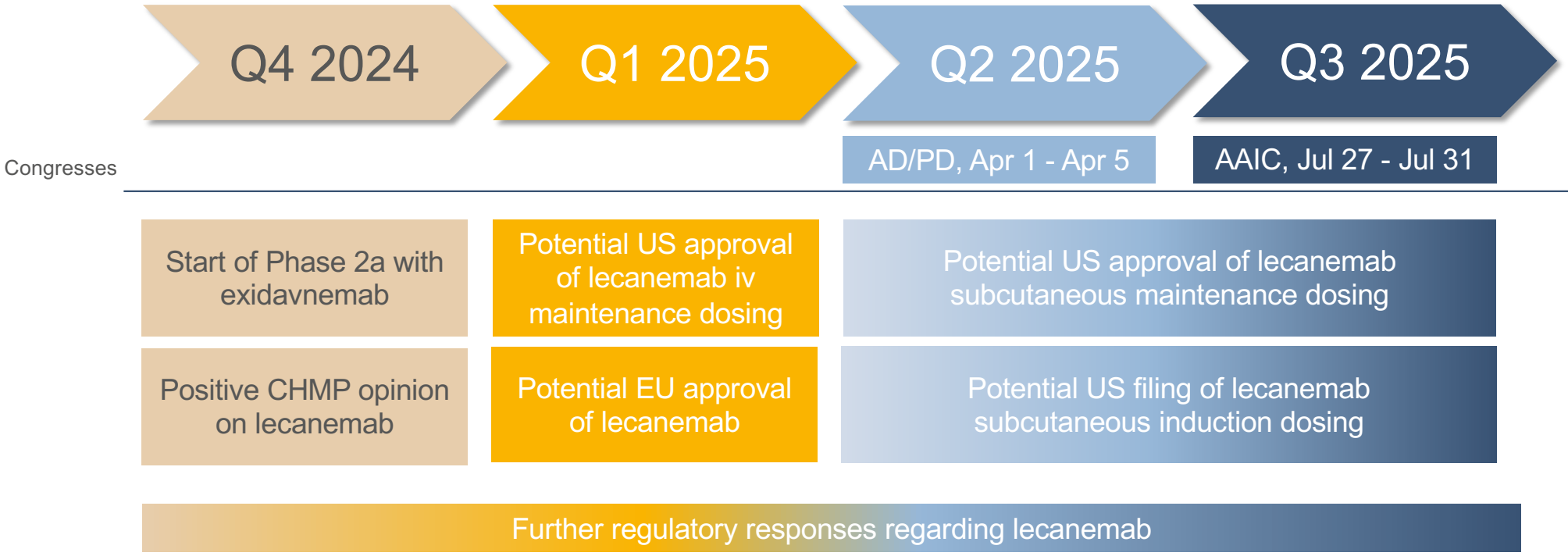
Upcoming news flow



AI – autoinjector
SC – subcutaneous

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In summary

Early pipeline progressing well

Leqembi royalty revenue continues to grow

Finances remain solid

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”

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

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