

BioArctic: Significant progress in the projects and additional milestone payment

Summary of key events for the second quarter 2019

- BioArctic received MEUR 15 milestone payment from Eisai for start of BAN2401 confirmatory Phase 3 study in early Alzheimer's disease
- Alzheimer's Clinical Trials Consortium and Eisai announced that BAN2401 will be evaluated in a clinical study for prevention of Alzheimer's disease
- Ewa Björling was elected new member of the board at the Annual General Meeting
- The Annual General Meeting approved the introduction of an employee warrant program 2019/2028 for the company's management, researchers and other staff

Key events after the period

- There are no key events to report after the period

Financial summary for the first half of 2019

- Net revenues for the period increased with MSEK 130.1 to MSEK 234.7 (104.6) as a result of the received milestone payment from Eisai
- Operating profit amounted to MSEK 144.1 (25.3) and the operating margin was 61.4 percent (24.2) for the period
- Profit for the period amounted to MSEK 113.9 (20.5) and earnings per share were SEK 1.29 (0.23)
- Cash flow from operating activities amounted to MSEK 430.8 (-79.3) for the period

Financial summary

MSEK	Apr-Jun 2019	Apr-Jun 2018	Jan-Jun 2019	Jan-Jun 2018	Jan-Dec 2018
Net revenues	171.3	52.3	234.7	104.6	714.0
Other operating income	-0.7	3.6	6.2	15.0	16.3
Operating profit	126.8	6.4	144.1	25.3	488.8
Operating margin, %	74.0	12.3	61.4	24.2	68.5
Profit for the period	100.3	5.1	113.9	20.5	381.6
Earnings per share, SEK ¹	1.14	0.06	1.29	0.23	4.33
Equity per share, SEK ¹	11.35	7.46	11.35	7.46	11.56
Cash flow from operating activities	97.2	-37.3	430.8	-79.3	-200.1
Cash flow from operating activities per share, SEK ¹	1.10	-0.42	4.89	-0.90	-2.27
Equity/assets ratio, %	78.4	61.7	78.4	61.7	73.1
Return on equity, %	9.9	0.8	11.3	3.2	46.1
Share price at the end of the period	74.40	21.80	74.40	21.80	82.00

¹ The allocation of the employee warrants program has not yet been concluded as of June 30, 2019; thus, there is no dilutive effect

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This information is information that BioArctic AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Swedish Securities Market Act (*Swe. Vpml*). This information was submitted for publication, through the agency of the named contact persons, at 08.00 a.m. CET on July 11, 2019.

Invitation to presentation of Interim Report for the period January – June 2019

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, July 11, at 09:30 – 10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson will present BioArctic, comment on the Interim Report and answer questions.

Webcast: <https://tv.streamfabriken.com/bioarctic-q2-2019>

To participate in the conference call, please call: +46 8 505 583 66 (Sweden), +45 781 501 08 (Denmark), +49 692 222 203 80 (Germany) +31 207 219 495 (Netherlands), +47 235 002 36 (Norway), +41 225 805 977 (Switzerland), +44 333 300 9274 (UK) or +1 844 625 1570 (USA)

CEO comments

In the first half of 2019, BioArctic made significant progress in that all three clinical projects advanced to the next phase in their respective development program and all of our research projects continued to generate results. All in all, this means that we have had a very successful first half of the year.

The global, confirmatory Phase 3 study (Clarity AD) has been started with the drug candidate BAN2401, a potential disease modifying treatment for early Alzheimer's disease. In May, the first patient was dosed which triggered a milestone payment of MEUR 15 to BioArctic from our partner Eisai. This large Phase 3 study, which is intended to support a regulatory filing, is based on the positive results from the Phase 2b study. According to Eisai, the final readout of the primary endpoint of the study is targeted for 2022.

The Phase 2b study with BAN2401 was the first study in late clinical phase to have successfully demonstrated potential disease modifying effects on both clinical function and clearance of amyloid beta in the brain. Further, the Phase 2b study also demonstrated effects on neurodegenerative biomarkers. These consistent results strengthen BioArctic's belief that BAN2401's unique binding profile is important and differentiates it from other antibodies.

For the participants in the Phase 2b study, an open-label extension study is ongoing with continued BAN2401 treatment with the highest dose and without placebo control.

BAN2401 has also recently been selected by the Alzheimer's Clinical Trials Consortium (ACTC) to be evaluated in a clinical trial aimed at prevention of Alzheimer's disease (the A45 study). According to ACTC and Eisai, the trial will be starting in early 2020. We are pleased to note Eisai's strong commitment to the continued clinical development of BAN2401 in Alzheimer's disease.

In the Parkinson's program, our partner AbbVie started the Phase 1 study with the drug candidate ABBV-0805.

AbbVie is responsible for running the clinical program and its financing. Within the framework of the collaboration, BioArctic continues to conduct two additional projects in research stages with antibodies targeting alpha-synuclein for treatment of Parkinson's disease.

Also, the Alzheimer projects as well as the projects on diagnostics and technologies in research phase have continued to develop well. In collaboration with Uppsala University, BioArctic develops a technology platform that facilitates the passage of antibodies across the blood-brain barrier. This innovative technology could potentially be used to treat various diseases of the brain. We have recently recruited an internationally renowned scientist to further strengthen the company's capabilities and competence in the neuroscience therapeutic area, antibody engineering and blood-brain barrier technology.

The product candidate SC0806 for complete spinal cord injury has advanced into Phase 2 in the ongoing Phase 1/2 study. An interim analysis of the first panel concerning efficacy and safety is planned for the first half of 2020, at the latest.

An important step to attract and retain competence in the company is the new employee warrant program which currently is being implemented. I am proud of our successes and to lead this innovative company with the aim to improve the quality of life for patients with central nervous systems disorders.



Gunilla Osswald
CEO, BioArctic AB

Project portfolio

BioArctic builds a unique and competitive portfolio of product candidates, diagnostics and technology in the company's indication areas. We run projects in three areas where effective treatments are lacking today: Alzheimer's disease, Parkinson's disease and complete spinal cord injury. The company's projects are in various phases: from early research phase to late clinical phase.

Summary at June 30, 2019:

- Three drug candidates in clinical phase: BAN2401 for early Alzheimer's disease (Phase 3), ABBV-0805 for Parkinson's disease (Phase 1) and SC0806 for complete spinal cord injury (Phase 2)
- Two drug projects in preclinical phase: BAN2401 for other indications such as Down's syndrome with dementia and BAN2401 back-up for Alzheimer's disease
- Five projects in research phase: three projects for Alzheimer's disease (AD1801, AD1502, AD 1503) and two projects for Parkinson's disease (PD1601, PD1602)
- Biomarker and diagnostics projects for Alzheimer's disease and Parkinson's disease, as well as a blood-brain barrier technology platform

	Product candidate	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	
Neurodegenerative diseases	BAN2401: anti-A β antibody	Alzheimer's Disease	Eisai, Biogen ¹	→					
	BAN2401: anti-A β antibody	Down's syndrome ² Traumatic Brain Injury	BioArctic	→					
	BAN2401 BACK-UP: anti-A β antibody	Alzheimer's Disease	Eisai	→					
	AD1801: Undisclosed information	Alzheimer's Disease	BioArctic	→					
	AD1502: Undisclosed information	Alzheimer's Disease	BioArctic	→					
	AD1503: Undisclosed information	Alzheimer's Disease	BioArctic	→					
	ABBV-0805³: anti- α -synuclein antibody	Parkinson's Disease	AbbVie	→					
	PD1601: anti- α -synuclein antibody	Parkinson's Disease	AbbVie	→					
	PD1602: anti- α -synuclein antibody	Parkinson's Disease	AbbVie	→					
Diagnostics & Technology	IMAGING & BIOCHEMICAL BIOMARKERS: A β	Alzheimer's Disease	BioArctic	→					
	IMAGING & BIOCHEMICAL BIOMARKERS: α -synuclein	Parkinson's Disease	AbbVie	→					
	BBB-TECHNOLOGY: blood-brain barrier	Multiple application areas	BioArctic	→					
Spine	SC0806: FGF1/medical device	Complete Spinal Cord Injury	BioArctic	→					

¹) Partner with Eisai on BAN2401 for treatment of Alzheimer's disease. Eisai partnered with Biogen on BAN2401 in 2014

²) Dementia and cognitive impairment 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

Neurodegenerative diseases

The key cause of Alzheimer's disease and Parkinson's disease is believed to be abnormal protein folding and aggregation. The spreading of aggregated soluble forms of proteins leads to neuronal dysfunction, cell death, brain damage and symptoms of disease. Each neurodegenerative disease is characterized by a different aggregated protein. In Alzheimer's disease the

protein is amyloid beta (A β), while in Parkinson's disease it is alpha-synuclein (α -synuclein).

BioArctic's disease modifying treatment strategy is to eliminate toxic aggregated forms (oligomers/protofibrils) of these proteins in the brain by means of the company's selective antibodies.

Drug candidate BAN2401

Alzheimer's disease (collaboration with Eisai):

In Alzheimer's disease, soluble, toxic amyloid beta aggregates are believed to contribute to the neurodegenerative process. The antibody BAN2401 selectively binds to these forms of amyloid beta and eliminates them. BAN2401's unique profile is highly selective for A β oligomers/protofibrils and binds more than 1,000 times stronger to these than to A β monomers and 10 - 15 times stronger than to A β fibrils.

During 2018, positive and robust results were presented from the Phase 2b study with BAN2401 in 856 patients with early Alzheimer's disease. The results demonstrated consistent, dose dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints and on biomarkers including amyloid-PET and was well tolerated.

A reduced degree of decline compared with placebo exceeding 25% was predefined as clinically relevant. At the analysis after 18 months of treatment a dose-dependent slowing of cognitive decline in the clinical cognition scale ADCOMS of 30% was demonstrated with the highest BAN2401 dose of 10 mg/kg twice a month. A statistically significant slowing of decline on ADCOMS was observed as early as at 6 months as well as at 12 months. With the cognition scale ADAS-Cog a significantly reduced degree of decline of 47% was seen with the highest dose. With the cognition scale CDR-SB a reduced decline of 26% compared with placebo was seen at 18 months.

Statistically significant and dose-dependent reduction of amyloid beta in the brain was seen with amyloid-PET at 18 months. The reduction was statistically significant for all doses. After 18 months treatment a drastic reduction in the brain could be demonstrated with amyloid-PET. 81% of the patients with the highest dose went from amyloid-positive to amyloid-negative. I.e., they could no longer be classified as having Alzheimer's disease.

A major reduction of amyloid beta in the brain was demonstrated in the whole study population of early Alzheimer patients and in all subgroups: ApoE4-carriers and non-ApoE4-carriers, mild cognitive impairment with Alzheimer pathology (MCI) and mild Alzheimer's disease, with or without concomitant symptomatic medication. The dose-dependent amyloid reduction in the brain correlated with the clinical effects of BAN2401 and the clinical effects of the treatment were shown to increase with longer treatment time. Significant effects were seen with the two highest doses after 18 months on a number of biomarkers in cerebrospinal fluid, such as total-tau, phospho-tau, neurogranin and neurofilament light chain. These effects of BAN2401 on biomarkers in cerebrospinal fluid are very important as they indicate that BAN2401 interferes in the neurodegenerative process downstream of the amyloid beta pathology.

BAN2401 was well tolerated during the 18 months treatment. The most common adverse events were reactions at the injection site and ARIA-E (Amyloid

Related Imaging Abnormalities-Edema). The reactions at the injection site were mostly mild to moderate in severity. The incidence of ARIA-E was not more than 10% in any of the treatment arms. The vast majority with this adverse event, 90%, were without any symptoms and could only be seen after MRI scans.

This is the first study in late clinical phase that demonstrated potential disease modifying effects on both clinical function and clearance of amyloid beta in the brain. Further, the Phase 2b study also demonstrated effects on neurodegenerative biomarkers. BAN2401 showed a good tolerability. The data support the positive effect of BAN2401 in all subgroups of early Alzheimer's disease.

For the participants in the Phase 2b study, an open-label extension study is ongoing with continued BAN2401 treatment with the highest study dose and without placebo control.

Based on the results of the Phase 2b clinical study and after discussion with regulatory agencies, our partner Eisai has started the global, single confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease patients to support a regulatory filing for BAN2401. The start of the study triggered a MEUR 15 milestone payment to BioArctic.

The Phase 3 study (named Clarity AD) is a global placebo-controlled, double-blind, parallel-group, randomized study in 1,566 patients with early Alzheimer's disease i.e. mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease with confirmed amyloid pathology in the brain. Patients are allocated in a 1:1 ratio to receive either placebo or treatment. Patients are dosed twice a month with placebo or BAN2401 10 mg/kg. The primary endpoint is the change from baseline in the cognition and function scale Clinical Dementia Rating-Sum of Boxes (CDR-SB) at 18 months of treatment. Changes in the clinical scales AD composite score (ADCOMS) and AD Assessment Scale-Cognitive Subscale (ADAS-Cog) will be key secondary endpoints together with brain amyloid levels as measured by amyloid PET. According to Eisai, the result from the study is targeted for 2022.

BAN2401 has recently been selected by the Alzheimer's Clinical Trials Consortium (ACTC) and Eisai to be evaluated in an upcoming clinical study targeting secondary prevention of Alzheimer's disease (the A45 study). The A45 study will target the preclinical (pre-symptomatic) stage of Alzheimer's disease. The study will enroll clinically normal participants (no/minor cognitive impairment) who have elevated levels of amyloid in the brain and are at high risk for progression to mild cognitive impairment and Alzheimer's disease dementia. This study will be conducted with funding from various sources including the United States National Institute on Aging (NIA), part of the National Institutes of Health (NIH), and Eisai. According to ACTC and Eisai, the trial will be starting in early 2020.

Eisai is responsible for the clinical development in Alzheimer's disease. The project is based on research from Uppsala University, Sweden.

Other potential indications for BAN2401 (owned by BioArctic):

BAN2401, which is now being clinically evaluated for the treatment of Alzheimer's disease, can potentially also be used for other indications. One such potential indication is Down's syndrome with dementia, as these patients typically starts developing dementia at around 40 years of age. Another potential indication is traumatic brain injury, TBI. In traumatic brain injury, some patients develop dementia after the injury. These indications are in preclinical phase.

Drug candidate BAN2401 back-up

Alzheimer's disease (collaboration with Eisai):

The antibody is a further developed version of BAN2401 for the treatment of Alzheimer's disease. The antibody was developed by BioArctic in collaboration with Eisai, which led to a new license agreement in 2015. The project is driven by Eisai and is in late preclinical phase.

Drug candidates AD1801, AD1502 and AD1503

Alzheimer's disease (owned by BioArctic):

At BioArctic, research is in progress to develop new antibodies for the treatment of Alzheimer's disease aimed at slowing down or stopping disease progression by addressing novel targets.

Drug candidate ABBV-0805

Parkinson's disease (collaboration with AbbVie):

The drug candidate ABBV-0805 is a monoclonal antibody that selectively binds and eliminates oligomers and protofibrils of alpha-synuclein. The goal is to develop a disease modifying treatment that stops or slows down disease progression. A collaboration with AbbVie was started in 2016 concerning the continued development of BioArctic's Parkinson's program focusing on BAN0805, now under the designation ABBV-0805, as well as additional antibodies and diagnostics.

At the end of 2018, AbbVie exercised its option to license BioArctic's alpha-synuclein antibody portfolio for Parkinson's disease and other potential indications. The license was acquired after clearance by the U.S. competition authority and triggered a milestone payment of USD 50 million. In February 2019, the U.S. Food and Drug Administration, FDA, approved the application to conduct a clinical study with ABBV-0805 and the Phase 1 study started already in March. AbbVie finances and progresses the development of ABBV-0805. The project is based on research from Uppsala University.

Drug candidates PD1601 and PD1602

Parkinson's disease (collaboration with AbbVie):

The antibodies PD1601 and PD1602 are targeting alpha-synuclein for treatment of Parkinson's disease. The goal is to develop a disease modifying treatment that stops or slows down disease progression. The projects are

conducted by BioArctic within the framework of the collaboration with AbbVie.

Diagnostics and technology

Alzheimer's disease diagnostics (owned by BioArctic) and Parkinson's disease diagnostics (collaboration with AbbVie):

In collaboration with scientists at Uppsala University, BioArctic is developing a new type of PET tracer for imaging of the brain in Alzheimer's disease by using BioArctic's antibodies. Within the Parkinson's field, the development of diagnostic methods based on BioArctic's antibodies is part of the collaboration with AbbVie. The goal is to create tools to better diagnose the disease, follow the disease progression and objectively measure the effect of drug treatment.

BioArctic also develops improved biochemical methods for the identification and precise measurement of responses to treatment and for the measurement of disease progression of Alzheimer's disease and Parkinson's disease. This is done in collaboration with Brain Biomarker Solutions in Gothenburg AB and the University of Gothenburg, Sweden.

Blood-brain barrier technology platform (owned by BioArctic):

The blood-brain barrier controls the exchange of substances between the blood and the brain. The barrier protects the brain from toxins and other pathogens, but it may also limit the delivery of therapeutic agents to the brain.

In collaboration with Uppsala University, BioArctic is developing novel technologies to increase the passage of antibodies into the brain across the blood-brain barrier. This technology platform has great commercial potential and could be a general technology for improved and more effective treatment of brain diseases.

Complete Spinal Cord Injury

Product candidate SC0806

Traumatic complete spinal cord injury (owned by BioArctic):

The product candidate SC0806 is a combination of a biodegradable medical device and a drug substance (FGF1). The first patient was treated in 2016 with subsequent rehabilitation for 18 months. Since August 2017, the patients receiving SC0806 treatment in the ongoing Phase 1/2 clinical trial have been given the option of 12 months additional participation in an extension study. The inclusion of patients with complete spinal cord injury to the first of three panels of BioArctic's ongoing clinical Phase 1/2 study was completed in April 2018. The study is approved for inclusion of patients by the regulatory authorities and ethics committees in Sweden, Estonia, Norway and Finland.

A safety evaluation of all the patients in the first panel has been performed and provided support to start the next panel. The first patient in the second panel has received treatment with SC0806 and hereby the Phase 2

has started. An interim analysis of the first panel regarding efficacy and safety is planned no later than the first half of 2020.

SC0806 obtained orphan drug designation in 2010 in the EU and in 2011 in the U.S., which may give the company 10 and 7 years of market exclusivity in Europe and the U.S., respectively.

The project is in-licensed from Swenora Biotech AB and

is based on research from Karolinska Institutet and Karolinska University Hospital, in Sweden.

Patents

Patents are crucial to the company's future commercial opportunities. BioArctic has therefore an active patent strategy covering all major pharmaceutical markets, including the US, EU, Japan and China. BioArctic's patent portfolio consisted at the end of the period of 14 patent families with more than 200 granted patents.

Comments to the financial report

The Group is referred to unless otherwise stated in this Interim Report. Figures in parentheses refer to the corresponding period last year. All amounts stated are rounded up or down, which may lead to some totals not matching exactly.

Revenues and results

Because of the nature of the business operations, there may be large fluctuations between revenues for different periods. Revenues may consist of milestone payments, payments from research agreements and research grants.

Net revenues in the second quarter amounted to MSEK 171.3 (52.3), an increase of MSEK 119.0 compared with the same period the previous year. Net revenues for the period January – June increased with MSEK 130.1 compared with the same period previous year and amounted to MSEK 234.7 (104.6). The increase during both the quarter and the period January – June is attributable to the milestone payment from Eisai of MEUR 15.

Other operating income relates to research grants, operating exchange rate gains and expenses incurred but onward invoiced. Other operating income amounted to MSEK -0.7 (3.6) for the second quarter and MSEK 6.2 (15.0) for the period January – June. The decrease during the second quarter and the period January – June relates to lower revenue recognition from research grants and lower unrealized exchange rate gains.

Operating expenses for the second quarter decreased with MSEK 5.6 to MSEK 43.8 (49.4) compared to the same period previous year and the operating expenses for the period January – June increased with MSEK 2.5 to MSEK 96.8 (94.3). Project expenses for the second quarter and for the period January – June decreased due to lower external expenses in the Parkinson program; however, expenses for own projects increased. The increase in personnel expenses for both the second quarter and the period January – June is related primarily to one-time incentive payments to employees based on performance and an increased number of employees. The increase in depreciations of tangible assets is an effect from the application of IFRS 16 Leases, see note 2. Other operating expenses consisted of realized operating exchange rate losses.

Since BioArctic did not meet all the conditions to capitalize R&D costs, all such costs have been charged to the P&L.

Operating profit before financial items (EBIT) amounted to MSEK 126.8 (6.4) for the second quarter and to MSEK 144.1 (25.3) for the period January – June. The increase of operating profit is attributable to the milestone payment.

Net financial items totaled MSEK 0.9 (0.2) for the second quarter and amounted to MSEK 0.9 (1.1) for the period January – June. Financial income consists of financial exchange rate gains and financial expenses consists of negative interest on cash and cash equivalents and interest on leasing debt according to IFRS 16 Leases.

Profit for the period amounted to MSEK 100.3 (5.1) for the second quarter and MSEK 113.9 (20.5) for the period January – June.

Earnings per share before and after dilution amounted to SEK 1.14 (0.06) for the second quarter and to SEK 1.29 (0.23) for the period January – June.

Financial position

Equity amounted to MSEK 999.5 (656.7) at June 30, 2019. This corresponds to an equity per outstanding share of SEK 11.35 (7.46).

The equity/asset ratio has increased from 73.1 percent at December 31, 2018 to 78.4 percent at June 30, 2019.

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to MSEK 1,218.4 (1,041.7). The leasing liabilities at June 30, 2019 of MSEK 30.0 relates to financial leasing and is an effect from the

application of IFRS 16 Leases. There were no loans at June 30, 2019 and no loans have been taken since this date. The Group has no other credit facility or loan commitments.

In order to reduce foreign exchange exposure some liquid funds are invested in foreign currency. This has reporting effects in connection with the recalculation of currency to the current rate. These effects are recognized in the operating profit and in financial income and expenses.

Investments and cash flow

Investments in the second quarter amounted to MSEK 0.7 (0.7) and to MSEK 1.3 (0.9) for the period January – June. The investments are mainly related to laboratory equipment.

Cash flow from financing activities amounted to MSEK -133.6 (0.0) for the second quarter and to MSEK -135.4 (0.0) for the period. MSEK 132.1 (0.0) of the cash flow from financing activities relates to dividend and remaining amounts relates to the application of IFRS 16 Leases.

Cash flow from operating activities for the second quarter amounted to MSEK 97.2 (-37.3), an increase of MSEK 134.5. The increase is explained by the milestone payment from Eisai during the second quarter. The cash flow from operating activities for the period January – June increased with MSEK 510.1 and amounted to MSEK 430.8 (-79.3). The increase in the cash flow for the period January – June relates to the received milestone payments from AbbVie and Eisai.

Employees

At the end of the period, the number of employees was 39 (31) of which 14 (12) are men and 25 (19) women. Approximately 90 percent are active in R&D and approximately 75 percent are PhDs; of these, one is Associate Professor and two are Professors.

Consultants

A cost efficient organization at BioArctic is achieved by hiring consultants for specific assignments and for tasks in competence areas that the company lacks or only has a need for periodically. As of June 30, 2019, these amounted to a total corresponding to 13 (12) full-time positions.

Key events during the period January – June

- BioArctic announced in February that the company's partner Eisai will initiate the single confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease and published information concerning the design of the study and timelines
- Eisai initiated in March the confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease
- The U.S. Food and Drug Administration approved in February the application to start a clinical study in the Parkinson program with ABBV-0805, previously named BAN0805
- BioArctic announced the start of the clinical Phase 1 study with ABBV-0805 in the Parkinson program in March
- BioArctic's product candidate SC0806 for complete spinal cord injury advanced into Phase 2 in the ongoing Phase 1/2 study in February
- BioArctic received MEUR 15 milestone payment from Eisai for start of BAN2401 confirmatory Phase 3 study in early Alzheimer's disease
- Alzheimer's Clinical Trials Consortium and Eisai announced that BAN2401 will be evaluated in a clinical study for prevention of Alzheimer's disease
- Ewa Björling was elected new member of the board at the Annual General Meeting
- The Annual General Meeting approved the introduction of an employee warrant program 2019/2028 for the company's management, researchers and other staff

The share and shareholdings

The share capital in BioArctic amounts to SEK 1,761,200 divided by 88,059,985 shares which is split between 14,399,996 A-shares and 73,659,989 B-shares. The quotient value for both A- and B-shares is SEK 0.02. The A-share has 10 votes per share and the B-share has 1 vote per share.

The largest shareholders at June 30, 2019¹

Shareholder	Number of A-shares	Number of B-shares	Share of capital, %	Share of votes, %
Demban AB (Lars Lannfelt)	8,639,998	22,723,707	35.6	50.1
Ackelsta AB (Pär Gellerfors)	5,759,998	15,150,036	23.7	33.4
Third Swedish National Pension Fund	-	4,012,032	4.6	1.8
Fourth Swedish National Pension Fund	-	3,786,684	4.3	1.7
Norron Funds	-	3,351,109	3.8	1.5
AMF Insurance & Funds	-	2,335,046	2.7	1.1
Handelsbanken Funds	-	2,100,000	2.4	1.0
Investment AB Öresund	-	2,050,000	2.3	0.9
Unionen	-	1,763,000	2.0	0.8
Second Swedish National Pension Fund	-	1,441,666	1.6	0.7
Total 10 largest shareholders	14,399,996	58,713,280	83.0	93.4
Other	-	14,946,709	17.0	6.6
Total	14,399,996	73,659,989	100.0	100.0

¹ Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

Risks and uncertainty factors

The management makes assumptions, judgments and estimates that affect the content of the financial statements. Actual results may differ from these assumptions and estimates, as is also stated in the accounting principles. The objective of the Group's risk management is to identify, measure, control and limit the risks of the business. Significant risks are the same for the Parent Company and the Group.

The risks can be divided into financial risks on the one hand and operational and external risks on the other. BioArctic's operational and external risks mainly consist of risks related to research and development, clinical trials and dependence on key employees.

A detailed description of exposure and risk management is presented in the Annual Report 2018, pp 44-46.

Parent Company

All the Group's business operations are conducted in the Parent Company.

Expected development of operating expenses

Operating expenses are expected to be in the range of MSEK 190 – 250 for the fiscal year January – December 2019.

Annual General Meeting 2019

The Annual General Meeting in BioArctic AB (publ) was held on May 9th. Ewa Björling was elected new member of the board. The other board members were re-elected.

Employee warrant program

The Annual General Meeting approved the Board of Directors' proposal for resolution concerning an employee warrant program for the company's management, researchers and other staff, on a directed issue of warrants and approved the transfer of warrants or shares in the company to the participants in the employee warrant program.

The employee warrant program 2019/2028 shall include not more than 1,000,000 warrants. To enable the company's delivery of shares under the employee warrant program 2019/2028, the Annual General Meeting decided on a directed issue of a maximum of 1,000,000 warrants.

The maximum dilution effect of the employee warrant program 2019/2028 is estimated to be a maximum of 1.1 percent of the share capital and 0.5 percent of the votes in the company (calculated on the number of existing shares in the company), provided full exercise of all employee warrants. The allocation of the employee warrants program has not yet been concluded. More information is available at www.bioarctic.com.

Future reports

The Interim Report for January – September 2019 will be published on October 24, 2019

The Full Year Report 2019 will be published on February 6, 2020

The Interim Report for the period January – June 2019 gives a fair overview of the Parent Company's and Group's operations, financial position and earnings, and describes significant risks and uncertainties facing the Parent Company and companies included in the Group.

This Interim Report has not been reviewed by the Company's auditors.

Stockholm, Sweden, July 10, 2019

Wenche Rolfsen
Chairman

Ivar Verner
Deputy Chairman

Ewa Björling
Board member

Hans Eklund
Board member

Pär Gellerfors
Board member

Lars Lannfelt
Board member

Mikael Smedeby
Board member

Eugen Steiner
Board member

Gunillas Osswald
CEO

Financial statements, Group

Consolidated income statement

kSEK	Apr-Jun 2019	Apr-Jun 2018	Jan-Jun 2019	Jan-Jun 2018	Jan-Dec 2018
Net revenues (note 4)	171,332	52,301	234,719	104,604	713,970
Other operating income	-742	3,576	6,189	14,996	16,259
Operating revenues	170,589	55,877	240,908	119,600	730,229
Operating expenses					
Project related expenses	-8,025	-28,452	-37,963	-54,589	-145,357
Other external expenses	-8,378	-7,214	-16,351	-15,232	-31,949
Personnel expenses	-21,113	-12,459	-33,131	-22,370	-57,039
Depreciations of tangible assets	-2,390	-181	-4,761	-768	-2,059
Other operating expenses	-3,896	-1,126	-4,580	-1,291	-5,031
Operating profit	126,787	6,446	144,122	25,349	488,794
Financial income	1,193	557	1,523	1,830	2,171
Financial expenses	-332	-363	-590	-726	-1,371
Profit before tax	127,647	6,640	145,055	26,453	489,593
Tax	-27,382	-1,519	-31,160	-5,913	-107,991
Profit for the period	100,266	5,121	113,895	20,540	381,602
Earnings per share					
Earnings per share, SEK ¹	1.14	0.06	1.29	0.23	4.33

¹ The allocation of the employee warrants program has not yet been concluded as of June 30, 2019; thus, there is no dilutive effect

Consolidated statement of comprehensive income

kSEK	Apr-Jun 2019	Apr-Jun 2018	Jan-Jun 2019	Jan-Jun 2018	Jan-Dec 2018
Profit for the period	100,266	5,121	113,895	20,540	381,602
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	100,266	5,121	113,895	20,540	381,602

Consolidated balance sheet (condensed)

kSEK	Jun 30, 2019	Jun 30, 2018	Dec 31, 2018
ASSETS			
Tangible fixed assets	9,130	7,191	9,289
Right-to-use assets	30,002	-	-
Deferred tax assets	319	166	189
Other financial assets	1,511	2,675	1,500
Current assets excluding cash and cash equivalents	15,869	11,955	464,757
Cash and cash equivalents	1,218,437	1,041,740	917,307
TOTAL ASSETS	1,275,267	1,063,727	1,393,042
EQUITY AND LIABILITIES			
Equity	999,541	656,674	1,017,736
Deferred tax liabilities	32,520	5,487	32,520
Long-term leasing liabilities	23,780	-	-
Short-term leasing liabilities	6,213	-	-
Other current liabilities	41,456	13,974	91,996
Accrued expenses and deferred income	171,758	387,592	250,791
EQUITY AND LIABILITIES	1,275,267	1,063,727	1,393,042

Consolidated statement of change in equity (condensed)

kSEK	Jun 30, 2019	Jun 30, 2018	Dec 31, 2018
Opening balance at 1 January	1,017,736	636,134	636,134
Comprehensive income for the period	113,895	20,540	381,602
Paid dividend	-132,090	-	-
Closing balance	999,541	656,674	1,017,736

Consolidated statement of cash flow (condensed)

kSEK	Apr-Jun 2019	Apr-Jun 2018	Jan-Jun 2019	Jan-Jun 2018	Jan-Dec 2018
Operating profit	126,787	6,446	144,122	25,349	488,794
Adjustment for non-cash items	-5,788	-55,742	-62,068	-117,601	-726,886
Interest received/paid	-342	-363	-390	-726	-1,331
Income tax paid	-2,067	-5,350	-76,784	-6,755	-10,889
Cash flow from operating activities before changes in working capital	118,590	-55,009	4,880	-99,733	-250,313
Change in working capital	-21,414	17,665	425,924	20,386	50,256
Cash flow from operating activities after changes in working capital	97,175	-37,344	430,804	-79,347	-200,057
Cash flow from investing activities	-716	-652	-1,279	-866	-3,080
Cash flow from financing activities	-133,604	-	-135,433	-	-
Cash flow for the period	-37,144	-37,996	294,092	-80,214	-203,136
Cash and cash equivalents at beginning of period	1,255,567	1,078,746	917,307	1,110,367	1,110,367
Exchange rate differences in cash and cash equivalents	15	989	7,039	11,587	10,076
Cash and cash equivalents at end of period	1,218,437	1,041,740	1,218,437	1,041,740	917,307

Consolidated quarterly data

MSEK	2019 Q2	2019 Q1	2018 Q4	2018 Q3	2018 Q2	2018 Q1	2017 Q4	2017 Q3
Income statement								
Net revenues	171.3	63.4	515.3	94.0	52.3	52.3	51.0	31.5
Other operating income	-0.7	6.9	0.7	0.6	3.6	11.4	10.4	2.8
Operating profit	126.8	17.3	430.3	33.1	6.4	18.9	14.7	0.6
Operating margin, %	74.0	27.3	83.5	35.2	12.3	36.1	28.9	2.0
Profit for the period	100.3	13.6	335.2	25.9	5.1	15.4	11.8	-0.1
Balance sheet								
Fixed assets	41.0	42.6	11.0	9.9	10.0	9.6	10.0	10.5
Current assets	15.9	16.3	464.8	13.8	12.0	20.3	20.1	9.8
Cash and cash equivalents	1,218.4	1,255.6	917.3	1,008.5	1,041.7	1,078.7	1,110.4	590.7
Equity	999.5	1,031.4	1,017.7	682.5	656.7	651.6	636.1	64.1
Deferred tax liabilities	32.5	32.5	32.5	5.5	5.5	5.5	5.5	4.1
Leasing liabilities	30.0	31.5	-	-	-	-	-	-
Current liabilities	213.2	219.0	342.8	344.2	401.6	451.6	498.9	542.7
Cash flow								
From operating activities	97.2	333.6	-89.3	-31.5	-37.3	-42.0	-45.7	-23.6
From investing activities	-0.7	-0.6	-1.7	-0.5	-0.7	-0.2	0.5	-2.8
From financing activities	-133.6	-1.8	-	-	-	-	560.2	-
Cash flow for the period	-37.1	331.2	-91.0	-32.0	-38.0	-42.2	515.0	-26.4
Data per share, SEK^{1, 2, 3}								
Earnings per share	1.14	0.15	3.81	0.29	0.06	0.18	0.16	0.00
Equity per share	11.35	11.71	11.56	7.75	7.46	7.40	7.22	1.02
Cash flow operating activities	1.10	3.79	-1.01	-0.36	-0.42	-0.48	-0.60	-0.37
Share price at the end of the period	74.40	78.00	82.00	118.90	21.80	21.40	26.00	-

¹ The allocation of the employee warrants program has not yet been concluded as of June 30, 2019; thus, there is no dilutive effect

² The comparative figures have been recalculated as a result of the 15:1 split executed on August 1, 2017

³ The company was listed in October 2017, so no observable share price exists before the listing

Financial statements, Parent company

Parent company income statement

kSEK	Apr-Jun 2019	Apr-Jun 2018	Jan-Jun 2019	Jan-Jun 2018	Jan-Dec 2018
Net revenues	182,762	52,301	234,719	104,604	713,970
Other operating income	-12,173	3,576	6,189	14,996	16,259
Operating revenues	170,589	55,877	240,908	119,600	730,229
Operating expenses					
Project related expenses	-8,025	-28,452	-37,963	-54,589	-145,357
Other external expenses	-10,223	-7,214	-19,727	-15,232	-31,949
Personnel expenses	-21,113	-12,459	-33,131	-22,370	-57,039
Depreciations of tangible assets	-723	-181	-1,427	-768	-2,059
Other operating expenses	-3,896	-1,126	-4,580	-1,291	-5,031
Operating profit	126,609	6,446	144,079	25,349	488,794
Financial income	1,193	557	1,523	1,830	2,171
Financial expenses	-27	-363	-74	-726	-1,371
Profit after financial items	127,774	6,640	145,527	26,453	489,594
Change in tax allocation reserves	-	-	-	-	-122,876
Profit before tax	127,774	6,640	145,527	26,453	366,718
Tax	-27,409	-1,519	-31,261	-5,913	-80,959
Profit for the period	100,366	5,121	114,266	20,540	285,759

There are no items in the parent company recognized as other comprehensive income, thus comprehensive income conforms to the result for the year.

Parent company balance sheet (condensed)

kSEK	Jun 30, 2019	Jun 30, 2018	Dec 31, 2018
ASSETS			
Tangible fixed assets	9,130	7,191	9,289
Deferred tax assets	217	166	189
Other financial assets	1,611	2,775	1,600
Current assets excluding cash and cash equivalents	15,869	11,955	464,757
Cash and cash equivalents	1,218,340	1,041,642	917,209
TOTAL ASSETS	1,245,166	1,063,728	1,393,044
EQUITY AND LIABILITIES			
Equity	884,617	637,222	902,441
Tax allocation reserve	147,817	24,941	147,817
Other current liabilities	41,174	13,974	91,996
Accrued expenses and deferred income	171,558	387,592	250,791
EQUITY AND LIABILITIES	1,245,166	1,063,728	1,393,044

Notes

Note 1 General information

This Interim Report for the period January – June 2019 covers the Swedish Parent Company BioArctic AB, Swedish Corporate Identity Number 556601-2679, and the two fully owned subsidiaries SpineMedical AB, Swedish Corporate Identity Number 559003-7080, and LPB Sweden AB, Swedish Corporate Identity Number 559035-9112. All the Group's business operations are conducted in the Parent Company. The Parent Company is a Swedish limited liability company registered in and with its registered office in Stockholm. The head office is located at Warfvings väg 35, SE-112 51, Stockholm, Sweden.

The BioArctic Group's Interim Report for the period January – June 2019 was approved by the Company's board on July 10, 2019.

Note 2 Accounting principles

The consolidated financial statements for BioArctic AB have been prepared in accordance with IFRS (International Financial Reporting Standards) as adopted by the EU, the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's RFR 1 Supplementary Accounting Rules for Groups. The Parent Company's financial statements are presented in accordance with the Swedish Annual Accounts Act and RFR 2 Accounting for Legal Entities.

The Interim Report for the period January – June 2019 is presented in accordance with IAS 34 Interim Financial Reporting and the Swedish Annual Accounts Act. Disclosures in accordance with IAS 34 are presented both in notes and elsewhere in the Interim Report.

The guidelines of the European Securities and Markets Authority (ESMA) on alternative performance measures have been applied. This involves disclosure requirements for financial measures that are not defined by IFRS. For performance measures not defined by IFRS, see the Calculations of key figures section.

IFRS 16 Leases has replaced IAS 17 Leases and the appropriate interpretations IFRIC 4, SIC-15 and SIC-27 as of January 1, 2019. This standard requires that assets and liabilities attributable to all leasing agreements, with a few exceptions, are recognized in the balance sheet. This reporting is based on the view that an asset is used for a specific period of time and at the same time an obligation arises to pay for this right. BioArctic has elected to apply the modified retrospective approach. The effect of the application of IFRS 16 Leases will be that BioArctic will account for a right-to-use asset and a leasing liability for office premises and parking lots that currently are accounted for as operational leasing contracts. The company has chosen to apply the relief rules concerning short-term agreements and low-value agreements. The effects of applying IFRS 16 Leases on January 1, 2019 can be seen below:

- The Group's assets and liabilities have increased with MSEK 33.3 million which means that the balance sheet increased with 2.4 percent
- Equity assets ratio has decreased with 1.7 percentage points from 73.1 percent to 71.4 percent

For more information of the application of IFRS 16 Leases see annual report for 2018, note 3.3.

The accounting principles and calculation methods applied are in all other respects in line with those described in the Annual Report 2018.

Note 3 Segment information

An operating segment is a part of the Group that conducts operations from which it can generate income and incur costs and for which independent financial information is available. The highest executive decision-maker in the Group follows up the operations on aggregated level, which means that the operations constitute one and the same segment and thus no separate segment information is presented. The Board of Directors is identified as the highest executive decision maker in the Group.

Note 4 Net revenues

kSEK	Apr-Jun 2019	Apr-Jun 2018	Jan-Jun 2019	Jan-Jun 2018	Jan-Dec 2018
Geographic breakdown of net revenues					
Europe	9,356	52,219	72,744	103,123	712,489
Asia	161,976	83	161,976	1,481	1,481
Total net revenues	171,332	52,301	234,720	104,604	713,970
Net revenues per revenue type					
Milestone payments	161,976	-	173,407	-	448,550
Income from research collaborations	9,356	52,301	61,313	104,604	265,420
Total net revenues	171,332	52,301	234,720	104,604	713,970

BioArctic's net revenues essentially consist of income from the research collaborations concerning Parkinson's disease with AbbVie and Alzheimer's disease with Eisai. Under the collaboration agreement with AbbVie, BioArctic received an initial payment of MSEK 701.6 (MUSD 80) during the third quarter 2016. This payment is related to compensation for the preclinical development work that BioArctic will carry out under the agreement. Of the initial payment, MSEK 70.4 was reported as a one-time payment in 2016. The rest of the payment will be accrued based on the costs incurred up until the completion of the project. The project is continuously evaluated with the regard to status and remaining costs. As of June 30, 2019, MSEK 553.8 has been recognized and the remaining amount to be recognized as a revenue up until the completion of the project is MSEK 147.8. A milestone payment of MSEK 162.0 (MEUR 15) from the research collaboration with Eisai was received during the second quarter.

Note 5 Transactions with affiliated parties

The board member Mikael Smedeby was until May 2019 active as lawyer and co-owner of Advokatfirman Lindahl KB, which provides ongoing business legal advice to BioArctic for compensation that is in line with market rates. During the period January – June, Advokatfirman Lindahl invoiced fees amounting to approximately MSEK 0.4 (0.4). The board member Pär Gellerfors has, in addition to the board fee, invoiced through Ackelsta AB a consultant fee in line with market rates of MSEK 0.1 (0.0) during the period January – June.

In addition to the compensation to Advokatfirman Lindahl and Pär Gellerfors described above and salary to Lars Lannfelt, no significant transactions have taken place between the Group and related parties. All transactions have been in line with market rates.

Definition of key ratios

In this financial report BioArctic reports key financial ratios, some of which are not defined by IFRS. The Company's assesses that these key ratios are important additional information, since they enable investors, securities analysts, management of the company and other stakeholders to better analyze and evaluate the company's business and financial trends. These key ratios should not be analyzed separately or replace key ratios that have been calculated in accordance with IFRS. These key ratios should not be compared to other key ratios with similar names applied by other companies. This is due to the fact that key ratios cannot always be defined in the same way and other companies may calculate them in a different way than BioArctic.

The key ratios "Net revenues", "Result for the period", "Earnings per share" and "Cash flow from operating activities" are defined according to IFRS.

Key ratios	Definition
Other income	Other income than net revenues
Operating profit	Result before financial items
Operating margin, %	Operating profit divided by net revenues
Cash flow from operating activities per share, SEK	The period's cash flow from operating activities divided by the weighted number of shares
Equity/asset ratio	Adjusted equity divided by the balance sheet total
Return on equity	Net income divided by equity as a percentage
Equity per share	Adjusted equity divided by the number of shares at the end of the period

About BioArctic

BioArctic AB (publ) is a research-based biopharmaceutical company focusing on disease modifying treatments and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. The company also develops a treatment for complete spinal cord injury. The company focuses on new types of treatments in areas with high unmet medical needs. BioArctic was founded in 2003 based on innovative research from Uppsala University, Sweden. The company has cutting-edge scientific competence and experience in developing drugs from idea to market. Collaborations with universities are of great importance to the company together with the strategically important global partners in the Alzheimer and Parkinson projects. BioArctic conducts its own clinical development in the field of complete spinal cord injury. Through long-term collaboration agreements with global pharmaceutical companies, BioArctic has demonstrated high skills and great ability to deliver innovative pharmaceutical projects.

In Alzheimer's disease, BioArctic has collaborated with Eisai since 2005. The company has entered into three research agreements and two license agreements relating to the antibodies BAN2401 and BAN2401 back-up. The total aggregated value of these agreements may amount to MEUR 218 and, in addition, payments of royalty. So far, MEUR 62 has been received. In Parkinson's disease, BioArctic has collaborated with AbbVie since 2016, when a research collaboration agreement was entered including i.a. the antibody BAN0805. The total aggregated value of the agreement may amount to MUSD 755 and, in addition, payments of royalty. So far, MUSD 130 has been received.

The project portfolio consists of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. For information about the projects, see the section Project portfolio. BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B).

Goal and strategy for sustainable growth

BioArctic's goal is to improve the quality of life for patients with diseases in the central nervous system. We would like to contribute to the society by developing innovative disease-modifying treatments based on antibodies (immunotherapy) for neurodegenerative diseases, i.e. disease where the nervous system atrophies. BioArctic develops entirely new types of treatments that hopefully may halt or delay the disease progression in patients with Alzheimer's disease and Parkinson's disease, unlike today's symptomatic treatments. The company is also developing a new treatment concept for complete spinal cord injuries.

The strategy work has been intensified to enable BioArctic to fully utilize the project portfolio's many opportunities. The company is well positioned to advance the on-going projects in order to build further value and to create new successful collaboration. In combination this creates sustainable growth.

Strategic target areas

BioArctic focuses on building unique and competitive portfolio of product candidates, diagnostics and technology in the company's indication areas. This is done partly through internal research and development, partly through research collaborations with strategic partners in the form of research groups at universities, in pharma companies, and the health care sector.

Our strategy is to out-license certain commercial rights to global pharma companies at an appropriate time. In line with this strategy, BioArctic's research and development work continues. Important elements of BioArctic's strategy are:

CONTINUE focusing on the partnership projects and on driving/intensifying the in-house projects with great out-licensing and market potential

DEVELOP projects further, up to the optimal point in time for partnership or exit, in order to maximize return on investment

EXPAND the portfolio with new targets, indications for orphan drug, new projects and diagnostics

INVEST in:

- technologies; antibodies, blood-brain barrier, diagnostics and biomarkers
- attracting/retaining employees
- preparing market activities in the Nordic region

Collaborations and partnerships

Collaborating with universities is of great importance to BioArctic. The company has on-going collaborations with academic research groups at a number of universities. Collaborations and license agreements with leading pharma and biopharma companies are also an important part of BioArctic's strategy. In addition to financial compensation we get access to our partners' skills in drug development, manufacturing and commercialization. BioArctic has entered into a number of such agreements with the Japanese international pharma company Eisai and the American global biopharma company AbbVie. These strategic partnerships with leading global companies confirm that BioArctic's research is of very high quality.

In the future BioArctic may enter into additional agreements that can contribute further funding and research and development competence for product candidates in preclinical and clinical phase, manufacturing and marketing competence, geographic coverage and other resources.

For more information regarding BioArctic's two large collaboration partners, please see the Annual Report 2018 on page 10.

Glossary

ADAS-Cog

ADAS-Cog (Alzheimer's Disease Assessment Scale-cognitive subscale) is a well-established cognition scale whereof parts are included in ADCOMS

ADCOMS

Alzheimer's Disease Composite Score – A cognition scale consisting of parts from three different scales (CDR-SB, ADAS-cog and MMSE) developed by Eisai. The cognition scale enables a sensitive detection of changes in clinical functions of symptoms in early Alzheimer's disease

Alpha-synuclein (α -synuclein)

A protein in the nervous system, present in Lewy bodies in some structures of the brain in Parkinson's disease

Amyloid beta ($A\beta$)

A 40-42 amino acids long peptide, split from the parent protein APP, amyloid precursor protein. Amyloid beta is the main constituent of the plaques found in the brain of Alzheimer patients

Antibody

Protein used by the body's immune system to detect and destroy foreign substances

ApoE4

Apolipoprotein E (ApoE) transports fats in the blood. Individuals expressing ApoE4 develop more Alzheimer changes in the form of plaques and amyloid beta in the brain blood vessel walls.

ARIA

Amyloid-Related Imaging Abnormalities (ARIA) are brain-changes seen in Magnetic Resonance Imaging of Alzheimer's disease patients, which are commonly observed in clinical trials of amyloid-modifying therapies

ARIA-E

There are two types of ARIA; ARIA-E and ARIA-H. ARIA-E refers to observations of edema and the other ARIA-H to observations of small hemorrhages

Biomarker

A measurable indicator of a medical condition

Blood-brain barrier

A physiological mechanism in which merged capillary walls in the brain's blood vessels regulate the transport of molecules between the blood and the brain tissue, with the function to protect the brain against viruses and other harmful agents

CDR-SB

CDR-SB (Clinical Dementia Rating Sum of Boxes) is a cognition and function scale which is part of ADCOMS

Central nervous system

The central nervous system consists of the brain and the spinal cord

Clinical studies

Drug trials performed in human subjects

Complete Spinal Cord Injury

A complete injury means that the spinal cord is complete severed. In an incomplete injury there are still a few nerve contacts left

Disease modifying treatment

A treatment that interferes with the processes of the disease and changes it in a positive way

Dose dependent

Increased effect at higher dose

Drug candidate

A drug under development that has not yet gained marketing approval

Humanized antibody

An antibody in which the sequence has been changed to resemble a human antibody

Interim analysis

In clinical trials and other scientific studies, an interim analysis is an analysis of data that is conducted before data collection has been completed

Investigational New Drug (IND) application

Application to the U.S. Food and Drug Administration (FDA) for the approval to conduct a clinical study in the U.S.

Ligand

Molecule that binds to the desired target in the body

Medical device for implantation

A medical device that is intended to be totally or partially introduced, surgically or medically, into the human body, or through a medical procedure in a body opening, and intended to remain there after the operation

Milestone payment

Financial compensation obtained within the framework of a project or collaboration agreement when a certain specified objective has been achieved

Monoclonal antibody

An antibody that can be produced so that all copies are exactly alike

Monomer

A monomer is the starting molecule in polymerization. The monomers are joined into long molecular chains through the polymerization, resulting in a polymer with the monomer as the repeating unit

Neurodegenerative disease

Disease in which the nervous system atrophies

Oligomer

A molecular chain consisting of several monomers aggregated

Orphan drugs

Drugs for patients with rare and serious diseases

Peptide

A molecule made up of amino acids connected into a short chain

PET

Positron emission tomography, an investigation imaging method

Phase 1 studies

Studies mainly of the safety and tolerability of a drug. Performed on a limited number of healthy human volunteers or patients

Phase 2 studies

Studies of the safety and efficacy of a drug and dose finding. Performed on a limited number of patients

Phase 3 studies

Confirmatory studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients

Preclinical phase

Preclinical studies of drug candidates to prepare for clinical studies

Preclinical studies

Studies performed in model systems, i.e. not in humans

Product candidate

A product under development that has not yet gained marketing approval

Protofibril

A molecular chain consisting of several monomers aggregated

Research phase

Early research is focused on studying and elucidating the underlying molecular disease mechanisms and development of potential drug candidates

Secondary prevention

Preventive measures where symptoms or biomarkers may indicate disease

Statistically significant

A clinical study result is defined as statistically significant in accordance with the preset criteria for the study or in adherence to a generally recognized standard, most commonly defined as less than 5% probability of obtaining a similar or stronger result due to chance, i.e. $p < 0.05$

Tolerability

How a person reacts to a drug

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This report has been prepared in a Swedish original version and translated into English. In the event of any inconsistency between the two versions, the Swedish language version should have precedence.