

Investornyheder

NeuroSearchs associerede selskab, NsGene A/S har nået en betydningsfuld milepæl med den succesfulde fase Ib dosering af NsG0202 i Alzheimers patienter

NsGene A/S, der er 25% ejet af NeuroSearch, har i dag meddelt, at tre patienter med Alzheimers sygdom har fået selskabets nye "biodelivery" produkt, NsG0202, succesfuldt implanteret i hjernen som led i et igangværende fase Ib klinisk studie. Fase Ib studiet blev indledt af NsGene i december 2007 i samarbejde med universitetshospitalet Karolinska i Stockholm, og efter evaluering af sikkerhed og funktionsdygtighed vil yderligere tre Alzheimers patienter få implanteret NsG0202 i dette 1-årige studie.

NsG0202 til behandling af Alzheimers sygdom bygger på NsGenes patenterede og unikke EC (indkapslede celler) biodelivery platform og består af et implanterbart produkt, der udskiller nervevækstfaktoren NGF (Nerve Growth Factor). NGF har vist sig at have en beskyttende og genopbyggende effekt på syge nerveceller ved levering til relevante områder i hjernen. Således repræsenterer NsG0202 en helt ny behandlingsform inden for Alzheimers sygdom og med det formål ikke blot at lindre symptomer, men at genetablere hjernefunktion.

EC biodelivery tilgangen kan udgøre et gennembrud inden for behandling af alvorlige neurologiske lidelser, såsom Alzheimers sygdom, Parkinsons sygdom og epilepsi, og NsG0202 er det første af flere sygdomsmodificerende produkter i NsGenes pipeline, der forventes at gå i klinisk udvikling inden for de næste to år.

Lars U. Wahlberg, Executive Vice President og COO i NsGene udtaler:

"Dette er en betydningsfuld milepæl for NsGene og for vores EC biodelivery platform og pipeline. Den succesfulde implantation i de første tre patienter med Alzheimers sygdom har påvist, at produktet kan indsættes både præcist og sikkert, hvilket baner vejen for yderligere kliniske studier."

Flemming Pedersen, adm. direktør i NeuroSearch udtaler:

"NsGenes EC biodelivery teknologi repræsenterer en helt ny og meget lovende tilgang til behandling af neurologiske sygdomme. Det er i dag kun muligt at tilbyde eksempelvis Alzheimers, Parkinsons og epilepsipatienter midlertidig symptomlindring, men NsGenes produkter har potentialet til at kunne introducere fremtidige sygdomsmodificerende behandlinger. Med den succesfulde implantation af NsG0202 er NsGene godt på vej til at bevise, at det er muligt at levere biologiske stoffer til hjernen på en sikker måde. Dette er et kvantespring fremad for NsGene, og som en storaktionær i selskabet er vi meget tilfredse med deres fremgang."

For yderligere oplysninger se vedlagte pressemeddelelse fra NsGene A/S.

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NeuroSearch (NEUR) er et skandinavisk biofarmaceutisk selskab noteret på OMX Den Nordiske Børs København A/S. Kerneforretningen dækker udvikling af nye lægemidler baseret på en bred og veletableret forskningsplatform med fokus på ionkanaler og sygdomme i centralnervesystemet (CNS). En betydelig del af selskabets aktiviteter er partnerfinansieret via en bred strategisk alliance med GlaxoSmithKline (GSK) og samarbejdsaftaler med bl.a. Abbott og Astellas. Lægemedelpipelinen omfatter 13 kliniske (fase I-III) udviklingsprogrammer: ACR16 inden for Huntingtons sygdom (fase III forberedelse), tesofensine inden for fedme (fase III forberedelse), NS2359 inden for depression (fase II) og ADHD (fase II) i samarbejde med GSK, ABT-894 inden for ADHD (fase II) og smerte (fase II) i samarbejde med Abbott, ACR16 inden for skizofreni (fase I) i samarbejde med Astellas, ACR325 inden for maniodepressiv sygdom/Parkinsons sygdom (fase I), ABT-107 og ABT-560 til behandling af flere forskellige CNS-sygdomme, begge (fase I) i samarbejde med Abbott, NSD-644 inden for smerte mv. (fase I) i samarbejde med GSK, ACR343 inden for Parkinsons sygdom (fase I) samt NSD-788 inden for angst mv. (fase I). NeuroSearch har desuden en bred portefølje af prækliniske lægemiddelkandidater og har kapitalandele i flere biotekvirksomheder.



Copenhagen, Denmark, April 7th, 2008

PRESS RELEASE - FOR IMMEDIATE RELEASE

Danish biotech company's restorative Alzheimer's product has successfully been implanted in patients

NsGene A/S today announced that its encapsulated cell (EC) biodelivery product, NsG0202, has successfully been implanted to the brains of three patients with Alzheimer's disease (AD).

The NsG0202 device for AD is the first in a pipeline of EC biodelivery products based on NsGene's proprietary platform expected to enter clinical trials for neurological disorders over the next two years. The product is a disease modifying implant that represents a novel treatment method aimed at restoring brain function and not only at alleviating symptoms. Thereby, it may constitute a breakthrough in the treatment of severe diseases of the central nervous system, such as AD, Parkinson's disease, and epilepsy.

The product consists of an implantable EC biodelivery device that secretes nerve growth factor (NGF). NGF has shown to have neuroprotective and regenerative effects when delivered to diseased neurons in relevant areas of the brain. NsG0202 is aimed at treating the progressive dementia associated with AD. The current phase Ib clinical trial is carried out in collaboration with the Department of Geriatrics and Department of Neurosurgery at the Karolinska University Hospital in Stockholm and is headed by Assoc. Prof. Maria Eriksson Jönhagen, Department of Geriatrics. Three patients were successfully implanted by the neurosurgical team headed by Prof. Bengt Linderöth. The devices were placed at precise anatomical locations using MRI-guided, stereotactic neurosurgery. After safety and functional evaluations, an additional three patients will be implanted. Thus, in total, six patients will participate in this year-long phase Ib study.

"This is a significant milestone for NsGene and our EC Biodelivery platform and pipeline" says Lars U. Wahlberg, Exec. Vice President and COO, NsGene. He continues: "The successful implantation of the first three patients suffering from Alzheimer's disease has demonstrated that the devices can be implanted with both precision and safety and is paving the way for additional clinical studies."

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Background on EC biodelivery device

The EC biodelivery device is a cell-based biodelivery system of protein factors to the nervous system providing a controlled, site-specific and safe delivery of a variety of therapeutic substances. For central nervous system (CNS) indications, one or multiple EC biodelivery devices can be implanted in defined regions of the brain to deliver any proteins, including growth factors, antibodies, and neuropeptides, across the blood-brain-barrier. The proprietary EC biodelivery system consists of a catheter-like device containing in its active portion a genetically modified human cell line enclosed behind a semi-permeable hollow fiber membrane. The membrane allows for the influx of nutrients and the outflow of the therapeutic factor(s) but prevents the direct contact between the therapeutic cells and the host tissue. The encapsulated cells provide long-term factor secretion from the implanted device.

EC biodelivery platform is a strongly and broadly patented technology platform offering great safety advantages over direct gene therapy approaches, and technical and functional advantages over pump technologies.

Background on NsGene,

NsGene A/S (www.nsgene.com) is a privately held Danish biotechnology company founded in December 1999 as a spin-off from NeuroSearch A/S, a Danish pharmaceutical company. NsGene develops novel biologicals for the treatment of neurological diseases. Based on the EC biodelivery platform, NsGene develops EC biodelivery products for neurological diseases including Alzheimer's disease (ECB-AD), Parkinson's disease (ECB-PD) and intractable epilepsy (ECB-EP). In addition hereto, a number of EC biodelivery products for other indications are under investigation. Today, NsGene employs 27 people at its research facility located near Copenhagen in the Medicon Valley Region. For more information please see www.nsgene.dk.