BioArctic AB

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Company Presentation

Nasdaq Stockholm: BIOA B

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BIOARCTIC

BioArctic – a Unique Swedish Biopharma Company

A **scientific breaktrough by our founder** enables development of disease modifying treatments for disorders in the central nervous system

Successful strategic collaborations with global pharmaceutical companies with a total **value of the agreements of 9.3 BSEK (ca 1 BUSD) plus royalties**

A confirmatory Phase 3 trial initiated for BAN2401 - our most advanced drug candidate – a promising game changing treatment for early Alzheimer´s disease

A **positive cash flow** during the last six years and **more than 1 BSEK in cash**

A broad project portfolio and a well-functioning research and development organization and fruitful collaborations with leading academic researchers generating **new projects with substantial marketing and out-licensing potential**

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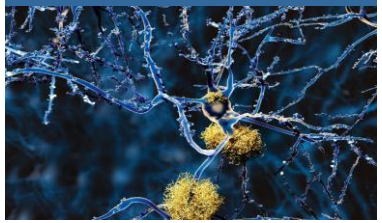
Helping Patients with Disorders in the Central Nervous System by Developing Innovative Treatments

Three key areas with high unmet medical needs – all lacking effective treatments today
Disease modifying treatment in AD and PD – huge and growing markets due to aging populations

Alzheimer's Disease



BAN2401 Phase 2b study in early AD in collaboration with Eisai – first late stage study demonstrating potential disease modifying effect on both cognition and biomarkers with a good tolerability profile
Phase 3 confirmatory study initiated

Parkinson's Disease

BAN0805/ABBV-0805 for PD in collaboration with AbbVie
Phase 1 ongoing

Complete Spinal Cord Injury

SC0806 a unique regenerative treatment for patients with Complete Spinal Cord Injuries in Phase 1/2
Phase 2 ongoing

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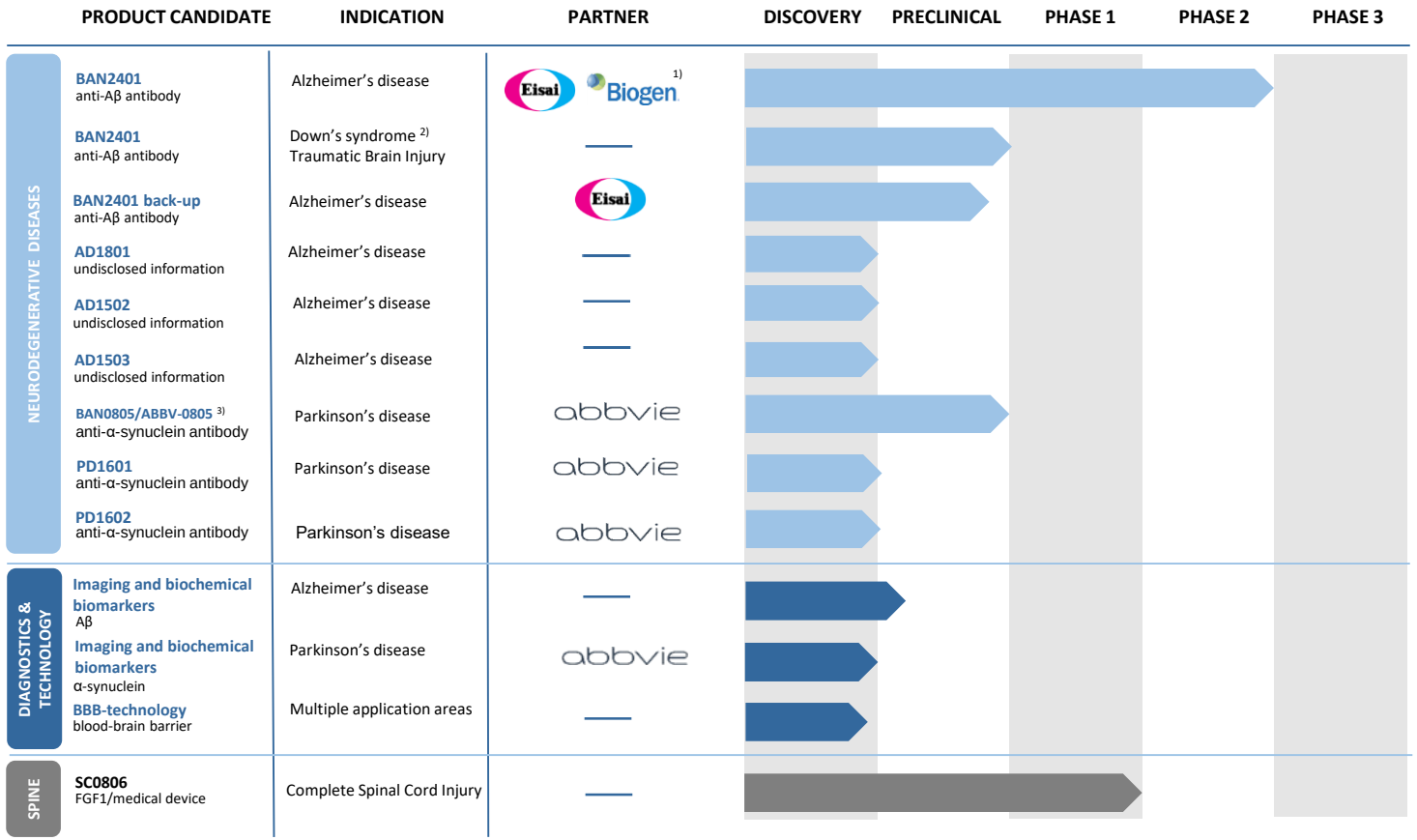
Strategic Partnerships and Cutting-Edge Proprietary R&D

per December 31, 2018



1) Partner with Eisai on BAN2401 for treatment of AD. Since 2014, Eisai partnered with Biogen in AD
2) Dementia and cognitive impairmet associated with Down's syndrome and Traumatic Brain Injury
3) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805

Source: Company data

- **Attractive combination** of fully financed partner projects and cutting-edge, proprietary R&D pipeline with substantial market and out-licensing potential

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Long-standing and Extensive Partnerships

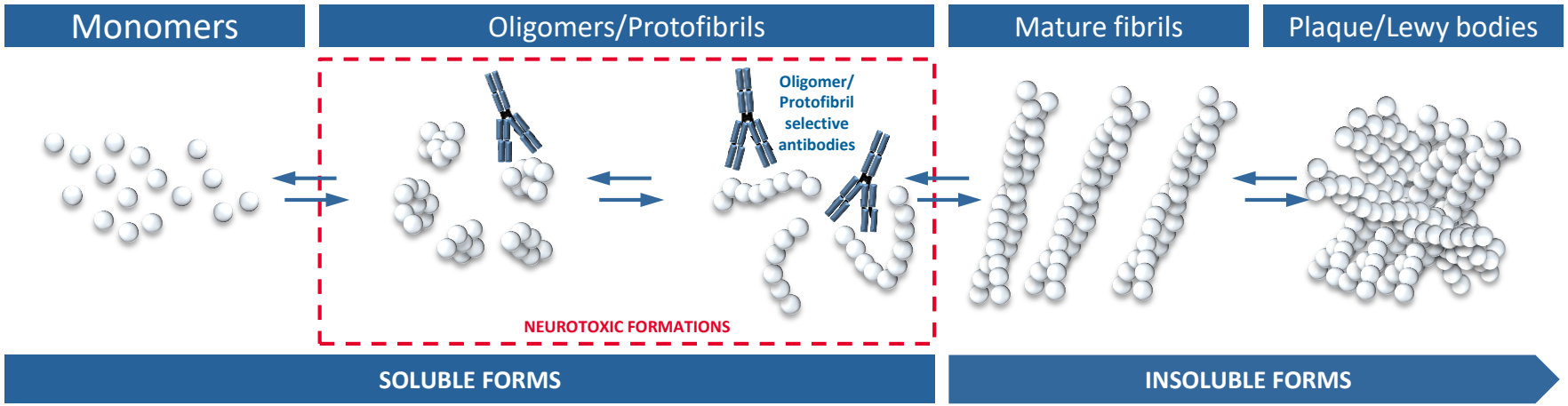
Eisai collaboration and license agreements Alzheimer's Disease

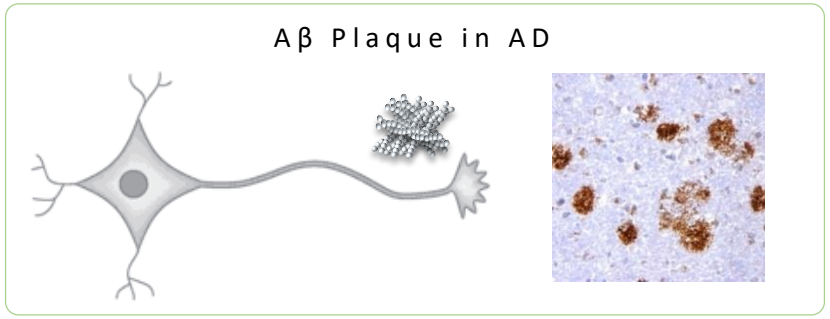
Description of agreements	Milestone/royalty potential
• Three research collaborations and two licenses for Abeta oligomer/protofibril antibodies BAN2401 and BAN2401 back-up as disease modifying treatments for Alzheimer's disease	• Total aggregated value of the research collaborations and license agreements is approx. EUR 218m in signing fee and milestones, plus high single digit royalties • Received approx. EUR 47m for the research collaborations, signing fees and milestones

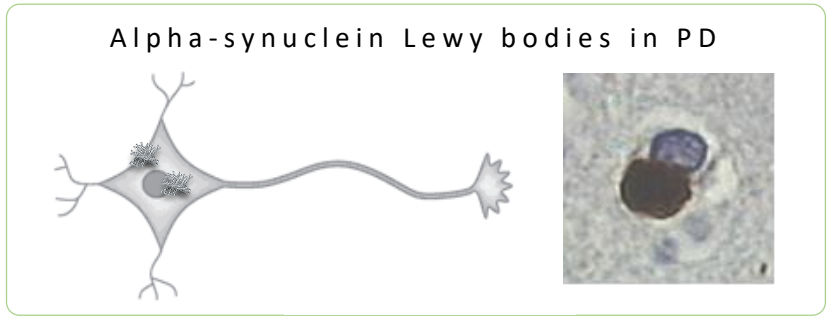
AbbVie collaboration and license agreement Parkinson's Disease

Description of agreements	Milestone/royalty potential
• Research collaboration alpha-synuclein anti-bodies as disease modifying therapies for PD incl. BAN0805 to IND, follow-up compounds and diagnostic • AbbVie licensed project portfolio for development and commercialization	• Total pot. value of the agreement up to USD 755m incl. an up-front fee, option exercise fee, and success-based milestones plus tiered royalties • Received USD 80m up-front payment for the research collaboration • Received USD 50m for the license

Protein Misfolding is Disease Causing in a Number of Neurodegenerative Diseases Including AD and PD







Source: company information.

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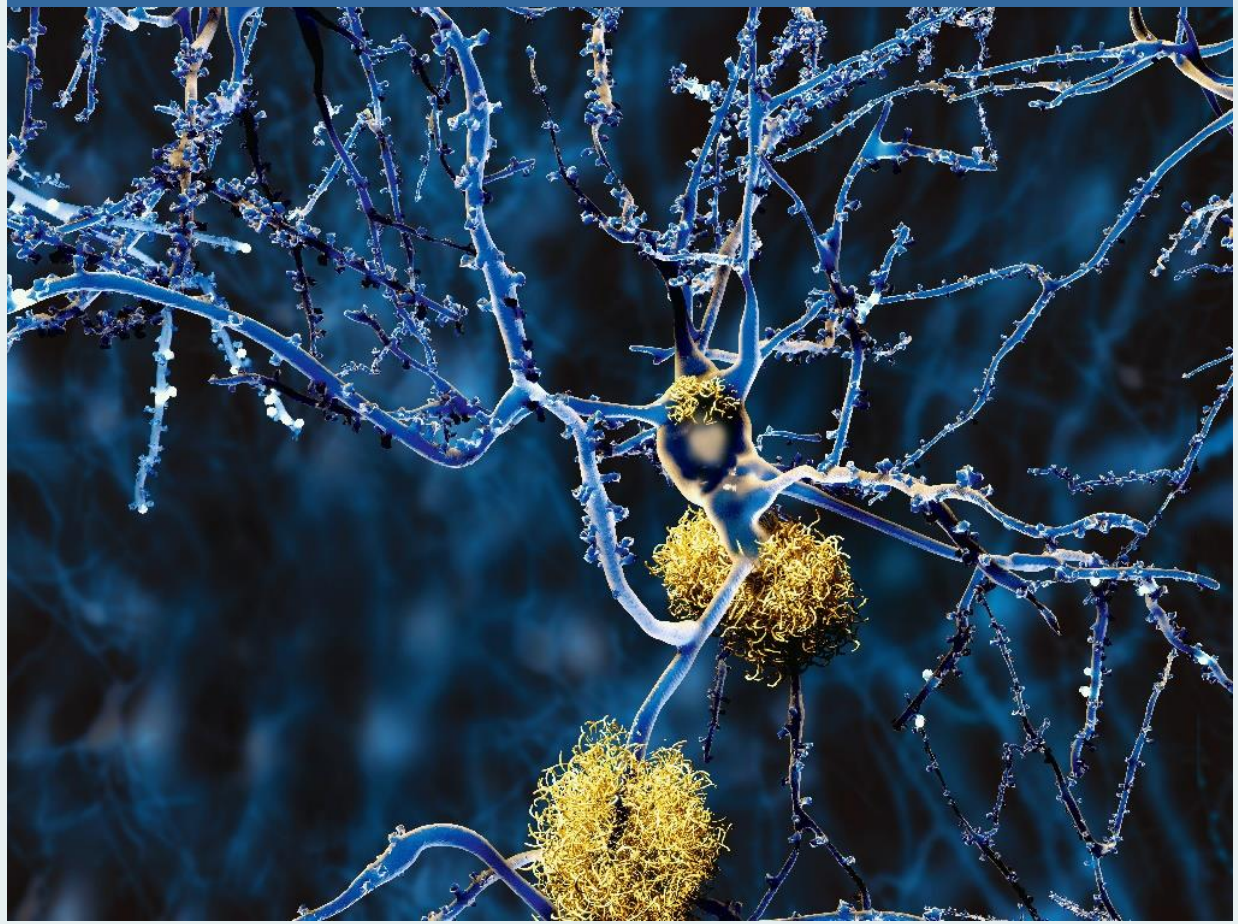
About Alzheimer’s Disease

Neurons with Amyloid Plaques in Alzheimer’s Disease



Alzheimer's Disease (AD)

- Irreversible neurodegenerative brain disease of the elderly, which, through the death of brain cells, leads to a progressive decline in memory and cognitive abilities, such as thinking, language, and learning capacity
- 47 million people worldwide suffer from dementia and by 2050 expected to be 130 million. >50 % of dementia diagnosed as AD
- 25 million people worldwide suffer from Alzheimer’s disease today and the number is expected to double in 20 years
- Early AD encompass mild AD and MCI due to AD
- Huge market with demand for several products and expected to be used in combination

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BAN2401 – Innovative Phase 2b Study Design
Positive 18 Month Results Reported by Eisai

Important parameters

Right target
- Address the soluble protofibrils – a toxic form of amyloid

Right patient population
- Early AD – MCI due to AD & Mild AD
- Identify right patients – biomarkers

Right dose & exposure
- Selecting doses with exposures above preclinical IC50
- Adaptive design testing several doses and dose regimens

Right measurements
- More sensitive cognition scales
- Biomarkers for disease progression and disease modification

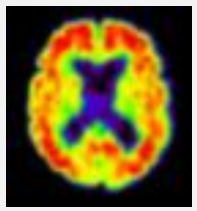
Right safety
- Well tolerated with a benign safety profile
- Low risk for amyloid related imaging abnormalities (ARIA) and no expected cardiovascular risk

Phase 2b study design

Patient inclusion

Multinational recruitment:
- 100 clinical centers included
- **Inclusion criteria:** MMSE >22-30
- Stable concomitant medication
- Positive amyloid PET/CSF

Inclusion completed with 856 ➔ patients



Treatment 12 months

Double-blind, placebo controlled, parallel-group study with Bayesian adaptive design

- Placebo
- 2.5 mg/kg twice a month
- 5 mg/kg once a month
- 5 mg/kg twice a month
- 10 mg/kg once a month
- 10 mg/kg twice a month

Primary analyses:
- Change from baseline in ADCOMS at 12 months
- Safety and tolerability

Treatment 18 months

Key analyses:
- Change from baseline in ADCOMS, CDR-SB, ADAS-cog at 18 months
- Change from baseline in brain amyloid as measured by amyloid PET
- Change from baseline in CSF biomarker
- Safety and tolerability

Source: Company information
Note: ADCOMS = Alzheimer's Disease Composite Score, an evaluation tool developed by Eisai

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BAN2401 Showed Effect on Clinical Parameters

Clinical effect:
- ADCOMS
- ADAS-Cog
- CDR-SB

- **ADCOMS** cognition scale (the key efficacy parameter) showed statistically significant slower decline of 30% (p=0.034) with 10 mg/kg twice a month (highest dose)
  - ADCOMS showed effect already at 6 months – as well as after 12 and 18 months of treatment
  - Slowing of disease progression observed across sub-groups*
  - The clinical effect increased over time
- **ADAS-Cog** (well-established cognition scale) showed statistically significant slower decline of 47% (p=0.017)
- **CDR-SB** (cognition and function scale) showed slower decline of 26% (p>0.05)

*MCI due to AD – mild AD, ApoE4 carriers – non-carriers, with or without symptomatic treatment

Presented at AAIC July 2018 by Eisai

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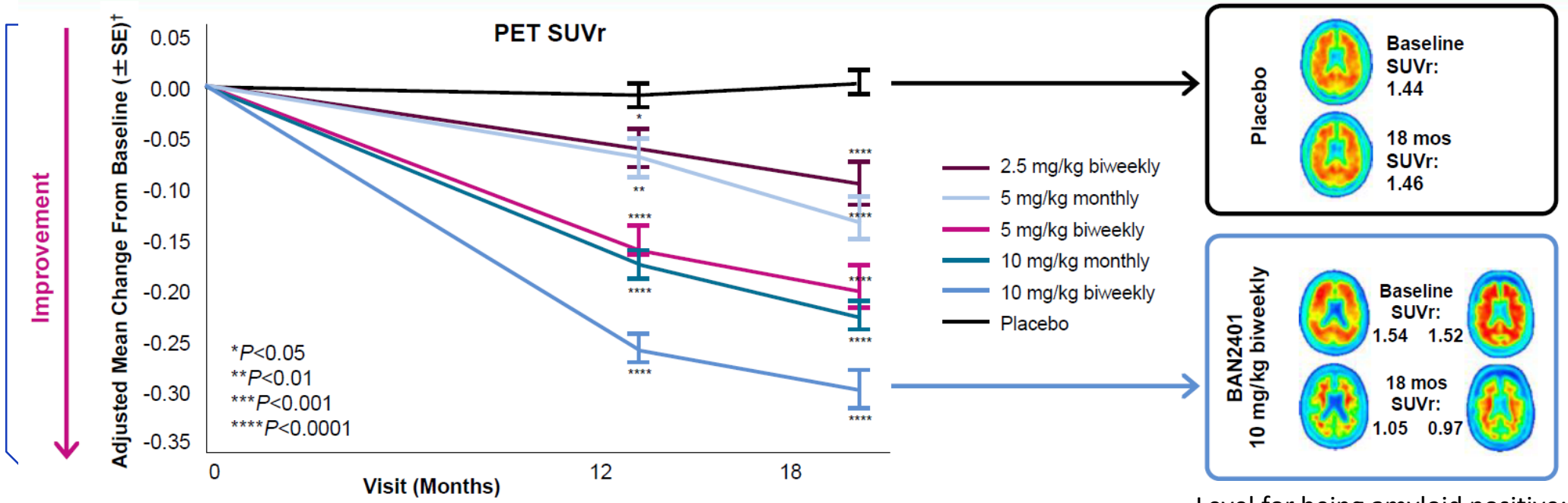
BAN2401 Reduces Amyloid Burden over 18 Months



Level for being amyloid positive: > 1.15 (SUVr)

81% of amyloid positive converted to negative at highest dose (visual read)

Presented at AD/PD March 2019 by Eisai

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BAN2401 Showed Effects on CSF Markers of Neurodegeneration Supporting a Disease Modifying Treatment

CSF Biomarkers:
- t-tau
- p-tau
- neurogranin
- NfL

- Neurodegenerative markers show effect of BAN2401 on underlying pathophysiology
  - Reduction in t-tau ($p<0.05$, neuron loss)
  - Reduction in p-tau (13%)
  - Reduction in neurogranin (11% synaptic damage)
  - Reduction in increase of Neurofilament Light (NfL) (48% axonal degeneration)

Presented at CTAD Oct 2018 by Eisai

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BAN2401 Showed Good Tolerability in Early AD Patients

Safety & tolerability

- BAN2401 was generally **well-tolerated** with infusion reactions and ARIA as the most common side effects (mostly mild to moderate)

- ARIA-E incidence:
  - <10% at any dose
  - <15% in APOE4 carriers at the highest dose
  - Only ~10% of ARIA-E cases (5/48) reported symptoms including headache, visual disturbances or confusion
  - Generally occurred within the first 3 months of treatment
  - Mostly mild to moderate in severity (radiographic)
  - Reversible and MRI findings typically resolved within 4-12 weeks

ARIA-E, Alzheimer's Related Imaging Abnormality-Edema

Presented at AAIC July 2018 by Eisai

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Eisai Reported Positive Phase 2b Study Results Support BAN2401 as a Potential Treatment for a Broad Population of Early Alzheimer Patients

BAN2401 Treatment Effect in Early AD

Clinical Outcome Measures

- Slowing of disease progression observed across clinical outcome measures at the highest dose, including 30% on ADCOMS
- Slowing of disease progression observed across sub-groups

Brain Amyloid PET

- Pronounced dose-dependent amyloid clearance across the dose range
- 81% of subjects converted to amyloid negative state
- Consistent and pronounced amyloid clearance across all sub-groups

CFS Biomarkers

- Elevated Abeta demonstrates target engagement
- Impact on AD pathophysiology with benefits on neuro-degeneration markers: t-tau, p-tau, neurogranin and NfL

BAN2401 was well tolerated with < 10% ARIA-E at any dose

Selectively targeting Abeta protofibrils with low affinity to monomers confer an advantageous benefit risk profile

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BAN2401 – Eisai has initiated a single Phase 3 confirmatory trial

- Eisai has interactions with regulatory authorities regarding the future BAN2401 program (Feb 4)
  - Eisai reported that authorities have acknowledged that the BAN2401 Phase 2b study showed robust data demonstrating dose dependent reduction of amyloid plaque in the brain and slowing of clinical decline
  - Eisai reported that they have confirmed with health authorities that a single Phase 3 study would meet the requirements for the approval as a confirmatory study
- Open-label extension study with BAN2401, without placebo, for patients from the Phase 2b study has started
- Eisai is exploring the potential for a preclinical AD Phase 3 study at even earlier stages of the disease (March 7)
- Eisai initiated the confirmatory Phase 3 study in early AD patients (March 22)

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BAN2401- **Eisai´s** Phase 3 study "Clarity" designed to confirm the positive Phase 2b results

Important parameters

Right target

- Address the soluble protofibrils – a toxic form of amyloid

Right patient population

- Early AD – MCI due to AD & Mild AD
- Identify right patients – biomarkers

Right dose & exposure

- Top dose in Phase 2 b study demonstrated positive effects

Right measurements

- Cognition scales
- Biomarkers for disease progression and disease modification

Right safety

- Well tolerated with a benign safety profile
- Low levels of amyloid related imaging abnormalities (ARIA), reversible and mostly without symptoms

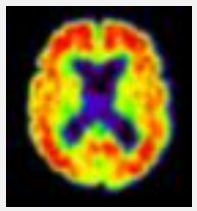
Phase 3 study design

Patient inclusion

Multinational recruitment:
US, EU, Asia

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

1566 Early Alzheimer patients



Treatment 18 months

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

Placebo

BAN2401
10 mg/kg twice a month

Read-outs at 18 months

Primary analysis:
Change from baseline in CDR-SB

Key analyses:

- Change from baseline in ADCOMS, ADAS-cog
- Change from baseline in brain amyloid measured by amyloid PET
- Change from baseline in CSF biomarkers: t-tau, p-tau, neurogranin, Neurofilament light
- Safety and tolerability

Source: Company information
Note: ADCOMS = Alzheimer's Disease Composite Score, an evaluation tool developed by Eisai

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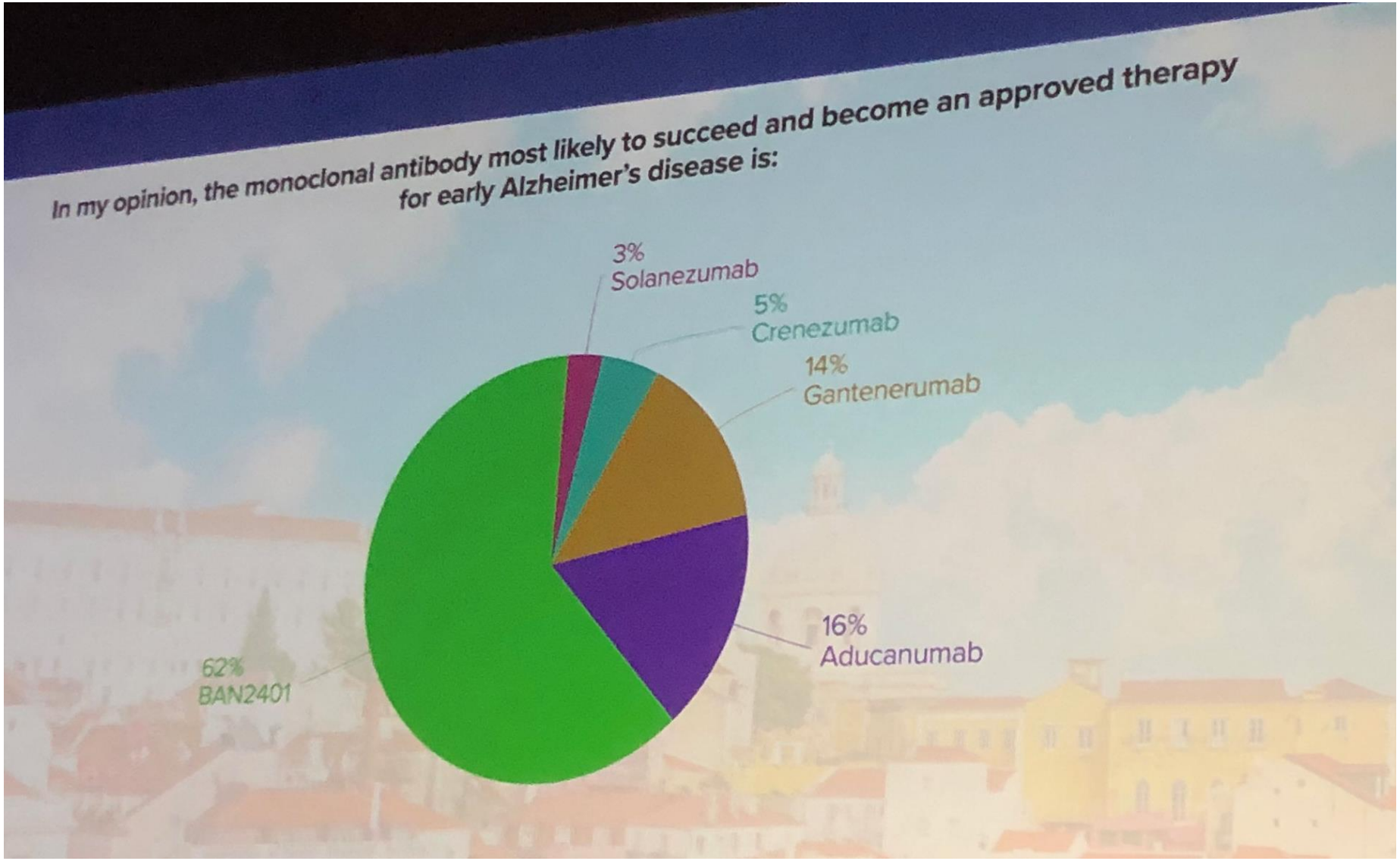
At AD/PD in March 2019 BAN2401 Was Seen as the Most Promising Monoclonal Drug Candidate as Disease Modifying Treatment in AD



Votes by an audience of approx. 1500
Key Opinion Leaders, researchers and physicians at AD/PD March 30, 2019

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About Parkinson's Disease

Network of Neurons in Parkinson's Disease

Parkinson's Disease (PD)

- Tremor is the best-known sign of the disease. The disease develops gradually and can start with tremor in one hand or disturbances in the REM sleep, smell and bowel function

  The disease often also leads to stiffness and slow movements
- PD is the second most common neurodegenerative disease
- Compared to AD it affects a younger patient group, still at working age
- In 2015 it was estimated that 6.2 million people suffered from PD worldwide
- There is currently no disease modifying treatment for PD

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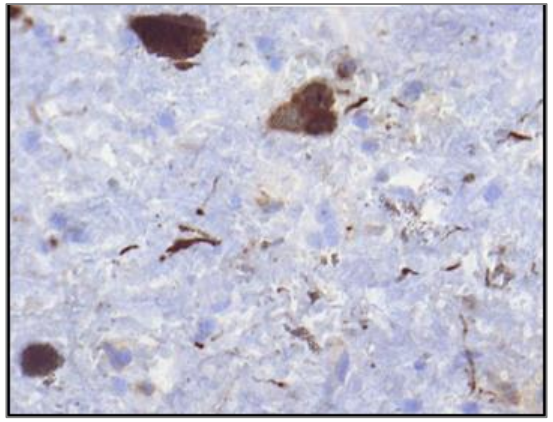
BAN0805 – Groundbreaking Disease Modifying Drug in PD with Rationale for Selective Targeting of Alpha-synuclein Oligomers/Protofibrils

Rationale for targeting alpha-synuclein

Human genetics → **Pathology** → **Pre-clinical proof of concept**

Alpha-synuclein mutations

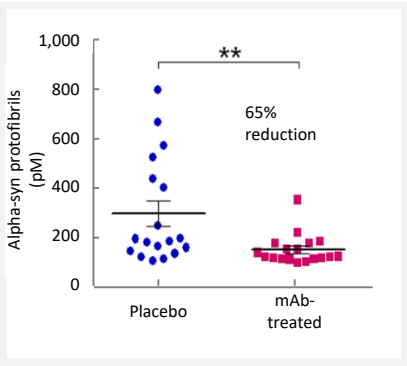
lead to PD or Dementia with Lewy Bodies and are associated with increased oligomer/ protofibril formation



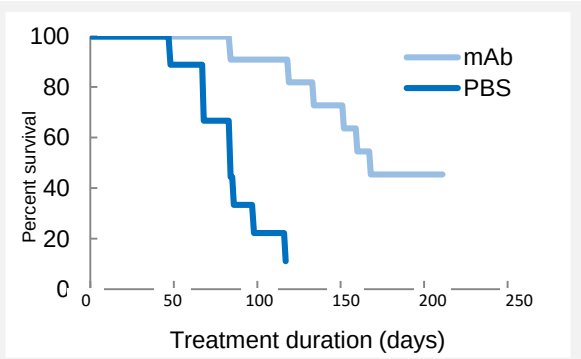
Alpha-synuclein deposition

is a hallmark of PD pathophysiology and alpha-synuclein oligomers/protofibrils are elevated in PD

Reduction of neurotoxic alpha-synuclein



Increases lifespan



Oligomer/protofibril selective antibody

reduces neurotoxic alpha-synuclein oligomer/protofibril levels, delays disease progression and increases lifespan in a PD mice model

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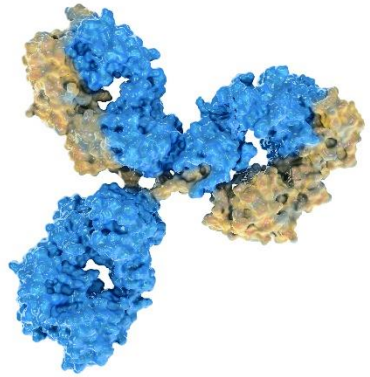
BAN0805/ABBV-0805

- Alpha-synuclein antibody portfolio licensed by AbbVie December 14, 2018
- Received a milestone payment of 50 MUSD for the license
- BAN0805/ABBV-0805 IND-application was approved by FDA in February 2019
- AbbVie started Phase 1 with ABBV-0805 in March 2019
- AbbVie is responsible for the clinical development in Parkinson´s disease
- BioArctic will deliver follow-up compounds in the continued collaboration with AbbVie



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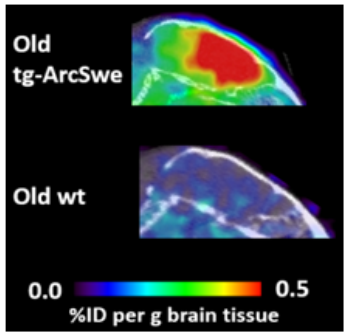
Several Novel Approaches to Improve Diagnostics and Treatment

Imaging and biochemical biomarkers in AD

Aβ protofibril PET tracer

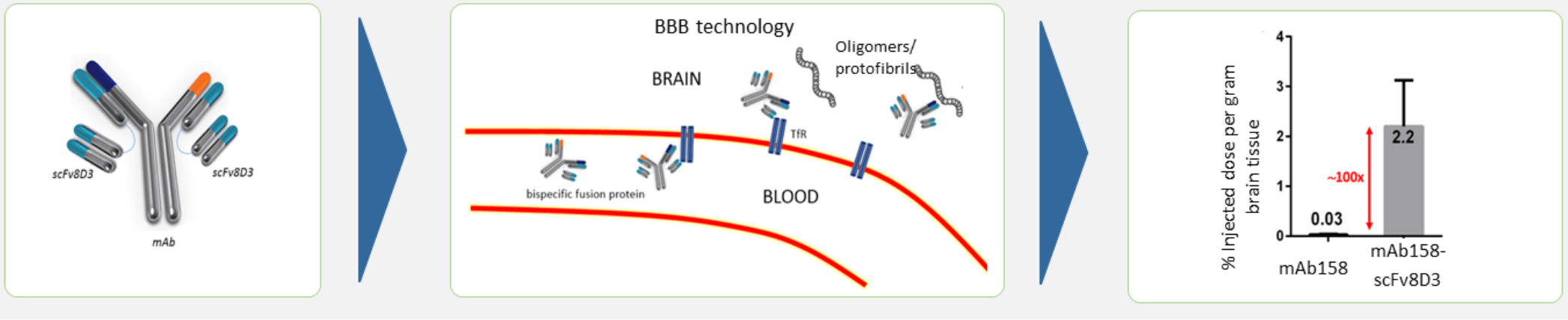


- PET with an antibody-based ligand
- Binding to Aβ oligomers/protofibrils
- Has short half-life
- Improved BBB penetration

Aβ protofibril biochemical biomarker

- Sensitive biochemical method for Aβ measurement in development is of great clinical importance

Blood-brain barrier technology



Source: Sehlin et al 2016 Nature Communications. Hultqvist et al 2017, Theranostics.

Substantially increased antibody brain uptake by BioArctic´s brain shuttle technology

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About Complete Spinal Cord Injury

Today there is no effective treatment for complete spinal cord injury

The patients require life-long treatment and care, which means high costs for healthcare systems and societies

Spinal Cord Injuries (SCI)

- A complete spinal cord injury (CSCI) is an injury where the patient can accomplish no voluntary movement or sensory feedback below the injury paralysis
- CSCI causes degeneration of the nerve fibers below the site of the injury as nerve cells do not regenerate
- Patients suffer from other serious symptoms, incl. neuropathic pain, bowel and bladder incontinence, sensory loss, pressure sores, infertility and sexual dysfunction
- Increasing stability, restoring bowel and bladder control, reducing pain or enabling sexual functionality would be a major improvement of the patient's quality of life
- 2.5 million people live with paralysis, 40% CSCI
- More common among younger men, injured in accidents

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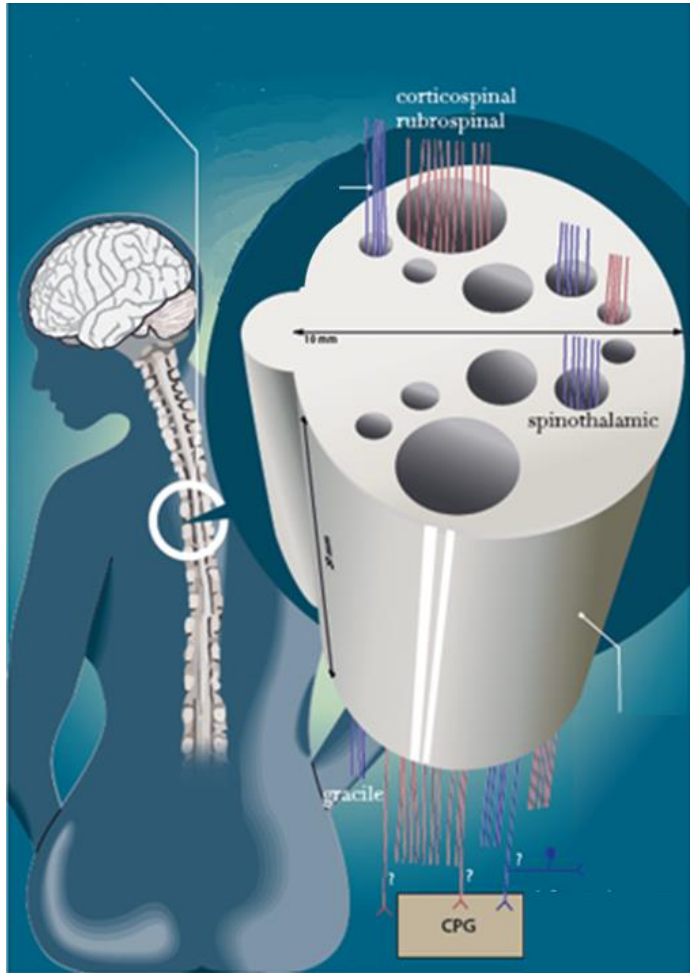
SC0806 – Unique Regenerative Treatment of Complete Spinal Cord Injury

SC0806 – Regenerative Treatment of CSCI

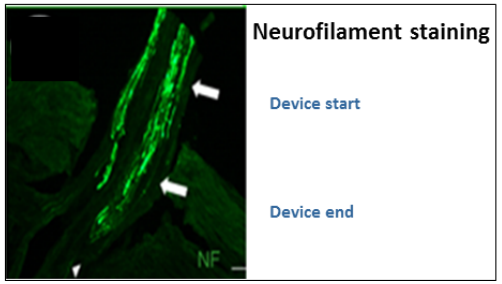


Treatment Rationale

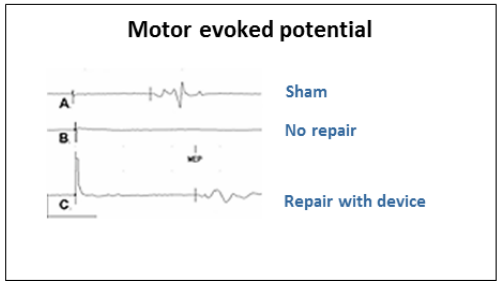
SC0806 makes nerve regeneration possible

FGF1 activated by heparin	•Stimulation of central axon outgrowth •Decreases gliosis
Peripheral nerve autografts	•Optimal regeneration environment
Biodegradable device	•Provides sustained release of FGF1 •Positioning of nerve grafts from white to gray matter

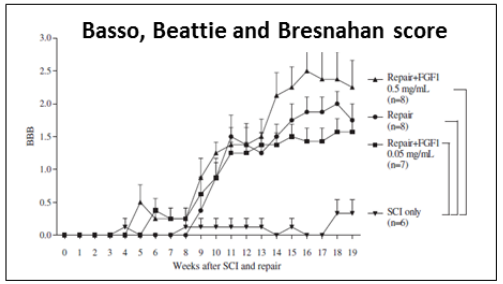
Nerve regeneration



Electrophysiology restored



Motor function improved



Preclinical Proof of Concept shown in rats with resected spinal cords

- Rat experiments demonstrate nerve regeneration, restored electrophysiology and motor function after SC0806 treatment

Source: Nordblom et al. Restorative Neurology and Neuroscience 30 (2012) 91–102

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SC0806 – Unique Regenerative Treatment of Complete SCI

The Lokomat™ used in the Rehabilitation

Project Status

- Clinical Phase 1/2 trial ongoing in patients with Complete Spinal Cord Injury
  - Surgery in Sweden
  - Rehabilitation 18 months with Lokomat™ in Sweden, Estonia, Finland and Norway
  - Patients receiving SC0806 has an option of 12 months additional participation in an extension study
  - 9 patients included in Panel A (6 treated with SC0806 and 3 control patients)
  - Safety evaluation of patients in Panel A performed and support progression into Panel B i.e. Phase 2
  - First patient included in Phase 2
  - Interim analysis planned no later than first half 2020
- Orphan Drug designation in US and EU – may grant 7 and 10 years exclusivity, respectively
- EU Horizon 2020 research and innovative program Grant Agreement No. 643853 of MEUR 6.4

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BioArctic has a Great Team and a Strong Financial Position

- A dedicated team of highly educated scientists with vast experience delivering with high quality
- Close collaboration with universities
- A successful business-model with research collaborations and license agreements with big pharma – Eisai and AbbVie
- Grants from Vinnova and EU Horizon 2020
- External validation of high quality deliverables
- Positive results last 6 years and all years but 3 since start 16 years ago
- Solid cash position
- Listed on Nasdaq Stockholm Mid Cap

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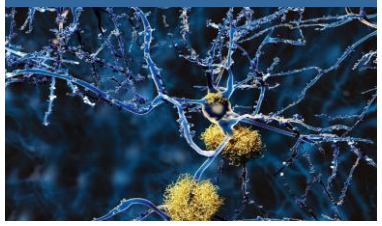
Planned Key Events Next 18 Months

Alzheimer's Disease



BAN2401

Phase 3 confirmatory study in early AD started by Eisai and BioArctic to receive a milestone

Parkinson's Disease

BAN0805/ABBV-0805

Phase 1 study started by AbbVie

Preparing for further clinical development in PD

Complete Spinal Cord Injury

SC0806

Phase 2 started in patients with Complete Spinal Cord

Interim analysis first half 2020 at the latest

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Q&A

Gunilla Osswald, PhD, CEO

Next Report & IR Contact

- **Next report:**
  Interim Report Jan-Mar
  May 9, 2019
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